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AMCP **MANAGED CARE &**
SPECIALTY PHARMACY
ANNUAL MEETING 20 19

Meeting Abstracts

AMCP Managed Care & Specialty Pharmacy
Annual Meeting 2019

San Diego, California
March 25-28, 2019

AMCP Abstracts Program

The AMCP Managed Care & Specialty Pharmacy Annual Meeting 2019 in San Diego, California, is expected to attract more than 4,000 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.

The AMCP Abstracts program provides a forum through which authors can share their insights and outcomes of advanced managed care practice. Poster presentations are scheduled for **Wednesday, March 27, from 11:30 am to 1:00 pm.** Posters will also be displayed on **Tuesday, March 26, from 5:30 pm to 7:00 pm,** during the opening night reception in the Expo, and on **Thursday, March 28, from 9:30 am to 11:00 am.** Podium presentations for the Platinum award-winning abstracts are **Tuesday, March 26, from 2:30 pm to 3:45 pm.**

Professional abstracts that have been reviewed are published in the *Journal of Managed Care & Specialty Pharmacy's* Meeting Abstracts supplement. Abstracts were submitted in the following categories:

Research Report: Describes 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 effects of unique benefit design strategies, and analyses of the effects of innovative administrative or clinical programs.

Economic Model: Describes models that predict the effects of various benefit design strategies 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.

Abstract Review Process

Seventy reviewers and 4 *JMCP* editorial reviewers were involved in the abstract review process for the 2019 Annual Meeting. Each abstract (with author name and affiliation blinded) was reviewed and scored using a 1-5 scale with the following 5 criteria (15 rating scores per abstract), which are used by *JMCP* to evaluate manuscripts for publication:

• Relevance • Originality • Quality • Bias • Clarity

Each of the reviewers also made an independent accept/reject recommendation. The 15 rating scores and 3 accept/reject recommendations for each abstract were reviewed by a *JMCP* editorial reviewer, who made an accept/reject decision. These decisions were further reviewed by the *JMCP* editor-in-chief to ensure consistency in decision making. The mean rating scores were used to award Platinum, Gold, Silver, and Bronze medals for the best abstracts submitted. The abstract reviewers for the 2019 Annual Meeting were as follows:

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J15 Real-World Incidence and Cost Assessment of Pneumonitis During Chemoradiotherapy for Unresectable Locally Advanced, Non-Small Cell Lung Cancer Patients

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K2 Healthcare Resource Utilization and Total Costs of Care Among Patients with Esophageal Cancer: An Administrative Claims Analysis

K3 Deprescribing Non-Steroidal Anti-Inflammatory Drugs in the Geriatric Population

K4 Prevalence of Crohn's Disease (CD) and Ulcerative Colitis (UC), Biologic Therapy Use, and Total Medical and Pharmacy Claims Expense Associated with CD and UC in a Population of 15 Million Commercially Insured Members

K5 Association Between Hospitalization for Crohn's Disease or Ulcerative Colitis and Biologic Drug Therapy Adherence

K6 Greater than Expected Dosing Assessment Among Targeted Immunomodulators in Management of Inflammatory Bowel Disease

K7 Infliximab Costs and Reasons for Treatment Discontinuation Among Patients with Crohn's Disease Receiving Treatment in U.S. Hospitals: 2012-2015

K8 Effectiveness of Switching from Infliximab to Infliximab-dyyb in Patients with Inflammatory Bowel Disease

K9 Health Care Spend of Patients with Crohn's Disease and Ulcerative Colitis with a Targeted Immunosuppressant

K10 Vedolizumab: What Is the Most Cost-Effective Drug Therapy in Treating Inflammatory Bowel Disease? A Systematic Review

K11 Treatment Persistence and Costs in New Initiators of Linaclotide and Lubiprostone

K12 Patterns of Pharmacotherapy in Patients with Chronic Idiopathic Constipation in the United States Initiating Treatment with Linaclotide or Lubiprostone

K13 Medication Regimen After Hospitalization for Hepatic Encephalopathy and Its Impact on Hospital Readmissions in Medicare Beneficiaries

K14 Rising and Higher Healthcare Resource Utilization and Costs of Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Liver Disease of Increasing Severity: Results of a U.S. Real-World Analysis

K15 Longitudinal Analyses of Comorbidities and Healthcare Costs Among Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Liver Disease

K16 Increased Risk of Mortality in Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients: Real-World Analysis of 2007-2015 Medicare Data

K17 Increasing Healthcare Resource Utilization and Costs Associated with Advanced Liver Disease: A Multivariate Analyses of Real-World Medicare Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients

K18 Fibrosis-4 Score Provides Consistent Assessment of Healthcare Costs and Healthcare Resource Utilization Among Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Fibrosis

K19 Identification and Characterization of Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Liver Fibrosis Identified Using Non-Invasive Tests of Hepatic Fibrosis: Real-World Results of 3,421 Patients

K20 Adherence to Subcutaneous Biologic Therapy Among Patients with Inflammatory Bowel Disease and Rheumatoid Arthritis: Impact of Therapy Management

L1 Psoriasis Patients Switching Biologics Within the First Year of Biologic Treatment Initiation Have More Comedications, Higher Healthcare Resource Utilization, and Are Costlier than Persistent Patients

L2 Healthcare Costs Among Psoriasis Patients Treated with Ixekizumab or Adalimumab

L3 Clinical Implications of Early PASI Responses to Tildrakizumab in Patients with Moderate to Severe Plaque Psoriasis

L4 Tildrakizumab Efficacy over Time Stratified by Week-28 Response Levels and by Prior Biologic Use

L5 Biologic and Apremilast Treatment Patterns in Moderate to Severe Plaque Psoriasis

L6 Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 3-Year Results from reSURFACE 2

L7 Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 3-Year Results from reSURFACE 1

L8 Tildrakizumab Efficacy and Drug Survival by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and 2)

L9 The Effect of Tildrakizumab on Cardiometabolic Risk Factors in Psoriasis by Metabolic Syndrome Status: Post Hoc Analysis of 2 Phase 3 Trials (reSURFACE 1 and reSURFACE 2)

L10 Safety of Tildrakizumab in Patients with Pre-Existing Metabolic Syndrome: Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and reSURFACE 2)

L11 Once-Daily Oral Sarecycline 1.5 mg/kg/day Is Effective for Moderate to Severe Acne Vulgaris: Results from 2 Identically Designed, Phase 3, Randomized, Double-Blind Clinical Trials

L12 Budget Impact Analysis of Glycopyrronium Cloth for the Treatment of Primary Axillary Hyperhidrosis

L13 Cost per Responder Analysis of Guselkumab Versus Secukinumab Using Efficacy Results from a Head-to-Head Clinical Trial in Patients with Moderate to Severe Plaque Psoriasis

L14 Cost per Responder Analysis of Guselkumab Versus Tildrakizumab Using Efficacy Results from Two Pivotal Clinical Trials in Patients with Moderate to Severe Plaque Psoriasis

L15 Treatment Adherence and Persistence of Five Commonly Prescribed Medications for Moderate to Severe Psoriasis in a U.S. Commercial Population

L16 Real-World Safe and Effective Use of Cryotherapy and Field-Directed Treatment for the Different Severities of Actinic Keratosis

L17 Estimated Cost of Reducing Anxiety and Depression in Moderate to Severe Plaque Psoriasis Patients Treated with Guselkumab Versus Adalimumab Using Results from the Phase 3 VOYAGE 2 Study

L18 Examining the Real-World Healthcare Costs of Treating Chronic Wounds

M1 Treatment Patterns in New User Cohorts of Non-Specialty First-Line Therapy for Immune-Mediated Inflammatory Diseases

Exhibit Hall Map and All Poster Titles
(Student, Encore, and Professional Reviewed)

M2 Real-World Treatment Patterns of Rheumatoid Arthritis Patients Who Switched from Infliximab to Infliximab-dyyb

M3 Treatment and Switching Patterns in Patients with Immune-Mediated Inflammatory Diseases Treated with Originator Infliximab or Its Biosimilars

M4 Impact of a Mandatory Specialty Pharmacy Benefit on Rheumatoid Arthritis Medication Adherence Among Members of a Commercial Client

M5 A Systematic Review of the Association Between Patient Out-of-Pocket Costs and the Non-Initiation of Biologics Used to Treat Rheumatoid Arthritis

M6 U.S. Rheumatology Practice-Based Real-World Evidence of Methotrexate Utilization and Response to Therapy in Rheumatoid Arthritis Patients Treated with Intravenous Golimumab

M7 Age and Gender Differences in Comorbidities Among Patients with Rheumatoid Arthritis in a Large U.S.-Based Real-World Cohort

M8 Serum Uric Acid and Health-Related Quality of Life in Patients with Gout and Hypertension

M9 Understanding the Impact of Dose Escalation on the Cost-Effectiveness of Etanercept Among Patients with Rheumatoid Arthritis

M10 Treatment Patterns in Rheumatoid Arthritis Patients Initiating DMARDs: Analysis of U.S. Health Plan Claims

M11 Curbing the Opioid Epidemic: 20% Reduction by 2020

M12 An Analysis of the Burden of Illness and Treatment in Knee Osteoarthritis in a U.S. Administrative Claims Database

M13 Impact of Intra-Articular Corticosteroid Injections on Opioid Utilization Patterns in Patients with Knee Osteoarthritis

M14 Healthcare Costs Among Patients with Ankylosing Spondylitis or Psoriatic Arthritis Who Switch or Discontinue Biologics

M15 Morphine Milligram Equivalent Reductions in a Multidisciplinary Chronic Pain Management Program

M16 Modeling the Costs and Outcomes Associated with Treatment Sequences, with and Without Tofacitinib, for Psoriatic Arthritis in the United States

M17 Characterization of Medicare Patients with a Fragility Fracture

M18 Effect of Abaloparatide on Bone Mineral Density and Fracture Incidence in a Subset of Younger Postmenopausal Women with Osteoporosis at High Risk for Fracture Representative of Covered Commercial Insurance Enrollees

M19 Characterizing Patients Initiating Abaloparatide, Teriparatide, or Denosumab in a Real-World Setting: A U.S.-Linked Claims and EMR Database Analysis

M20 The Impact of Prescription NSAIDs on Opioid Use in Opioid-Naïve Patients Following Orthopedic Surgery

M21 Improving Quality of Care in Rheumatoid Arthritis Utilizing Hospital-Based Specialty Pharmacies in Monitoring Disease Activity

N1 Use of a Real-Time Clinical Decision Support Tool to Identify Renal Dosing Opportunities for Clinical Pharmacist Intervention on Drug Spend

N2 Burden of Complicated Urinary Tract Infections: Epidemiology, Health Care Resource Utilization, and Readmission Rates

O1 Evaluation of Progesterone Utilization and Adherence in Women with a High-Risk Pregnancy Covered by Texas Medicaid

O2 The Change in Prescription of Pregnancy-Contraindicated Drugs in Korea

Q1 Evaluation of Pharmacist Intervention, Medication Compliance, and Their Impact on Long-Term Outcomes for Patients with Cystic Fibrosis on CFTR Modulator Therapy

R1 Burden of Atherosclerotic Cardiovascular Disease Risk in Persons with Elevated Triglyceride Levels According to Statin Use

R2 The Humanistic Burden of Chronic Idiopathic Constipation in the US: A Systematic Review

R3 The Economic Burden of Chronic Idiopathic Constipation in the US: A Systematic Literature Review

R4 Decrease in Therapeutic Effect Among Botulinum Toxin Type A Agents: Analysis of the FDA Adverse Event Reporting System Database

R5 Pharmacist Intervention to Facilitate Coordination of Prescriber Care in Response to Opioid Overutilization in Members with Multiple Providers

T1 Opioid Misuse-Related Health Care Resource Utilization and Costs in Texas

T2 Pharmacoeconomic Evaluation of Naloxone Distribution for the Prevention of Opioid Overdose Fatalities: A Systematic Review

T3 Opioid Overdose Incidence Among Medicaid Members Receiving Opioids with and Without Mental Illness Diagnosis

T4 Effect of Naloxone Access Law Type Variability Enactment on Dispensing of Naloxone Prescriptions in the Medicaid Population from 2013 through 2017

T5 Understanding Opioid Overdose Risk in a Medicare Population: Identification of High-Risk Variables

T6 An Observational Case-Control Study of Risk Factors for Overdose in Members of a State Medicaid Program Prescribed Concurrent Benzodiazepines and Opioids

T7 Is Naloxone the Answer? A Review of the Long-Term Effects of Naloxone Use

T8 Botulinum Toxin Type A Overdoses: Analysis of the FDA Adverse Event Reporting System Database

T9 Evaluating the Use and Perception of E-Cigarettes/Vaping Among College Students at Rutgers University

T10 Design, Implementation, and Assessment of an Adverse Event Monitoring Program Within a Self-Administered Prescription Drug Plan

U1 Clinical Adherence Programs at a Specialty Pharmacy: A Quantitative Analysis

U2 A Motivational Factors Assessment Instrument for Employees Providing Medication Therapy Management Services: A Rasch Analysis

U3 Impact of a Pharmacy Lock-In Program in a Medicaid Managed Plan

U4 Exclusion Formulary: Assessment of Medical Costs, Pharmacy Costs, and Resource Utilization Compared to a Concurrent Control Group

U5 Evaluation of Providers' Response to Statin Re-Challenge Intervention

U6 ICER: Payer Use and Perspective

U7 Accuracy and Efficiency: Validating the Financial Impact of Pharmacist Interventions

U8 The Benefits of Pharmacist-Led Interventions in the Health Plan Setting

U9 Re-Designing a Value-Based Formulary to Address Current Pharmaceutical Spending Trends: Changes in Drug-Tier Classifications

U10 Managed Care Pharmacists and Top of License Practice: Understanding the Perceptions, Barriers, and Readiness

U11 Results of Using Integrated Healthcare Data with a Clinical Safety Program to Improve Health Outcomes

U12 Improving Continuity of Care for Patients on High-Risk Medications

U13 Analysis of Anti-Narcotic Therapy Across a Self-Insured Population

U14 An Evaluation of Value-Based Frameworks for Non-Small Cell Lung Cancer Drug Regimens: ASCO Value Framework, ESMO Magnitude of Clinical Benefit Scale, ICER Report, and NCCN Evidence Blocks

U15 Management of Specialty Drugs, Specialty Pharmacies, and Biosimilars in the United States

U16 The 2019 U.S. Payor Landscape: Trends and Results from Surveys on Formulary Management

U17 Identification of Exposure to Reference Biologics and Biosimilars: Use of Medical Claim Line NDC Code and Healthcare Common Procedure Coding System Code Modifiers

U18 Payer Perceptions on Access to Breastfeeding Support in the United States

U19 Impact of Non-Medical Switching Among Ambulatory Patients: Results of a Systematic Literature Review

U20 Patterns of On-Demand Medication Use Among Patients with Hereditary Angioedema Treated Long-Term with Prophylactic Subcutaneous C1-Inhibitor

U21 Evaluating the Impact of a Targeted Program Tailored to Address Patient's Specific Medication Adherence Barriers

U22 Forces Driving Change in Healthcare: Payer Insights on Key Trends

U23 Payer Perceptions of Patient-Reported Outcomes and Other Clinical Outcome Assessments in the United States

U24 Listening to the Medicare Beneficiaries: Findings from a National Survey on the Medication Therapy Management Standardized Format

U25 Changing Prescriber Use of Pharmaceutical Manufacturer Coupons Within a Clinically Integrated Healthcare System

U26 Differences on Work Productivity Loss, Healthcare Resource Utilization, and Costs by Patient Activation Level

U27 Hereditary Angioedema C1-Inhibitor Replacement Therapy and Coexisting Autoimmune Disorders: Findings from a Claims Database

U28 A Framework for Vetting "Good" Outcomes-Based Measures in Alternative Payment Models

U29 Pharmacists in ACOs and Roles for Managed Care Pharmacists

U30 The Effect of Different Lookback Periods on the Identification of New Users of Opioids

Exhibit Hall Map and All Poster Titles
(Student, Encore, and Professional Reviewed)

U31 The Effect of Different Methods on the Identification of Cancer Members and Overall Opioid Utilization

U32 Economic Evaluations of Sugammadex for Reversal of Neuromuscular Block in Surgical Procedures: A Systematic Review

U33 Effectiveness of a Health Plan-Driven Opioid Management Program on Member Opioid Use

U34 The Effect of Implementing Electronic Prior Authorization on Provider Satisfaction

U35 The Impact of Synergizing Pharmacist Coaching Calls with Compliance Packaging to Optimize Medication Adherence

U36 Impact of Lidocaine Utilization Management Strategy on Drug Utilization and Cost

U37 Impact of a Medicare Part D Compound Strategy on Member Utilization and Spend

U38 Exploring Awareness of Performance Criteria and Motivating Factors of Clinical Employees at an Academic-Based Medication Management Call Center: Findings from Focus Groups

U39 The Impact of a Dose Optimization Program Implemented at a Specialty Pharmacy

U40 Companion Diagnostics: Effectiveness of an Intervention and Survey of Prescribers' Understanding and Clinical Utilization

U41 Impact of Implementing Narrow Pharmacy Networks on Medication Adherence

U42 Correlation Between Medication Regimen Complexity Index and Access Restrictions for New Molecular Entities Approved by the FDA from 2015 through 2017

U43 Prescriber Acceptance Rate of Regional Care Team Pharmacist Recommendations

U44 A Comparison of the Emerging E-Healthcare Market with the Traditional Channels of Acquiring Finasteride for Alopecia

U45 Impact of Automated Telephone Call and Text Message Refill Reminder Program on Adherence Rates in a Managed Care Population

U46 Analysis of Clinical Secure Messaging on Adherence Outcomes Within a Specialty Pharmacy Population

U47 Evaluation of Pharmaceutical Industry Medical Engagement Content and Tools for Payers

U48 Clinical Outcomes of Infliximab Biosimilar Switching Versus Maintained Therapy: A Retrospective Analysis of the Veteran Affairs Database

U49 Impact of Pharmacist Outreach to Providers for Patients with Primary Medication Non-Adherence

U50 Acute Opioid-Prescribing Patterns and Trends Related to Conversion of Chronic Opioid Use in a Medicare PDP Population

U51 Utilization of a Linear Probability Model to Predict Member Behavior Following a Formulary Change for Long-Acting Opioids

U52 Evaluating Methodology for Medication Therapy Management Member Identification to Improve Accuracy When Using Pharmacy Claims Only: Focus on Chronic Heart Failure Member Qualification

U53 Effectiveness of Digital Messaging on Patient Engagement with Their Infusion Benefit

U54 Comparing Productivity Rates and Quality of Medication Therapy Management Services Between Clinical Staff Pharmacists and Clinical Contract Pharmacists at the Center for Quality Medication Management at the University of Florida

U55 Evaluation of Community Pharmacies' Knowledge and Patient Services on Medicare Star Adherence Measures

U56 Evaluation of the Pharmaceutical Properties of Compounded Topical Formulations for Pain Management

U57 Identifying Skills and Knowledge Needed by PharmD Graduates for Roles in Non-Direct Patient Care Careers: An Employer Survey

U58 Assessment on Effectiveness of Implementation of Educational Managed Care Program

U59 The Clinical Use of Inositol in Polycystic Ovarian Syndrome and Depression: A Systematic Literature Review

U60 Does a Low-Touch Prescriber Fax Intervention Decrease Concurrent Use of Opioids and Benzodiazepines?

U61 Analyzing the Success Rates of Resolving Medication Therapy Problems Utilizing Telephonic and Non-Telephonic Interventions at the Center for Quality Medication Management at the University of Florida in a Medicaid Population

U62 Climate Study of Ethnically Homogenous Versus Heterogeneous Pharmacy Schools in the Northeast Region

U63 Cost Analysis on the Impact of Part B Step Therapy Implementation with Biosimilars as Alternative Agents

U65 Making the Economic Value Proposition for Pharmacist Comprehensive Medication Management in Primary Care: A Conceptual Framework

U66 Impact of Automatic Prescription Refill Enrollment on Total Cost of Care in a Managed Medicaid Population

U67 Evaluating the Effect of Exclusionary Formularies for Self-Insured Employers in a Group Purchasing Organization

U68 Targeted Specialty Medication Referral Form Updates: How Do They Impact Patients and Providers?

U69 Redefining Medication Access: Designing a Conceptual Framework to Advance Quality Measurement

U70 Examining Treatment of Patient-Reported Comorbidities Using SEER-Medicare Health Outcome Survey in Elderly Cancer Patients

U71 Efficacy of Hepatitis B Vaccine in Adults with Chronic Liver Disease

U72 Cost and Utilization Analysis on the Impact of Volcanic Activity for Respiratory and Ophthalmic Agents

U73 Interventions Impacting Medication Access: A Scoping Review

U74 Refining a Research Agenda for Managed Care Pharmacy: A Survey Across Health Care Stakeholders

Z1 Unmet Needs in the Diagnosis and Treatment of Women with Hypoactive Sexual Desire Disorder

Z2 Understanding the Association Between Diabetes and Its Comorbidities Among DSRIP Patients through the Diabetes Prevention and Management Program

Z3 A Discrete Choice Experiment on Payer Preferences for Innovative Payment Schemes Aimed at Financing High-Cost, Potentially Curative Therapies

Z4 Analysis of Pharmacogenomics Program with Pharmacy Benefit Manager Intervention

Z5 Adherence to Specialty Medications: Assessing Rates and Correlates of Nonadherence at an Integrated Specialty Pharmacy

Z6 Evaluation of a Value-Based Pharmacy Model to Improve Quality Measures in the Medicare Advantage and Medicaid Population

Z7 Virtual Reality Therapy: Budget Impact Model on Inpatient Costs

Z8 Quantifying the Healthcare Burden Associated with Opioid Use After Discharge Following Inpatient and Outpatient Surgery Among Previously Opioid-Naïve Patients

Z9 Cost-Effectiveness Analysis of a Community Pharmacy-Enhanced Service Program: Should the Managed Care Organization Reimburse Enhanced Pharmacy Services?

Z10 Correlation Between Provider Density and Antipsychotic Prevalence Among Children in Foster Care

Z11 Medication Therapy Management: Outcomes of Telephonic Pharmacist Outreach

Z12 Assessing Utilization Management Edit on Concurrent Opioid, Benzodiazepine, and Carisoprodol in Commercial and Healthcare Reform Lines of Business

Z13 Assisting Colorado Seniors in Medicare Part D Personalized Plan Optimization

Z14 Healthcare Resource Utilization and Direct Healthcare Cost Related to Peanut Allergy in Medicaid Patients

Z15 Comorbidity and Economic Burden of Peanut Allergy in Privately Insured Patients in the United States

Z16 Development of a Collaborative Pharmacy Practice Agreement to Improve Efficiency and Management of Prescribing in a Renal Transplant Clinic

Student Poster Titles and Presenters

A2 **Examining the Impact of Prior Antibiotic Exposure and Antibiotic Prescribing Patterns on *Clostridium difficile* Lab Events at an Integrated Delivery Network from 2015 to 2018**
Marie Yasuda, PharmD, Paul J. Godley, PharmD; marie.yasuda@bswhealth.org

B8 **Protease Inhibitor-Based Treatment and Risk of Diabetes in Elderly Medicare Beneficiaries with HIV/AIDS**
Eric E. Chinaeke, MSC, Kevin Lu, PhD, BSPharm; chinaeke@email.sc.edu

C7 **Adherence Patterns to Oral Anticancer Medications at an Academic Medical Center for Patients Filling at an Internal Specialty Pharmacy Versus an External Specialty Pharmacy**
Colleen McCabe, PharmD, Meagan Barbee, PharmD, BCOP, Marley Watson, PharmD, BCOP, Alyssa Billmeyer, PharmD, MHA, Collin Lee, PharmD, BCPS, Zhengjia Chen, PhD, Bassel El-Rayes, MD, Ryan Haumschild, PharmD, MS, MBA; colleen.mccabe@emoryhealthcare.org

C11 **Budget Impact of Adopting PARP Inhibitors as Maintenance Therapy for Patients with Recurrent Ovarian Cancer**
Lixian Zhong, PhD, Lei Wu, MS, PharmD candidate; zhong@pharmacy.tamhsc.edu

C16 **Medicare Part D Spending for Abiraterone and Enzalutamide in 2016**
Eric P. Borrelli, PharmD, MBA, Conor G. McGladrigan, PharmD, Stephen J. Kogut, PhD, MBA, RPh; ericborrelli@my.uri.edu

D5 **Evaluating the Impact of a Nurse Case Manager-Led Program on a Hemophilia Population**
Ettien Kadjo, PharmD, Kim Bent, RN, Binal Patel, MPharm, RPh, BCGP, Devon Trumbower, PharmD, BCPS, Lauren Megargell, PharmD; ekadjo@performrx.com

D6 **Comparison of Extended to Standard Half-Life Factor VIII Therapy in Patients with Hemophilia A on Prophylaxis Treatment: A Retrospective Study to Evaluate the Efficacy, Safety, Cost, and Utilization of Treatment**
Michael McCall, PharmD, Pamela Koerner, BS, PharmD, BCPS, Richard T. Miller, RPh, CSP, MBA, MS, Melanie Radi, PharmD, CSP; michael.mccall@walgreens.com

D7 **A Retrospective Claims Analysis of Bleeding Rates Among Hemophilia Factor Products**
Tyler E. Borup, PharmD, Eric K. Abanquah, PharmD, Nancy D. Archila, PharmD, Sean P. Burke, Akshay Saxena, Ellen M. Feeney, PharmD, BCPS; tyler.borup@highmark.com

E15 **Long-Acting Insulin Formulary Change Impact on Health Care Utilization and Cost in a Medicaid Population**
Hansel Fernandes, PharmD, Erika Kaplan, PharmD, Mohamed Juboori, PharmD, Devon Trumbower, PharmD, BCPS, Lauren Megargell, PharmD; hfernandes@performrx.com

E16 **Evaluation of Patient Satisfaction for New Enrollees with Type 2 Diabetes Within an Integrated Health Care System**
Rachael O. Fagbamila, Urvi Choksi, PharmD, Nadia Hason, PharmD; rachael.fagbamila@live.mercer.edu

E17 **SyncDiabetes: An Evaluation of Savings and Adherence Due to Medication Synchronization**
Danielle E. Coutee, PharmD; danicee123@gmail.com

E18 **Evaluation of Cardiovascular Outcomes and Healthcare Resource and Medication Utilization Patterns of Patients with Type 2 Diabetes on Sodium-Glucose Cotransporter-2 Inhibitors Compared to Glucagon-Like Peptide 1 Receptor Agonists**
Elmor D. Pineda, PharmD, Paul J. Godley, PharmD, I-Chia Liao, MPH; elmor.pineda95@gmail.com

E19 **Clinical Outcomes of Starting Patients on Basal-Acting Insulin Products in a Commercially Insured Population**
Mary Anne Choi, PharmD, MBA, Alex C. Kang, PharmD, APh, BCPS, BCACP, BCGP, David Lopez, PharmD, Ann Phan, PharmD, BCGP; mchoi@lacare.org

E20 **Medication Persistence to Fixed-Dose Combination SGLT-2 Inhibitor Synjardy Compared to Its Single-Agent Counterparts Taken Separately**
Hilare Kimmel, PharmD, Claire Wei, Josephine Tran; hilare.kimmel@uhc.com

E21 **Evaluation of the Correlation Between Metformin Adherence and Glycemic Control**
Kent Truong, PharmD, Jessica Shost, PharmD, Tammie Chau, PharmD, Kaitlin Hawkins, PharmD, Lisa Ghotbi, PharmD; ktruong08@gmail.com

E22 **Evaluating the Outcome of a Health Plan's Diabetes Management Program: Impact of Social Determinants of Health**
Michelle Liang, PharmD, Amanda Bain, PharmD, MBA, MPH, Erika Smith, PharmD, J.L. Nelson, PharmD, Tasneem Motiwala, PhD, MPH; michelle.liang@osumc.edu

E23 **Analysis of Pharmacological and Supplemental Interventions to Prevent the Progression of Prediabetes to Diabetes**
Jane Yi; yy339@scarletmail.rutgers.edu

E24 **DSRIP Diabetes Prevention and Management Program: Assessing the Need for Free Diabetes Screening Within the Latino Population in New Brunswick, NJ**
Juan Alvarado, PharmD candidate, Drym Oh, PharmD candidate, Joelle Jo, PharmD candidate, Lana Luong, PharmD candidate, Carissa Ganihong, PharmD candidate; jma334@scarletmail.rutgers.edu

E25 **DSRIP Diabetes Prevention and Management Program: Assessing the Impact of the DSRIP Program on Diabetes Education and Awareness**
Muhil Ravichandran, PharmD candidate, Drym Oh, PharmD candidate, Bernice Lee, PharmD candidate, Hannah Lee, PharmD candidate; muhilravi@gmail.com

E26 **Evaluate the Clinical Effectiveness of Interdisciplinary Collaborative Care in Poorly Controlled Diabetes Type 2 Patients**
Sara M. Ramos, PharmD, Nury Toledo, PharmD, Jeanette Melendez, PharmD, Dennice Miner, LND; sara.ramos-gonzalez@mmmhc.com

E27 **Clinical Outcomes from Non-Medical Switch of Short-Acting/ Rapid-Acting Insulin Products Among a Commercially Insured Population**
Salley K. Park, PharmD, MBA, Jacob Chaffee, PharmD, Alexandra Tungol Lin, PharmD; spark2@bcbsm.com

E28 **Drug Utilization Review Program Recommending Medication Therapy for Horizon NJ Health Members with Diabetes and Elevated Blood Hemoglobin A1c Levels**
Elizabeth Cannon-Dang, PharmD, MPH, Kevin McCloy, PharmD, BCPS; elizabeth_cannon-dang@horizonblue.com

Student Poster Titles and Presenters

E29 **Longitudinal Evaluation of a High School Outreach Program for Healthy Lifestyle Choices, Diabetes Risk, and Opioid Abuse**

Eric Zhu, PharmD candidate, Toni Uzoho, PharmD candidate, Soo Jeong Hwang, PharmD candidate, Jonathan Kim, PharmD candidate, Angela Hu, PharmD candidate, Arthur Kwong, Alina Jan, Serena Lam, PharmD candidate, Kishan Patel, PharmD candidate, Saira Jan, MS, PharmD, Luigi Brunetti, MPH, PharmD; ez109@scarletmail.rutgers.edu

E30 **Effects of a Proactive Pharmacist-Led Telephonic Intervention on Second-Time Fill Rates of Metformin in the Setting of a Medicare Advantage Plan**

Helen Walker, PharmD, MPH, Daniel Inboden, PharmD, MBA, BCPS, Matthew Parker, MS, MBA; helenlea443@mac.com

E31 **Budget Impact of a mHealth Application for Type 2 Diabetes Mellitus**

Ngan N. Pham, PharmD, Lauren Bartolome, PharmD, Siyeon Park, PharmD; nganfiction@gmail.com

E44 **PCSK9 Inhibitor Persistence in a Medicare Population**

Caitlin C. Arnwine, PharmD/MBA; caitlinarnwine@gmail.com

F6 **Risk of Delirium Associated with Baclofen Use in Older Adults**

Tauhid A. Bhuiyan, PharmD, BCPS, Fang Niu, MS, Rita Hui, PharmD, MS, Christopher C. DiStasio, Eric Lee, MD; tauhid.a.bhuiyan@kp.org

F7 **Evaluating the Impact of Pharmacist-Led Intervention on Potential Controlled Substance Misuse**

Tyler Earley, PharmD, Kathy Ponatoski, Junqiao Chen, Holly Hawes, PharmD; tearley@evolenthealth.com

F8 **Cost-Effectiveness of Oral Buprenorphine-Naloxone Versus Long-Acting Naltrexone Injection for Opioid Dependence in a Medicaid Population**

Christopher V. Quenelle, PharmD, Carrie Armstrong, PharmD, MBA, Karen McClenton, BS; cquenelle@evolenthealth.com

F9 **The Effectiveness of a Health Plan-Initiated Provider Intervention on Combination Therapy with High-Dose Opioids and Gabapentinoids in the Medicare Population**

Victoria Facchini, PharmD, BS, Kim Moon, PharmD, Krystyna Mott, PharmD; vfacchini@bcbsm.com

F10 **Association Between Initial Opioid-Prescribing Characteristics and Healthcare Resource Utilization in the Acute Pain Setting**

Sharon Thomas, PharmD, Andrew Himsel, PharmD, MBA, BCPS, David A. Jacob, PharmD; sharonthomas@utexas.edu

F11 **A Comparison of Medication-Assisted Treatment Outcomes for Opioid Use Disorder and Development of Best Practices**

Thuc Quyen Vu, PharmD, Alex Wiggall, PharmD, Saira Jan, MS, PharmD; tvu@umaryland.edu

F12 **Defining the Landscape and Treatment Patterns of Medication-Assisted Treatments for Opioid Use Disorder**

Layla Jaludi, PharmD, Alex Wiggall, PharmD, Saira Jan, MS, PharmD; layla_jaludi1@horizonblue.com

F13 **Injectable Naltrexone Versus Oral Buprenorphine and Total Cost of Care in a Managed Medicaid Population**

Jordan Breitigam, PharmD; jordan.breitigam@caresource.com

F14 **Development and Implementation of an Opioid Dashboard to Improve Data Transparency and Guide Clinical Interventions**

Kali Schweitzer, PharmD, Melissa Brewster, PharmD, BCPS; schweitzerk@careoregon.org

F22 **Changes in Medical and Pharmacy Utilization Following Initiation of Clozapine in Members with Treatment-Resistant Schizophrenia in a Medicaid Population**

Mckenzie Taylor, PharmD, Stephanie Tran, PharmD, Thomas Pomfret, PharmD, MPH, Mark Tesell, PharmD, Caroline Alper, MD, Andrew Coelho, PharmD, Karen Clements, ScD, Kimberly Lenz, PharmD, Youkavet Samih, PharmD, Paul Jeffrey, PharmD; mckenzie.taylor@umassmed.edu

F27 **Assessing the Impact of a Formulary-Based Cost Optimization Intervention in a Regional Managed Care Population: Switching from Fluoxetine Tablets to Capsules**

Andrew Gudac, PharmD, Casey Koch, PharmD, Curtis Wander, PharmD, Natalia Ruiz-Negron; andrew.gudac@selecthealth.org

F35 **Psychotropic Medication Utilization Review of Members of Aetna Better Health of Texas Aged 18 Years Old and Under**

Julian Lamptey, PharmD, Ramie Ramirez, RPh, MBA, Mary Obeng, MPH, PharmD; lampteyj@aetna.com

F37 **The Effect of Comorbidities on Specific Domains of Patient's Financial Access to Healthcare Among Patients with Dementia**

Eric E. Chinaeke, MSC, Kevin Lu, PhD, BSPharm; chinaeke@email.sc.edu

G17 **Retrospective Analysis of Patient-Specific Differences Between Patients on Valbenazine 40 Mg Once Daily and 80 Mg Once Daily**

Olivia G. Goss, PharmD, Christa Eans, PharmD, Pamela Koerner, PharmD, Chuck Yonan, PharmD, Richard Faris, PhD; ogoss@pantherspecialty.com

G29 **The Clinical and Financial Outcomes of Removing Pre-Authorization for Disease-Modifying Therapies for Multiple Sclerosis: A Retrospective Drug Utilization Review from a U.S. Commercial Payer Perspective**

Gary Deng, PharmD, Kevin Chang, PharmD; gary.deng@regence.com

G58 **A Morphine Milligram Equivalent Drug Utilization Review Focused on Prescriber Interventions**

Fatima Ali, PharmD, Kevin McCloy, PharmD, BCPS; fatima_ali@horizonblue.com

I13 **Impact of Obesity on Real-World Clinical Outcomes in Patients with Non-Valvular Atrial Fibrillation on Direct Oral Anticoagulant Therapy: A Retrospective Cohort Study**

Nina Kim, PharmD, Paul J. Godley, PharmD, Karen L. Rascati, PhD, Jeffrey Michel, MD; nina.kim@bswhealth.org

I14 **Real-World Comparative Effectiveness, Safety, and Health Care Costs of Sacubitril/Valsartan Versus Angiotensin-II Receptor Blockers in a Medicare Population**

Claire Bugner, PharmD, Jamieson Vaccaro, MA, Phil Schwab, PhD, Daniel Cornett, PharmD, BCPS, Dana Drzayich Jankus, MS, Diego Martinez Vasquez, MD, MBA, MPH, CPE, FACP, Jennifer Harris, PharmD, Manni Sethi, MD, Brian Cole, PharmD; mbugner@humana.com

Student Poster Titles and Presenters

I15 **Correlation Btween Entresto's Utilization and Its Formulary Status to Determine the Necessity of a PA Requirement for Entresto**
Anthony J. Sandoval, PharmD, Jeffrey He, PharmD, Elsa Tchakoute, PharmD, Samuel Chang, PharmD; sandovala1@aetna.com

I2 **Retrospective Analysis of 3.5 Months of Valsartan Active Pharmaceutical Ingredient Recalls in a Commercial Population: Impact on Utilization Patterns and Trend**
Heidi Anderson, PharmD, Laura Weber, MS, Panita Luangkesorn, PharmD, Iuliana Mihu, PharmD, BCPS, MPH; heidi_l_anderson@bcbsil.com

I3 **Develop and Evaluate the Clinical Impact of a Pharmacist-Driven Virtual Hypertension Program in a Large Multi-Specialty Clinic System**
Rowena Kristina Fadullon, PharmD, Hiresh Tailor, PharmD, Donnie Aga, MD, Patrick Carter, MD, MBA, Denise Martinez Jonathan, PharmD, Kirti Gandhi, PharmD, Lin Guan, PharmD, Hannia Qureshi, PharmD, Kristine Lopez, PharmD; rowena.fadullon@kelsey-seybold.com

J13 **Exploration of Proportion of Days Covered Thresholds for Medical Cost Offset/Outcomes Among Patients Using Inhaled Therapies for Moderate to Severe Chronic Obstructive Pulmonary Disease**
Sang-A Yun, PharmD, Phil Schwab, PhD, Brandon Piazza, PharmD, Eric Dickinson, MBA; syun@humana.com

J14 **A Retrospective Analysis Evaluating the Impact of Non-Adherence to Inhaled Asthma Controller Medications on Subsequent Use of Monoclonal Antibodies in a Medicaid Managed Care Population**
Timothy S. Crabtree, PharmD, Timothy J. Mizak, PharmD, MS, Monica Rotellini-Myers, Majid Mirzai, PharmD; tcrabtree@gatewayhealthplan.com

K3 **Deprescribing Non-Steroidal Anti-Inflammatory Drugs in the Geriatric Population**
Rezoana Rashid, PharmD, Rita Hui, PharmD, MS, Christopher C. Chang, PharmD, Fang Niu, MS, Lynn Deguzman, PharmD, Maisha Draves, MD, MPH; rrashid@usc.edu

K8 **Effectiveness of Switching from Infliximab to Infliximab-dyyb in Patients with Inflammatory Bowel Disease**
Stephanie L. Ho, PharmD, BCPS, Fang Niu, MS, Xian Ning, MS, Jennie Yee, PharmD, Fernando Velayos, MD, Suresh Pola, MD, Doris J. Kao, PharmD, BCPS, Rita Hui, PharmD, MS; stephanie.l.ho@gmail.com

K9 **Health Care Spend of Patients with Crohn's Disease and Ulcerative Colitis with a Targeted Immunosuppressant**
Mirza Begovic, PharmD, Jeff Huether, PharmD, Donald Klepser, PhD; mirza.begovic@nebraskablue.com

K10 **Vedolizumab: What Is the Most Cost-Effective Drug Therapy in Treating Inflammatory Bowel Disease? A Systematic Review**
Veniamin Yagudayev, Khusni Izrailova, Daniella Zabih, Rose Quintero, Aleena Khalid, Feng-hua Loh, BPharm, PhD, MBA; vyaguday@student.touro.edu

N1 **Use of a Real-Time Clinical Decision Support Tool to Identify Renal Dosing Opportunities for Clinical Pharmacist Intervention on Drug Spend**
Michelle Yazdchi, PharmD, Elizabeth Hofammann, PharmD, Carol White, PharmD, Joan Kramer, PharmD, Mandelin Cooper, PharmD, Ty Elders, MS, Laurel Goldin, MA, Hayley Burgess, PharmD; michelle.yazdchi@hcahealthcare.com

O1 **Evaluation of Progesterone Utilization and Adherence in Women with a High-Risk Pregnancy Covered by Texas Medicaid**
Shiyu Zhang, PhD candidate, Gladys Brown, PharmD candidate, Shiyu Zhang, PhD candidate, Karen L. Rascati, PhD; shiyuzhang@utexas.edu

Q1 **Evaluation of Pharmacist Intervention, Medication Compliance, and Their Impact on Long-Term Outcomes for Patients with Cystic Fibrosis on CFTR Modulator Therapy**
Holly McIlvain, PharmD, Michelle Simonsen, PharmD, BCPS, Lindsey Fitzpatrick, PharmD, BCPS; hcarmody@kumc.edu

R5 **Pharmacist Intervention to Facilitate Coordination of Prescriber Care in Response to Opioid Overutilization in Members with Multiple Providers**
Vivi T. Tran, PharmD, Samantha Huynh, PharmD, Rodney Hendershot, PD, RPh; tranv1@aetna.com

T2 **Pharmacoeconomic Evaluation of Naloxone Distribution for the Prevention of Opioid Overdose Fatalities: A Systematic Review**
Lixian Zhong, PhD, Toney Duong, BS, Anh Thu Tran, BS, Joy Alonzo, PharmD; zhong@pharmacy.tamhsc.edu

T4 **Effect of Naloxone Access Law Type Variability Enactment on Dispensing of Naloxone Prescriptions in the Medicaid Population from 2013 Through 2017**
Sarai Connell, PharmD, MBA, Ashley Teel, PharmD, Bethany Holderread, PharmD, Burl Beasley, DPh, MPH, MSPharm, Terry Cothran, RPh, Grant Skrepnek, RPh, PhD, Shellie Keast, PharmD, PhD; sarai-connell@ouhsc.edu

T5 **Understanding Opioid Overdose Risk in a Medicare Population: Identification of High-Risk Variables**
Kassie J. Herbst, PharmD, Oliver W. Holmes III, PharmD, Joseph Couto, PharmD, MBA, Leslie Schroeder, RPh, MBA, Jeffrey Tunney, PharmD, Christopher Beets, PharmD, Jennifer Snyders, PharmD, Courtney Cooper, LCSW; kassie.herbst@cigna.com

T6 **An Observational Case-Control Study of Risk Factors for Overdose in Members of a State Medicaid Program Prescribed Concurrent Benzodiazepines and Opioids**
Kaelyn C. Boss, PharmD, Karen Stevens, PharmD, Bonnie Greenwood, PharmD, Kimberly Lenz, PharmD, Michael C. Angelini, PharmD, Pavel Lavitas, PharmD, Karen Clements, ScD, Rachel Bacon, PharmD, Michael Jones, PharmD, Paul Jeffrey, PharmD, Maria Garcia, MD; kaelyn.boss@umassmed.edu

T7 **Is Naloxone the Answer? A Review of the Long-Term Effects of Naloxone Use**
Maureen Ahn, Richard Ko, Michael Toscani, PharmD, BS; ma1147@scarletmail.rutgers.edu

T9 **Evaluating the Use and Perception of E-Cigarettes/Vaping Among College Students at Rutgers University**
Serena Lam, PharmD candidate, Sumie Kakehi, PharmD candidate, Lois Ko, PharmD candidate, Sophia Seo, PharmD candidate, Susanna Bae, PharmD candidate; sl1387@scarletmail.rutgers.edu

Student Poster Titles and Presenters

T10 Design, Implementation, and Assessment of an Adverse Event Monitoring Program Within a Self-Administered Prescription Drug Plan
Connie Chow, PharmD, Stephen Lott, PharmD, MS, CSP, Steven Erickson, PharmD; constalc@med.umich.edu

U33 Effectiveness of a Health Plan-Driven Opioid Management Program on Member Opioid Use
Adrian Lau, PharmD, Krista Yokoyama, PharmD, Kevin Wu, PharmD; adrian.lau@blueshieldca.com

U34 The Effect of Implementing Electronic Prior Authorization on Provider Satisfaction
Oritsematosan I. Isemede, PharmD, Marcus Hunt, CPhT, Jasmine Phillips, CPhT, Taofeek Oyewole, PharmD; isemedeo@aetna.com

U35 The Impact of Synergizing Pharmacist Coaching Calls with Compliance Packaging to Optimize Medication Adherence
Andrew Bless, PharmD, Stephanie Englert, PharmD, James Notaro, RPh, PhD, Michael MacEvoy, PharmD, BCPS, CDE; andrewbless65@yahoo.com

U36 Impact of Lidocaine Utilization Management Strategy on Drug Utilization and Cost
Nishta Patel, PharmD, Jennifer Heasley, PharmD, MS, Abraham Jose, PharmD; nishta.patel@cvshealth.com

U37 Impact of a Medicare Part D Compound Strategy on Member Utilization and Spend
Alexa Hospodar, PharmD, Danfeng Ni, PharmD, Jennifer Heasley, PharmD, MS; hospodaralexa@yahoo.com

U38 Exploring Awareness of Performance Criteria and Motivating Factors of Clinical Employees at an Academic-Based Medication Management Call Center: Findings from Focus Groups
Srujitha Marupuru, PharmD, David R. Axon, MPharm, MS, Chanadda Chinthammit, BSPharm, MS, PhD, Patrick Campbell, PharmD, PhD, Stephanie Forbes, PharmD, Terri Warholak, PhD; msrujitha1@gmail.com

U39 The Impact of a Dose Optimization Program Implemented at a Specialty Pharmacy
Song Lee, PharmD, MBA, Stephanie Lapointe, PharmD, CSPO, FMPA, Kanika Kapoor, PharmD, CSP, Linda Lampi, PharmD, CSP, CPHQ, Jeffrey Steinke, Karl Renius, PharmD, BCPS, BCOP, Steven Schwartz, PhD; songlee21@gmail.com

U40 Companion Diagnostics: Effectiveness of an Intervention and Survey of Prescribers' Understanding and Clinical Utilization
Kathleen Lau, PharmD, Kanika Kapoor, PharmD, CSP, Steven Schwartz, PhD, Stephanie Lapointe, PharmD, CSPO, FMPA, Linda Lampi, PharmD, CSP, CPHQ, Karl Renius, PharmD, BCPS, BCOP, Jeffrey Steinke; klau@diplomat.is

U41 Impact of Implementing Narrow Pharmacy Networks on Medication Adherence
Mohit B. Bhakta, PharmD, LeeAnn Madrid, Curtis Wander, PharmD, Natalia Ruiz-Negron; mohit.bhakta@selecthealth.org

U42 Correlation Between Medication Regimen Complexity Index and Access Restrictions for New Molecular Entities Approved by the FDA from 2015 Through 2017
Emily Hiroi, Rebekah Anguiano, PharmD, BCPS, BCACP, Michael Gannon, PharmD, JoAnn Stubbings, BSPharm, MHCA; ehiroi2@uic.edu

U43 Prescriber Acceptance Rate of Regional Care Team Pharmacist Recommendations
Marine Schmitt, PharmD; Jessica Dizon, PharmD, MHA, BCPS; schmittm@careoregon.org

U44 A Comparison of the Emerging E-Healthcare Market with the Traditional Channels of Acquiring Finasteride for Alopecia
Griffin T. Sauvageau, Jay Shah, T. Joseph Mattingly, PharmD, MBA; griffin.sauvageau@umaryland.edu

U45 Impact of Automated Telephone Call and Text Message Refill Reminder Program on Adherence Rates in a Managed Care Population
Steve Vuong, PharmD, Ashley Reilly, PharmD, Kirti Gandhi, PharmD, Denise Martinez Jonathan, PharmD, Lin Guan, PharmD, Hannia Qureshi, PharmD, Kristine Lopez, PharmD, Donnie Aga, MD, Patrick Carter, MD, MBA; steve.vuong@kelsey-seybold.com

U46 Analysis of Clinical Secure Messaging on Adherence Outcomes Within a Specialty Pharmacy Population
Christine Sawicki, RPh, MBA, LSSMBB, Sarah K. McLarty, PharmD; christine.sawicki@cvshealth.com

U47 Evaluation of Pharmaceutical Industry Medical Engagement Content and Tools for Payers
Elyse Prather, PharmD, Dawn Beach, PharmD, Jaimie Bertino, PharmD, John Byrd, PhD; elyse.j.prather@gsk.com

U48 Clinical Outcomes of Infliximab Biosimilar Switching Versus Maintained Therapy: A Retrospective Analysis of the Veteran Affairs Database
Cindy A. Wu, PharmD, David A. Jacob, PharmD, Jennifer T. Gunter, PharmD, BCPS; cindy.wu2@va.gov

U49 Impact of Pharmacist Outreach to Providers for Patients with Primary Medication Non-Adherence
Leonard Deleon, PharmD, Nick Page, PharmD, Patty Taddei-Allen, PharmD, MBA, BCACP, BCGP; ldeleon@welldynerx.com

U50 Acute Opioid-Prescribing Patterns and Trends Related to Conversion of Chronic Opioid Use in a Medicare PDP Population
Sarah Nestlehut, PharmD; deihimis@magellanhealth.com

U51 Utilization of a Linear Probability Model to Predict Member Behavior Following a Formulary Change for Long-Acting Opioids
Erin Brannick, PharmD, Harry Lee, PharmD, MS, Christine Bagley, PharmD, PhD, Kevin Leung, PharmD, MS, BCPS; erin.brannick@anthem.com

U52 Evaluating Methodology for Medication Therapy Management Member Identification to Improve Accuracy When Using Pharmacy Claims Only: Focus on Chronic Heart Failure Member Qualification
Jake B. Powers, PharmD, MBA, Kevin Leung, PharmD, MS, BCPS, Harry Lee, PharmD, MS, John Sendzik, BS, Jeffrey Clyman, MD, PhD, Christine Bagley, PharmD, PhD; jake.powers@anthem.com

U53 Effectiveness of Digital Messaging on Patient Engagement with Their Infusion Benefit
John J. Morrison, PharmD, Kayla E. Friend, PharmD, BCGP, Christine Sawicki, RPH, MBA, LSSMBB, Brian Richmond, MBA, Alice Chung, PharmD, LaChelle Wright, MBA; john.morrison@cvshealth.com

Student Poster Titles and Presenters

U54 **Comparing Productivity Rates and Quality of Medication Therapy Management Services Between Clinical Staff Pharmacists and Clinical Contract Pharmacists at the Center for Quality Medication Management at the University of Florida**
Desiree M. Sucar, PharmD, Teresa Roane, PharmD, MBA, BCACP, Amber Connelly, PharmD, Trinity Williams, PharmD; dsucar@cop.ufl.edu

U55 **Evaluation of Community Pharmacies' Knowledge and Patient Services on Medicare Star Adherence Measures**
Victoria Hom, PharmD, Helen Kourlas, PharmD, BCPS, Bhavesh Modi, RPh; vhom@healthfirst.org

U56 **Evaluation of the Pharmaceutical Properties of Compounded Topical Formulations for Pain Management**
Myla Marshall, BS, PharmD candidate, Myla Marshall, BS, PharmD candidate, John Arnold, PhD; mmarsha2@samford.edu

U57 **Identifying Skills and Knowledge Needed by PharmD Graduates for Roles in Non-Direct Patient Care Careers: An Employer Survey**
Kristen Tripicchio, PharmD candidate, Benjamin D. Muller, PharmD candidate, Kristen Wines, PharmD candidate; kristen_tripicchio@unc.edu

U58 **Assessment on Effectiveness of Implementation of Educational Managed Care Program**
Congjian Zhou, PharmD, Soomin Jin, PharmD candidate, Krupal Ray, PharmD candidate, Grace Tam, PharmD candidate, Edward Gu, PharmD candidate, Sung Jae Lee, PharmD candidate, Sam Golbin, PharmD candidate; rebecca.zhou.98@gmail.com

U59 **The Clinical Use of Inositol in Polycystic Ovarian Syndrome and Depression: A Systematic Literature Review**
Khang Nong, PharmD candidate, Sara Kreshpanji, Sejeong Yoon, PharmD, Ashlee Mattingly, PharmD; knong@umaryland.edu

U60 **Does a Low-Touch Prescriber Fax Intervention Decrease Concurrent Use of Opioids and Benzodiazepines?**
Rochelle Yang, PharmD, Sara E. Carruth, PharmD, Amanda Qiu, MS, Scott Leslie, PhD, MPH; rochelle.yang@medimpact.com

U61 **Analyzing the Success Rates of Resolving Medication Therapy Problems Utilizing Telephonic and Non-Telephonic Interventions at the Center for Quality Medication Management at the University of Florida in a Medicaid Population**
Ailey J. Pestcoe, PharmD, Teresa Roane, PharmD, MBA, BCACP, Amber Connelly, PharmD, Trinity Williams, PharmD; a.pestcoe@cop.ufl.edu

U62 **Climate Study of Ethnically Homogenous Versus Heterogeneous Pharmacy Schools in the Northeast Region**
Reshmee Patel; reshlvlee@yahoo.com

U63 **Cost Analysis on the Impact of Part B Step Therapy Implementation with Biosimilars as Alternative Agents**
Annie Vuong, PharmD, Marcia Drummond, PharmD, Ahmed Guhad, PharmD, Melissa Jay, PharmD, Alvah Stahlnecker, PharmD; annie.vuong@cvshealth.com

U65 **Making the Economic Value Proposition for Pharmacist Comprehensive Medication Management in Primary Care: A Conceptual Framework**
Kristen G. Tripicchio, PharmD, Benjamin Urick, PharmD, PhD, Sachiko Ozawa, PhD, MHS; ktripicc@gmail.com

U66 **Impact of Automatic Prescription Refill Enrollment on Total Cost of Care in a Managed Medicaid Population**
Sara Evans, PharmD; sara.evans@caresource.com

U67 **Evaluating the Effect of Exclusionary Formularies for Self-Insured Employers in a Group Purchasing Organization**
Kevin A. Wenceslao, PharmD; kwenceslao@employershealthco.com

U68 **Targeted Specialty Medication Referral Form Updates: How Do They Impact Patients and Providers?**
Brandon Barry, PharmD, Christa Eans, PharmD, Pamela Koerner, PharmD, Richard Faris, PhD; bbarry@pantherspecialty.com

U69 **Redefining Medication Access: Designing a Conceptual Framework to Advance Quality Measurement**
Lee Holland, PharmD, MPH, Matthew Pickering, PharmD, Mel Nelson, PharmD, CPHQ; lholland@pqaalliance.org

U70 **Examining Treatment of Patient-Reported Comorbidities Using SEER-Medicare Health Outcome Survey in Elderly Cancer Patients**
Catherine Wang, PharmD, Erin Kent, PhD, MS; catherine.wang@nih.gov

U71 **Efficacy of Hepatitis B Vaccine in Adults with Chronic Liver Disease**
Yae-Ji Kim, PharmD, Jennifer Loucks, PharmD, BCPS, Meera Shah, PharmD, AAHIVP; ykim7@kumc.edu

U72 **Cost and Utilization Analysis on the Impact of Volcanic Activity for Respiratory and Ophthalmic Agents**
Annie Vuong, PharmD, Kavita Dave, PharmD, Ahmed Guhad, PharmD, Melissa Jay, PharmD, Alvah Stahlnecker, PharmD; annie.vuong@cvshealth.com

U73 **Interventions Impacting Medication Access: A Scoping Review**
Hannah Lee-Brown, PharmD, Emma Gugala, Mel Nelson, PharmD, CPHQ, Matthew Pickering, PharmD; hleebrown@pqaalliance.org

U74 **Refining a Research Agenda for Managed Care Pharmacy: A Survey Across Health Care Stakeholders**
Amber Reinert, Jody Gembarski, PharmD, Joseph Couto, PharmD, MBA, Daniel Tomaszewski, PhD, PharmD, Soumi Saha, PharmD, JD, Paula Eichenbrenner, MBA, CAE, Mandy Renfro; reinertrx@gmail.com

Z2 **Understanding the Association Between Diabetes and Its Comorbidities Among DSRIP Patients Through the Diabetes Prevention and Management Program**
Sumie Kakehi, PharmD candidate, Drym Oh, PharmD candidate, Jasmine Sham; sk1607@scarletmail.rutgers.edu

Z6 **Evaluation of a Value-Based Pharmacy Model to Improve Quality Measures in the Medicare Advantage and Medicaid Population**
Jennifer Dijaili, PharmD, Jason Kwan, PharmD, Brandon Koolick, Chaz Washington, PharmD, Donna Lynn Obra, PharmD, Stephanie Saba, PharmD; dijailij@aetna.com

Z7 **Virtual Reality Therapy: Budget Impact Model on Inpatient Costs**
Siddharth Jain, Yash Thaker, Young Kim, Eun Hyun Kim, Subin Cho, Soham Shukla, Nihal Narsipur; siddharth.jain@rutgers.edu

Z10 **Correlation Between Provider Density and Antipsychotic Prevalence Among Children in Foster Care**
Henry Tran, PharmD candidate, Susan dosReis, PhD, Laura Bozzi, MS; henrytran@umaryland.edu

Student Poster Titles and Presenters

Z11 Medication Therapy Management: Outcomes of Telephonic Pharmacist Outreach

Hillary H. Parkin, PharmD candidate, Jonathan W. Magness, PharmD, Kibum Kim, BPharm, MSc, PhD; hillary.parkin@pharm.utah.edu

Z12 Assessing Utilization Management Edit on Concurrent Opioid, Benzodiazepine, and Carisoprodol in Commercial and Healthcare Reform Lines of Business

Iris Tang, PharmD, Eric K. Abanquah, PharmD, Nancy D. Archila, PharmD, Melih Ozbek, PhD, Raja H. Khan, MS, Ellen M. Feeney, PharmD, BCPS; iris.tang@highmark.com

Z13 Assisting Colorado Seniors in Medicare Part D Personalized Plan Optimization

Susie Kim, PharmD, Megha Dhingra, PharmD, Clare M. Livingston, BS; susie.kim@ucdenver.edu

Encore Poster Titles and Presenters

C28 Real-World Healthcare Resource Utilization in Patients with Indolent Non-Hodgkin's Lymphoma: Differences Between Patients Treated First-Line with Ibrutinib or Bendamustine + Rituximab

Erika Szabo, MPH, Debra E. Irwin, PhD, Kathleen Wilson, MPH, Gerard Hoehn, PhD, Boxiong Tang, MD, PhD; erika.szabo@tevapharm.com

C29 Real-World Healthcare Resource Utilization in Patients with Chronic Lymphocytic Leukemia: Differences Between Patients Treated with First-Line Ibrutinib Monotherapy or Bendamustine + Rituximab

Erika Szabo, MPH, Debra E. Irwin, PhD, Kathleen Wilson, MPH, Gerard Hoehn, PhD, Boxiong Tang, MD, PhD; erika.szabo@tevapharm.com

D14 Lanadelumab Improves Health-Related Quality of Life in Patients with Hereditary Angioedema in the HELP Study

Gagan Jain, PhD, William R. Lumry, MD, Karsten Weller, MD, Markus Magerl, MD, Jennifer Schranz, MD, Helen Doll, DPhil, Marcus Maurer, MD; gjain0@shire.com

D15 Lanadelumab 300 Mg Every 2 Weeks Effectively Prevented Hereditary Angioedema Attacks in the HELP Study

Peng Lu, MD, PhD, Aleena Banerji, MD, Marc A. Riedl, MD, William R. Lumry, MD, James Hao, PhD, Marcus Maurer, MD, H. Henry Li, MD, PhD; plu0@shire.com

D16 Lanadelumab Safety and Immunogenicity: Results from the Phase 3 HELP Study

James Hao, PhD, Douglas T. Johnston, MD, Aleena Banerji, MD, Marc A. Riedl, MD, William R. Lumry, MD, Jonathan A. Bernstein, MD, H. Henry Li, MD, PhD, Peng Lu, MD, PhD, Richard Gower, MD; jhao@shire.com

E13 Patiromer and Maintenance of RAASi Therapy in Hyperkalemic Medicare Patients

Paula J. Alvarez, RPh, MPH, Robert D. Toto, MD, Christopher G. Rowan, PhD, Jeanene Fogli, PhD, RD, Nihar R. Desai, MD, MPH; palvarez@relypsa.com

E14 Critical Components of an Effective Medication Adherence Program: A Case Study Analysis

Jenny Glennon, PharmD, RPH, Stephen O'Malley, MS, Renee Gulotta, MBA; jglennon@healthdialog.com

F4 Higher Abstinence Rates with Greater Buprenorphine Exposure Among Patients Who Inject Opioids

Norma Lynn Fox, PhD, Anne Andorn, MD, Barbara Haight, PharmD, Mark Greenwald, PhD, Yue Zhao, MD, Christian Heidbreder, PhD, Susan M. Learned, MD, PharmD, PhD; normalynn.fox@indivior.com

F5 Impact of RBP-6000 on Patient-Reported Outcomes in Patients with Opioid Use Disorder: Results of a Randomized, Placebo-Controlled, Phase 3 Study

Vijay R. Nadipelli, BPharm, MS, Caitlyn Solem, PhD, Naoko Ronquest, PhD, Yu-Chen Yeh, MS, Christian Heidbreder, PhD, Susan M. Learned, MD, PharmD, PhD, Vishaal Mehra, MD; vijay.nadipelli@indivior.com

F31 Improvements in At-Home Functional Impairment with DR/ER-MPH in Children with Attention-Deficit/Hyperactivity Disorder: Post Hoc Analysis of BSFQ and PREMB-R by Norm-Referenced Cut-Offs

Norberto DeSousa, MA, Stephen Faraone, PhD, Timothy Wilens, MD, Steven Pliszka, MD, F. Randy Sallee, MD, PhD, Bev Incledon, PhD, Jeffrey Newcorn, MD; bert@ironshorepharma.com

F32 Extended-Release Viloxazine (SPN-812) for the Treatment of ADHD in Children: Topline Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study (P301)

Welton O'Neal, PharmD, Azmi Nasser, PhD, Joseph Hull, PhD, Fatima Chowdhry, MD, Toyin Adewole, MD, MPH, Tesfaye Liranso, PhD, Ronald Marcus, MD; woneal@supernus.com

F33 Extended-Release Viloxazine (SPN-812) for the Treatment of ADHD in Children: Topline Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study (P303)

Welton O'Neal, PharmD, Azmi Nasser, PhD, Joseph Hull, PhD, Fatima Chowdhry, MD, Toyin Adewole, MD, MPH, Tesfaye Liranso, PhD, Ronald Marcus, MD; woneal@supernus.com

F34 Efficacy and Safety of DR/ER-MPH, a Delayed-Release and Extended-Release Methylphenidate, in Children with ADHD: Results from a Pivotal Phase 3 Classroom Trial

Norberto DeSousa, MA, Ann C. Childress, MD, Andrew J. Cutler, MD, Andrea Marraffino, PhD, Bev Incledon, PhD, F. Randy Sallee, MD, PhD; bert@ironshorepharma.com

Encore Poster Titles and Presenters

G4 **Early Diagnosis and Speed to Effect in Spinal Muscular Atrophy Type 1**
Omar Dabbous, MD, MPH, MPH, Marcus Droege, PhD, MBA, Douglas Feltner, MD, Aaron Novak, PhD, Melissa Menier, MS, Douglas M. Sproule, MD, MSc; odabbous902@avexis.com

G5 **How Do We Measure Utilities Outside of Trials in Rare Diseases?**
Omar Dabbous, MD, MPH, Andrew J. Lloyd, DPhil, Rebecca Dean, MS, Natalia Piglowska, MSc, Benit Maru, MD, PhD; odabbous902@avexis.com

G6 **Economic Burden of Infant-Onset (Type 1) Spinal Muscular Atrophy: A Retrospective Claims Database Analysis**
Omar Dabbous, MD, MPH, Jennifer Seda, MD, Marcus Droege, PhD, MBA, Douglas M. Sproule, MD, MSc; odabbous902@avexis.com

G7 **Survival, Motor Function, and Motor Milestones Comparison of AVXS-101 Relative to Nusinersen for the Treatment of Infants with Spinal Muscular Atrophy Type 1**
Omar Dabbous, MD, MPH, Benit Maru, MD, PhD, Jeroen P. Jansen, PhD, Maria Lorenzi, MSc, Martin Cloutier, MSc, Annie Guérin, MSc, Irina Pivneva, PhD, Eric Q. Wu, PhD, Ramesh Arjunji, PhD, Douglas Feltner, MD, Douglas M. Sproule, MD, MSc; odabbous902@avexis.com

G11 **Impact of Antipsychotic Treatment Switching in Patients with Schizophrenia, Bipolar Disorder, and Major Depressive Disorder**
Benjamin Carroll, PharmD, Rajeev Ayyagari, PhD, Darren Thomason, MBA, Fan Mu, PhD, Michael Philbin, MBA, MSc; benjamin.carroll02@tevapharm.com

G12 **Safety Results of a 12-Month, Dose-Level Blinded Study of CVT-301 (Levodopa Inhalation Powder) in Patients with Parkinson's Disease**
Charles Oh, MD, Mark Lew, MD, Robert A. Hauser, MD, Cheryl H. Waters, MD, Eric S. Farbman, MD, Michael Klingler, MPH; coh@acorda.com

G13 **Efficacy Results of a 12-Month, Dose-Level Blinded Study of CVT-301 (Levodopa Inhalation Powder) in Patients with Parkinson's Disease**
Eric S. Farbman, MD, Mark Lew, MD, Cheryl H. Waters, MD, Robert A. Hauser, MD, Michael Klingler, MPH, Charles Oh, MD; farbmaer@yahoo.com

G14 **Efficacy and Safety of Apomorphine Sublingual Film for the Treatment of "OFF" Episodes in Patients with Parkinson's Disease: Phase 3, Double-Blind, Placebo-Controlled Trial**
Stewart A. Factor, DO, Stuart Isaacson, MD, Robert A. Hauser, MD, Rajesh Pahwa, MD, Ken Sciarappa, PhD, Parul Bhargava, PhD, Gazal Vakili, MSHS, David Blum, MD, Bradford Navia, MD, PhD, C. Warren Olanow, MD; sfactor@emory.edu

G15 **Clinical Efficacy of Valbenazine and Deutetrabenazine for the Treatment of Tardive Dyskinesia: Indirect Treatment Comparison of Randomized Controlled Trials**
Michael Serbin, PharmD, Saurabh Aggarwal, PhD, Chuck Yonan, PharmD; mserbin@neurocrine.com

G16 **Efficacy of CVT-301 (Levodopa Inhalation Powder) for Treatment of OFF Periods in Parkinson's Disease**
Iresha Abeynayake, MPH, Charles Oh, MD, Michael Klingler, MPH, Christopher Kenney, MD, Rajesh Pahwa, MD; iabeynayake@acorda.com

G23 **Patterns of Treatment Among Multiple Sclerosis Patients Treated with Disease-Modifying Therapies in Puerto Rico**
Alvin Ong, PharmD, Joanne Odom, PharmD, Manuel Nunez, PharmD, Hector Hernandez, PharmD, MPH, Gustavo Jimenez, PharmD, Lobat Hashemi, ScD; alvin.ong@sanofi.com

G24 **Characteristics of Multiple Sclerosis Patients in Puerto Rico Who Were Treated with Disease-Modifying Therapies Between 2010 and 2016**
Joanne Odom, PharmD, Manuel Nunez, PharmD, Hector Hernandez, PharmD, MPH, Gustavo Jimenez, PharmD, Sibin Stephen, PharmD, Lobat Hashemi, ScD; joanne.chia@sanofi.com

G25 **Significant Improvement in Treatment Satisfaction Among RRMS Patients Receiving Alemtuzumab in Real-World Clinical Practice in the United States: Interim Results from a Prospective, Non-Interventional, Online Survey of Patient-Reported Outcomes**
Denise Bury, PhD, Bhupendra O. Khatri, MD, Luke Chung, MD, MPH, Elizabeth Poole, PhD, Lobat Hashemi, ScD; denise.bury@sanofi.com

G26 **Significant and Clinically Meaningful Quality of Life Improvements in RRMS Patients Receiving Alemtuzumab in Real-World Clinical Practice: Interim Results from a Prospective, Non-Interventional, Online Survey of Patient-Reported Outcomes (PROMiS)**
Lobat Hashemi, ScD, Bhupendra O. Khatri, MD, Luke Chung, MD, MPH, Elizabeth Poole, PhD, Denise Bury, PhD; lobat.hashemi@sanofi.com

G27 **Prevalence Rates of Multiple Sclerosis Within a Northern California Healthcare Delivery System Between 2010 and 2016: A Retrospective, Electronic Health Records-Based Study**
Robert J. Romanelli, PhD, MPH; Qiwen Huang, MS, Joseph Lacy, MD, Alana Wong, , Lobat Hashemi, ScD, Alden Smith, PharmD; romanerj1@sutterhealth.org

G28 **Adherence Among Patients with Multiple Sclerosis Newly Initiating Once- or Twice-Daily Oral Disease-Modifying Drugs**
Amy L. Phillips, PharmD, Jacqueline Nicholas, MD, MPH, Natalie C. Edwards, MSc, Danielle E. Harlow, PhD; amy.phillips@emdserono.com

G49 **OnabotulinumtoxinA Is Safe and Effective in Patients Who Discontinue Topiramate: Results of the FORWARD Study**
John Rothrock, MD, Richard B. Lipton, MD, William B. Young, MD, Esther Jo, MPH, Aubrey Manack Adams, PhD, Andrew Blumenfeld, MD; jrothrock@mfa.gwu.edu

G50 **The Impact of Fremanezumab on Medication Overuse in Patients with Chronic Migraine**
Michael Philbin, MBA, MSc, Stephen D. Silberstein, MD, Sait Ashina, MD, Zaza Katsarava, MD, Michael Seminerio, PhD, MBA, Joshua Cohen, MD, MPH, FAHS; mike.philbin@tevapharm.com

G51 **The Impact of Offering Monthly and Quarterly Dosing Options for a New Class of Migraine Preventive Therapy on Likelihood of Acceptance and Adherence in Adults with Migraine**
Fawad Malik, PharmD, Robert Cowan, MD, FAAN, Joshua Cohen, MD, MPH, FAHS, Erik Rosenman, MPH, Ravi Iyer, MBA, PhD; fawad.malik@tevapharm.com

Encore Poster Titles and Presenters

G52 **The Impact of Fremanezumab on Migraine-Specific Health-Related Quality of Life in Chronic or Episodic Migraine**
Paul Isikwe, PharmD, Richard B. Lipton, MD, Sanjay Gandhi, PhD, Paul Yeung, MD, MPH, DFAPA, FAHS, Joshua Cohen, MD, MPH, FAHS, Ronghua Yang, PhD; paul.isikwe@tevapharm.com

G53 **Respiratory Function Decline in Eteplirsen-Treated Patients Diverges from Natural History Comparators over Time**
Navid Khan, PhD, Craig M. McDonald, MD, Lixin Han, PhD, Bernard T. Kinane, MD, Heather Gordish-Dressman, PhD, Linda Lowes, PhD; nkhan@sarepta.com

H2 **Pooled Analysis of OTX-101, a Novel Nanomicellar Cyclosporine Formulation, on Corneal Fluorescein Staining in Individual Zones over 3 Months**
Paul Karpecki, OD, Ranjan Malhotra, MD, FACS, Charles Darby, Abayomi Ogundele, PharmD, BCMAS, Jodi Luchs, MD; karpecki@karpecki.com

H3 **Effect of OTX-101, a Novel Nanomicellar Cyclosporine Formulation, on Total Conjunctival Staining Score**
Josh Johnston, OD, Paul Karpecki, OD, Shane Kannarr, OD, Bridgitte Shen Lee, OD, George Varghese, OD, Simon Lowry, MD, April Jasper, OD, Douglas Devries, OD; josh.johnston@gaeyepartners.com

I8 **Healthcare Resource Utilization and Costs Associated with Venous Thromboembolism Recurrence in Patients with Cancer**
Dejan Milentijevic, PhD, MBA, Alok A. Khorana, MD, Keith McCrae, MD, Jonathan Fortier, MA, François Laliberté, MA, Concetta Crivera, PharmD, MPH, Patrick Lefebvre, MA, Jeff Schein, DrPH, MPH; dmilenti@its.jnj.com

I9 **Incidence and Cost of Major Cardiovascular Events Among Patients with Chronic Coronary Artery Disease or Peripheral Artery Disease Identified in a Large U.S. Healthcare Database**
Qi Zhao, MD, MPH, Ariel Berger, MPH, Tarun Bhagnani, MD, Brian Murphy, BS, MS, Beth Nordstrom, PhD, MPH, Windsor Ting, MD, Nicholas Leeper, MD, Jeffrey Berger, MD, MS, FAHA, FACC; qzhao23@its.jnj.com

I10 **Healthcare Costs Before and After Stroke in Non-Valvular Atrial Fibrillation Patients Who Initiated Treatment with Rivaroxaban or Warfarin**
Dejan Milentijevic, PhD, MBA, Jennifer H. Lin, PhD, MA, Kun Wang, PhD, MSc, Deepti Bisht, BS, Emily Kogan, MS, Kathryn Twyman, PhD, Mark Alberts, Physician-in Chief; dmilenti@its.jnj.com

I11 **VTE-Related Healthcare Resource Utilization and Costs Associated with Venous Thromboembolism in Cancer Patients Treated with Anticoagulants**
Dejan Milentijevic, PhD, MBA, Michael B. Streiff, MD, Keith McCrae, MD, Jonathan Fortier, MA, François Laliberté, MA, Patrick Lefebvre, MA, Jeff Schein, DrPH, MPH, Alok A. Khorana, MD; dmilenti@its.jnj.com

I12 **Comparative Effectiveness, Safety, and Costs of Rivaroxaban and Warfarin Among Morbidly Obese Patients with Non-Valvular Atrial Fibrillation**
Veronica Ashton, MPH, Eric D. Peterson, MD, MPH, Yen-Wen Chen, PhD, Bingcao Wu, MS, Kamal Kant Mangla, BS, Alex C. Spyropoulos, MD, FACP, FCCP, FRCPC; vashton1@its.jnj.com

J2 **Incidence and Prevalence of Nontuberculous Mycobacterial Lung Disease in U.S. Medicare Beneficiaries, 2008-2015**
Ping Wang, PhD, Kevin Winthrop, MD, MPH, Jennifer Adjemian, PhD, Mehdi Mirsaeidi, MD, MPH, Theodore Marras, MD, FRCPC, MSc, Gina Eagle, MD, Raymond Zhang, MBA, Quanwu Zhang, PhD; ping.wang@insmed.com

J3 **All-Cause Mortality Increased with Nontuberculous Mycobacterial Lung Disease in U.S. Medicare Beneficiaries**
Ping Wang, PhD, Theodore Marras, MD, FRCPC, MSc, Quanwu Zhang, PhD, Mehdi Mirsaeidi, MD, MPH, Christopher Vinnard, MD, MPH, MSCE, Keith Hamilton, MD, Jennifer Adjemian, PhD, Gina Eagle, MD, Raymond Zhang, MBA, Kevin Winthrop, MD, MPH; ping.wang@insmed.com

J4 **Rapid Onset of Action and Improvement of Nasal and Ocular Symptoms with Olopatadine/Mometasone Combination Nasal Spray in Patients with Seasonal Allergic Rhinitis**
Sudeesh K. Tantry, PhD, Niran J. Amar, MD, Craig F. LaForce, MD, Cynthia F. Caracta, MD; adufour@prescottmed.com

J5 **Efficacy and Safety of Olopatadine/Mometasone Combination Nasal Spray for the Treatment of Seasonal Allergic Rhinitis**
Sudeesh K. Tantry, PhD, Gary N. Gross, MD, Frank Hampel, MD, Cynthia F. Caracta, MD; adufour@prescottmed.com

K12 **Patterns of Pharmacotherapy in Patients with Chronic Idiopathic Constipation in the United States Initiating Treatment with Linaclotide or Lubiprostone**
Arpita Nag, PhD, MBA, MS, Rebecca Bornheimer, BA, Margaret Gerbasi, PhD, Gerry Oster, PhD; anag0@shire.com

K14 **Rising and Higher Healthcare Resource Utilization and Costs of Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Liver Disease of Increasing Severity: Results of a U.S. Real-World Analysis**
Nandita Kachru, Robert Wong, Nicole Fulcher, PhD, Stuart Gordon; nandita.kachru@gilead.com

K15 **Longitudinal Analyses of Comorbidities and Healthcare Costs Among Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Liver Disease**
Nandita Kachru, Stephen Harrison, Emily Parker, Stephanie Korrer, Rohit Loomba; nandita.kachru@gilead.com

K16 **Increased Risk of Mortality in Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients: Real-World Analysis of 2007-2015 Medicare Data**
Jeremy Fraysse, Rohit Loomba, Suying Li, Stephen Harrison; jeremy.fraysse@gilead.com

K17 **Increasing Healthcare Resource Utilization and Costs Associated with Advanced Liver Disease: A Multivariate Analyses of Real-World Medicare Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients**
Jeremy Fraysse, Stuart Gordon, Suying Li, Robert Wong; jeremy.fraysse@gilead.com

K18 **Fibrosis-4 Score Provides Consistent Assessment of Healthcare Costs and Healthcare Resource Utilization Among Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Fibrosis**
A. Burak Ozbay, Stuart Gordon, Emily Parker, Stephanie Korre, Robert Wong; burak.ozbay@gilead.com

K19 **Identification and Characterization of Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Patients with Advanced Liver Fibrosis Identified Using Non-Invasive Tests of Hepatic Fibrosis: Real-World Results of 3,421 Patients**
Sanatan Shreay, Zobair Younossi, Emily Parker, Rohit Loomba; sanatan.shreay@gilead.com

Encore Poster Titles and Presenters

L6 **Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 3-Year Results from reSURFACE 2**
Melinda Gooderham, MSc, MD, FRCPC, Kim Papp, MD, PhD, FRCPC, Andrew Blauvelt, MD, MBA, Diamant Thaçi, MD, Qing Li, PhD, Kristian Reich, MD, PhD; mjgooderham@gmail.com

L7 **Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 3-Year Results from reSURFACE 1**
Stephen K. Tyring, MD, PhD, MBA, Lynda Spelman, MBBS, FACD, Atsuyuki Igarashi, MD, PhD, Mamitaro Ohtsuki, MD, PhD, Qing Li, PhD, Alan M. Mendelsohn, MD, Scott Guenthner, MD, FAAD; styring@ccstexas.com

L8 **Tildrakizumab Efficacy and Drug Survival by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and 2)**
Mark G. Lebwohl, MD, Nehal N. Mehta, MD, Alice B. Gottlieb, MD, PhD, Alan M. Mendelsohn, MD, Jeff Parno, MS, Stephen J. Rozzo, PhD, Alan Menter, MD; lebwohl@aol.com

L9 **The Effect of Tildrakizumab on Cardiometabolic Risk Factors in Psoriasis by Metabolic Syndrome Status: Post Hoc Analysis of 2 Phase 3 Trials (reSURFACE 1 and reSURFACE 2)**
Nehal N. Mehta, MD, Mark G. Lebwohl, MD, Alice B. Gottlieb, MD, PhD, Alan M. Mendelsohn, MD, Jeff Parno, MS, Stephen J. Rozzo, PhD, Alan Menter, MD; nehal.mehta@nih.gov

L10 **Safety of Tildrakizumab in Patients with Pre-Existing Metabolic Syndrome: Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and reSURFACE 2)**
Nehal N. Mehta, MD, Mark G. Lebwohl, MD, Alice B. Gottlieb, MD, PhD, Alan M. Mendelsohn, MD, Jeff Parno, MS, Stephen J. Rozzo, PhD, Alan Menter, MD; nehal.mehta@nih.gov

L11 **Once-Daily Oral Sarecycline 1.5 mg/kg/day Is Effective for Moderate to Severe Acne Vulgaris: Results from 2 Identically Designed, Phase 3, Randomized, Double-Blind Clinical Trials**
Sunil Dhawan, MD, Stephen K. Tyring, MD, PhD, MBA, Phoebe Rich, MD, Neil Sadick, MD, Robert Weiss, MD, Linda Stein-Gold, MD; sdhaw@yahoo.com

L12 **Budget Impact Analysis of Glycopyrronium Cloth for the Treatment of Primary Axillary Hyperhidrosis**
Kristin K. Gillard, PharmD, PhD, Ashton Moradi, PharmD, PhD, Lisa Bloudek, PharmD; kristin.gillard@dermira.com

L15 **Treatment Adherence and Persistence of Five Commonly Prescribed Medications for Moderate to Severe Psoriasis in a U.S. Commercial Population**
Amanda M. Teeple, MPH, Bingcao Wu, MS, Erik Muser, PharmD, MPH, Chris Pericone, PhD, Steven R. Feldman, MD; ateeple@its.jnj.com

L16 **Real-World Safe and Effective Use of Cryotherapy and Field-Directed Treatment for the Different Severities of Actinic Keratosis**
Meg Corliss, PhD, Jes B. Hansen, PhD, MSc, Mads D. Faurby, MSc, BsC, Thomas Larsson, DrMedSci, Nikeshia Dunkelly-Allen, PharmD, Steven R. Feldman, MD, PhD; mgcus@leo-pharma.com

L17 **Estimated Cost of Reducing Anxiety and Depression in Moderate to Severe Plaque Psoriasis Patients Treated with Guselkumab Versus Adalimumab Using Results from the Phase 3 VOYAGE 2 Study**
Amanda M. Teeple, MPH, Chenglong Han, PhD, Erik Muser, PharmD, MPH, April Armstrong, MD, MPH; ateeple@its.jnj.com

M10 **Treatment Patterns in Rheumatoid Arthritis Patients Initiating DMARDs: Analysis of U.S. Health Plan Claims**
Jenya Antonova, MS, PhD, Robin K. Dore, MD, Jerrold Hill, PhD; jenya.antonova@gilead.com

M16 **Modeling the Costs and Outcomes Associated with Treatment Sequences, with and Without Tofacitinib, for Psoriatic Arthritis in the United States**
John Woolcott, George Bungey, Stacey Chang-Douglass, Ming-Ann Hsu, Joseph C. Cappelleri, Pamela Young; john.woolcott@pfizer.com

M18 **Effect of Abaloparatide on Bone Mineral Density and Fracture Incidence in a Subset of Younger Postmenopausal Women with Osteoporosis at High Risk for Fracture Representative of Covered Commercial Insurance Enrollees**
Setareh A. Williams, PhD, Kenneth G. Saag, MD, MSc, Yamei Wang, PhD, Richard Weiss, MD, Jane Cauley, DrPH; swilliams@radiuspharm.com

M19 **Characterizing Patients Initiating Abaloparatide, Teriparatide, or Denosumab in a Real-World Setting: a U.S.-Linked Claims and EMR Database Analysis**
Setareh A. Williams, PhD, Erik Imel, MD, Kathryn Starzyk, ScM, Rich Gliklich, MD, Keith Hines, PhD; swilliams@radiuspharm.com

R1 **Burden of Atherosclerotic Cardiovascular Disease Risk in Persons with Elevated Triglyceride Levels According to Statin Use**
Sephy Philip, RPh, PharmD, Wenjun Fan, MD, MS, Craig Granowitz, MD, PhD, Peter Toth, MD, PhD, Nathan D. Wong, PhD; sephy.philip@amarincorp.com

R2 **The Humanistic Burden of Chronic Idiopathic Constipation in the United States: A Systematic Review**
Arpita Nag, PhD, MBA, MS, Bimpe Olayinka-Amao, PharmD, MPH, Susan Martin, MSPH, Molly Purser, PhD, Deirdre Mladsi, BA; anag0@shire.com

R3 **The Economic Burden of Chronic Idiopathic Constipation in the United States: A Systematic Literature Review**
Arpita Nag, PhD, MBA, MS, Renu Verkaria, PhD, Molly Purser, PhD, Deirdre Mladsi, BA; anag0@shire.com

R4 **Decrease in Therapeutic Effect Among Botulinum Toxin Type A Agents: Analysis of the FDA Adverse Event Reporting System Database**
Rashid Kazerooni, PharmD, MS; rashid.kazerooni@merz.com

T8 **Botulinum Toxin Type A Overdoses: Analysis of the FDA Adverse Event Reporting System Database**
Rashid Kazerooni, PharmD, MS; rashid.kazerooni@merz.com

U30 **The Effect of Different Lookback Periods on the Identification of New Users of Opioids**
Denis Y. Ishisaka, PharmD, MS, Jane Nichol, MPP, MS, Krista Yokoyama, PharmD; denis.ishisaka@blueshieldca.com

U31 **The Effect of Different Methods on the Identification of Cancer Members and Overall Opioid Utilization**
Denis Y. Ishisaka, PharmD, MS, Krista Yokoyama, PharmD, Jane Nichol, MPP, MS; denis.ishisaka@blueshieldca.com

U32 **Economic Evaluations of Sugammadex for Reversal of Neuromuscular Block in Surgical Procedures: A Systematic Review**
Ishita Doshi, MPH, Amit D. Raval, PhD, Sumesh Kachroo, PhD, Lori D. Bash, PhD, MPH; ishita.doshi@merck.com

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.

PLATINUM

Steven W. Champaloux, PhD, MPH, [U4] Exclusion Formulary: Assessment of Medical Costs, Pharmacy Costs, and Resource Utilization Compared to a Concurrent Control Group

Rita Hui, PharmD, MS, [E4] One-Year Outcomes of a Pharmacist-Managed Antidiabetic Deprescribing Program in an Integrated Healthcare System

Francis C. Staskon, PhD, [C21] Cost and Wastage Estimates for an Oral Oncology Medication Split-Fill Option in a Patient Management Program.

GOLD

Carmela Benson, MS, MSHP, [B5] Estimating Costs of Health Resource Utilization for Patients Living with Human Immunodeficiency Virus

Christine Birchwood, PhD, [Z14] Healthcare Resource Utilization and Direct Healthcare Cost Related to Peanut Allergy in Medicaid Patients

Nicole J. Brandt, PharmD, MBA, BCGP, BCPP, FASCP, [U24] Listening to the Medicare Beneficiaries: Findings from a National Survey on the Medication Therapy Management Standardized Format

Rachel Chelewski, PharmD, [Z16] Development of a Collaborative Pharmacy Practice Agreement to Improve Efficiency and Management of Prescribing in a Renal Transplant Clinic

Barb Goldberg, BSPharm, RPh, [U13] Analysis of Anti-Narcotic Therapy Across a Self-Insured Population

Nada Hindiyeh, MD, [G36] Shift from Chronic Migraine to Episodic Migraine Status in a Long-Term Phase 3 Study of Galcanezumab

Edward Lee, PharmD, [L1] Psoriasis Patients Switching Biologics Within the First Year of Biologic Treatment Initiation Have More Comedications, Higher Healthcare Resource Utilization, and Are Costlier than Persistent Patients

Brooke Looney, PharmD, [C3] A Targeted Approach to Reducing Rates of Discontinuation and Dose Reduction in Patients Receiving Sorafenib or Regorafenib

Stephen Lott, PharmD, MS, CSP, [E6] The Clinical and Financial Impact of Active and Passive Dipeptidyl Peptidase-4 Medication Switch Programs

Christina Polomoff, PharmD, [U25] Changing Prescriber Use of Pharmaceutical Manufacturer Coupons Within a Clinically Integrated Healthcare System

Yiran Rong, MS, [J9] Association Between Transient Opioid Use and Short-Term Respiratory Outcomes Among Adults with Chronic Obstructive Pulmonary Disease

Susan Yount, PhD, [D9] Assessing Patient Preferences for Rare Disease Treatment: Qualitative Development of the Paroxysmal Nocturnal Hemoglobinuria Patient Preference Questionnaire

SILVER

Carmela Benson, MS, MSHP, [B6] Rapid Initiation of Antiretroviral Treatment Following Diagnosis of Human Immunodeficiency Virus Among Commercially Insured Patients in the United States

Urvi Desai, PhD, [J1] Medicare Savings Resulting from Reductions in Prevalence of Respiratory Tract Infections Among the Elderly

Michael DiMatteo, PhD, [E42] Barth Registry and Repository: Summary of Findings and Key Points for Moving Forward

Monica Fay, PharmD, [E33] Assessing Healthcare Resource Utilization Across Segments of Obesity: A Retrospective Claims Study

Andrew S. Gaiser, PharmD, [U23] Payer Perceptions of Patient-Reported Outcomes and Other Clinical Outcome Assessments in the United States

Jenny Griffith, PharmD, [K6] Greater than Expected Dosing Assessment Among Targeted Immunomodulators in Management of Inflammatory Bowel Disease

Fiona M. Herr, PhD, [C25] A Systematic Literature Review of Clinical Evidence in Cutaneous T-Cell Lymphoma

Devin Incerti, PhD, [M9] Understanding the Impact of Dose Escalation on the Cost-Effectiveness of Etanercept Among Patients with Rheumatoid Arthritis

Medal-Winning Abstracts *(continued)*

SILVER

Shellie Keast, PharmD, PhD, [B2] Predictive Modeling of Fibrosis Scores for Patients Diagnosed with Chronic Hepatitis C in a State Medicaid Program

Nina Kim, PharmD, [U14] An Evaluation of Value-Based Frameworks for Non-Small Cell Lung Cancer Drug Regimens: ASCO Value Framework, ESMO Magnitude of Clinical Benefit Scale, ICER Report, and NCCN Evidence Blocks

Ashton Moradi, PharmD, [Z3] A Discrete Choice Experiment on Payer Preferences for Innovative Payment Schemes Aimed at Financing High-Cost, Potentially Curative Therapies

Kathy L. Schulman, MA, [B7] Characteristics of Early Adopters of a Two-Drug Regimen (Dolutegravir/Rilpivirine) for Treatment of Human Immunodeficiency Virus Type 1 in the United States

Phil Schwab, PhD, [M1] Treatment Patterns in New User Cohorts of Non-Specialty First-Line Therapy for Immune-Mediated Inflammatory Diseases

Mriga Shrikhande, MS, [J11] Effects of Psychological Distress on Medication Utilization in Asthma

Catherine I. Starner, PharmD, [G1] Spinal Muscular Atrophy: An Integrated Medical and Pharmacy Claims Analysis of Nusinersen Uptake and Gene Therapy Forecast Among 15 Million Commercially Insured

Donald Stull, PhD, [G3] Minimal Clinically Important Differences in Motor Function in Patients with Infantile-Onset Spinal Muscular Atrophy: Results from the Phase 3 ENDEAR Trial

Setareh A. Williams, PhD, [M17] Characterization of Medicare Patients with a Fragility Fracture

Gary Zammit, PhD, [G57] Lemborexant Versus Zolpidem Extended Release on Morning Postural Stability in Older Adults

BRONZE

David R. Axon, MPharm, MS, [I1] A Retrospective Database Analysis Evaluating the Relationship Between Pharmacy Quality Alliance-Defined Adherence and Healthcare Costs and Utilization for Commercially Insured Patients on Renin-Angiotensin System Antagonists

Kevin L. Bowen, MD, MBA, [K5] Association Between Hospitalization for Crohn's Disease or Ulcerative Colitis and Biologic Drug Therapy Adherence

Chad Brummett, [Z8] Quantifying the Healthcare Burden Associated with Opioid Use After Discharge Following Inpatient and Outpatient Surgery Among Previously Opioid-Naïve Patients

Jagadeswara Rao Earla, PharmD, MBA, [F30] Factors Associated with the Healthcare Effectiveness Data and Information Set Follow-Up Measures in Medicaid-Insured Children with Attention-Deficit Hyperactivity Disorder

Kelly A. Hollenack, PharmD, [G30] Prevalence of Probable Dravet Syndrome, Lennox-Gastaut Syndrome, and Other Refractory Epilepsies in Commercial and Medicaid Populations in the United States

Kruti Joshi, MPH, [F25] Healthcare Use and Associated Cost Among Patients with Treatment-Resistant Depression Across U.S. Payers: A Comprehensive Analysis

Jenny H. Kang, PharmD, [G55] Pain Medication Utilization Patterns in Cancer Survivors with Chronic Pain

Andrew Klink, PhD, MPH, [M2] Real-World Treatment Patterns of Rheumatoid Arthritis Patients Who Switched from Infliximab to Infliximab-dyyb

Eugene Daniel Kreys, PharmD, PhD, [G46] Comparing Fall Risk Among Antiepileptic Drugs in the Elderly: A Nested, Case-Control Study of a Medicare Database

Jackie Kwong, PhD, PharmD, [D1] Impact of Hemoglobin Normalization on Healthcare Resource Utilization in Patients Receiving Parenteral Iron Therapy

Lea Mendez, PharmD, [U7] Accuracy and Efficiency: Validating the Financial Impact of Pharmacist Interventions

Jacqueline Pesa, MSEd, PhD, MPH, [F26] Assessment Using Claims-Based and Patient-Reported Data to Identify Treatment-Resistant Depression: Implications for Research and Practice

Sean D. Sullivan, BScPharm, PhD, [C20] Budget Impact Analysis of Larotrectinib for 8 Tumors in the United States

Kai Yeung, PharmD, PhD, [U9] Re-Designing a Value-Based Formulary to Address Current Pharmaceutical Spending Trends: Changes in Drug-Tier Classifications

Jingchuan Zhang, PhD, [L3] Clinical Implications of Early PASI Responses to Tildrakizumab in Patients with Moderate to Severe Plaque Psoriasis

Podium Abstracts
(Presentations: Tuesday, March 26, 2:30 pm-3:45 pm)

C21 Cost and Wastage Estimates for an Oral Oncology Medication Split-Fill Option in a Patient Management Program

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BACKGROUND: In 2008, a national specialty pharmacy implemented a "split-fill" option within an oral oncology patient management program to reduce pharmacy costs by decreasing medication wastage due to early discontinuations. Recent expansions of the split-fill option include coverage to the third month post-initiation of therapy as well as to 15 oral oncolytics. Payers cover dispensed medications at half-quantity intervals including copay modifications for each dispense. There is proactive patient outreach prior to completing the initial dispensed medication quantity, to assess the patient's toleration to the new medication and side effects.

OBJECTIVE: To compare patients with pharmacy benefit designs that include a split-fill option to similar patients without this option on patient discontinuation rates, patient reported side-effects, estimated pharmacy costs, and potential wastage.

METHODS: This retrospective cohort study included patients who were new-to-therapy on one of the split-fill medications between September 2015 and August 2017. A 1:1 greedy match algorithm was conducted using propensity variables to match split-fill to non split-fill patients by patient age, gender, state census areas, index medication, start date, and switching to another medication. Per-month discontinuation rates were determined for both split-fill and non split-fill groups. The non split-fill potential wastage was calculated as per monthly costs for those who discontinued in the following month and weighted by split-fill discontinuation rates.

RESULTS: Of the 2,363 patients within the managed program meeting selection criteria for the 11 medications, 671 patients from each group were matched, and post-matched comparisons on propensity variables indicated standardized differences < 0.083. Monthly utilization trends found a significantly higher persistency rate ($P<0.0001$) in first two months and lower copays in the first month by $132.50 ($P<0.007$) for split-fill compared to non split-fill patients. Payers with a split-fill program had a mean $2,724.97 AWP savings per month ($P<0.0001$) on medications. Based on modeled wastage for the first three months, payers without a split-fill program could expect to save $2,782.29 AWP if changed to this option. All patients were clinically managed through the same management program; both cohorts had similar side-effects rates and time until first reported side-effect.

CONCLUSIONS: In the first three months, the split-fill patient managed program had lower discontinuation rates, significantly reduced pharmacy costs, and reduced potential wastage.

SPONSORSHIP: AllianceRx Walgreens Prime.

E4 One-Year Outcomes of a Pharmacist-Managed Antidiabetic Deprescribing Program in an Integrated Healthcare System

Hui R[1], Chang C[1], Niu F[1], Harano D[1], Deguzman L[1], Kao D[1], Awsare S[2], Draves M[2]. 1800 Harrison St., Ste 1301, Oakland, CA 94612; rita.l.hui@kp.org; (510) 625-3948
[1]Kaiser Permanente; [2]The Permanente Medical Group

BACKGROUND: Deprescribing is the planned and supervised process of dose reduction or discontinuation of medications that may lead to harm or are no longer beneficial. A collaborative drug therapy management protocol on deprescribing was created under a partnership between physicians and clinical pharmacy services at Kaiser Permanente Northern California. While there are studies detailing strategies to deprescribe benzodiazepines and antipsychotics in nursing homes or in those with dementia, there is a lack of guidance and evidence to safely deprescribe chronic medications, such as antidiabetics, for older patients in the community setting.

OBJECTIVE: To compare the effectiveness and safety outcomes between pharmacist-managed deprescribing and usual care on selected antidiabetic medications within an integrated healthcare system one year after the intervention.

METHODS: This was a retrospective propensity score-matched (PSM) cohort study. The deprescribing group included patients who were enrolled in the deprescribing program between July 1, 2016 and June 30, 2017. The usual care group included eligible patients who did not receive the deprescribing intervention and were matched to the deprescribing group on baseline demographics and clinical variables using PSM at a 3:1 ratio. Patients were followed for one year or the end of membership or death, whichever occurred first. Effectiveness outcomes were the incidence of hypoglycemia requiring acute care and death. Safety outcomes included incidence rate of hyperglycemia requiring acute care, proportion of patients at goal hemoglobin A1c (HbA1c) <7% and change in HbA1c.

RESULTS: After PSM, 685 patients in the deprescribing group and 2,055 patients in the usual care group were similar in age, gender, weight and comorbidity burden (mean age 82.4±5.4 years old, 48% female, mean weight 81.7±19.2 kg, mean Charlson Comorbidity Index 3.2±1.6). Compared to the usual care group, the deprescribing group had a significant lower incidence rate of hypoglycemia (1.6% vs. 3.5%, P=0.01), lower mortality rate (6.0% vs. 10.8%, $P<0.01$) and greater change in HbA1c (0.3±0.6 vs. 0.2±0.7, $P<0.01$). There were no differences in the incidence rate of hyperglycemia and proportion of patients at goal HbA1c.

CONCLUSIONS: This study showed that deprescribing of selected antidiabetics in older patients with well-controlled type 2 diabetes had sustained benefit after one year in reducing the risk of hypoglycemia and mortality. This was accomplished without elevating the risk for hyperglycemia nor negatively impacting the proportion of patients at goal HbA1c.

SPONSORSHIP: Kaiser Permanente.

U4 Exclusion Formulary: Assessment of Medical Costs, Pharmacy Costs, and Resource Utilization Compared to a Concurrent Control Group

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BACKGROUND: Formulary exclusions have arisen to address escalating drug expenditures. An exclusion formulary (EF) places select medication(s) within a drug class that have clinically supported alternative(s) in a non-coverage status. Individuals may appeal non-coverage. On January 1, 2017, four BlueCross BlueShield plans implemented an EF consisting of over 300 excluded drugs. Concern exists for increased medical resource utilization and cost impact associated with an EF.

OBJECTIVE: To assess the impact of an EF on (a) medical and pharmacy costs and (b) medical resource utilization.

METHODS: The study design was a retrospective cohort utilizing administrative medical and pharmacy claims. A control group was created from members of the same Blues plans that did not have an exclusion formulary (non-EF). Members in the analysis were required to be continuously enrolled in a fully-insured line of business from January 2016 through December 2017. The study outcomes were: (1) medical and pharmacy costs, defined as annual plan and member expenditures, and (2) medical resource utilization defined as annual member hospitalizations and emergency room (ER) visits. A pre (2016)-post (2017) difference-in-difference analysis was used to assess the change in cost and utilization in EF compared to the non-EF population. For cost of care, a general estimating equation (GEE) was fit with a gamma distribution adjusting for Blue plan, Charlson Index Score (severity of illness proxy), rural-urban, age, gender, and zip-code derived sociodemographic variables. For utilization, a GEE was fit with a negative binomial distribution generating incidence rate ratios (IRRs). Sub-analysis separately assessed members with three chronic conditions: diabetes, heart failure, and asthma.

RESULTS: A total of 116,300 EF and 750,446 non-EF members met inclusion criteria. From 2016 to 2017, the EF population had significantly lower pharmacy costs (EF: 0.2% vs. non-EF: 5.4%, $P<0.01$) with no increase to medical costs (EF: 11.9% vs. Non-EF: 12.7%, $P=0.69$) compared to controls. IRRs from 2016 to 2017 showed non-significant differences for hospitalizations (EF: 1.10 vs. non-EF: 1.07, $P=0.32$); and ER visits (EF: 1.03 vs. non-EF: 1.02, $P=0.52$). Lower pharmacy costs without a significant difference to medical costs or utilization was also found for the three conditions.

CONCLUSIONS: The exclusion formulary was associated with significant pharmacy savings and was not associated with increased medical cost or resource utilization. Further research is needed to evaluate EF healthcare impact.

SPONSORSHIP: Prime Therapeutics.

Professional Reviewed Abstracts
(Presentations: Wednesday, March 27, 11:30 pm-1:00 pm)

A00-B99 Certain Infectious and Parasitic Diseases
(e.g., HIV, Hepatitis C)

A1 Risk of Time-to-Hospitalization in Patients with Nontuberculous Mycobacterial Lung Disease in the U.S. Medicare Population

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BACKGROUND: The diagnosis of nontuberculous mycobacterial lung disease (NTMLD) is increasing in the United States, particularly among persons aged > 50 years. However, the associated risk of hospitalizations remains unclear.

OBJECTIVE: To compare risks for hospitalization (all-cause, lung-related) between NTMLD patients to age-sex matched controls among U.S. Medicare beneficiaries.

METHODS: We extracted data from the Centers for Medicare & Medicaid Services database for the study period 2007-2015, for all beneficiaries aged ≥ 65 years with ≥ 2 claims for NTMLD (ICD-9 031.0, ICD-10 A31.0) ≥ 30 days apart. We matched each patient to 2 controls by age and sex. The date of first NTMLD diagnosis was the index date, and it was assigned to matched controls as theirs. Follow-up time was the interval from index date until the earliest date of enrollment to Part C, date of death, or end of study period. Time-to-hospitalization was measured as the interval between index date and the first hospitalization (all-cause, lung-related). We used Cox proportional hazards models with time-to-hospitalization as the outcome to estimate the risk of hospitalization, adjusting for relevant demographic and comorbid factors identified during the 12 months prior to the index date. We used Poisson regression to estimate hospitalization rates.

RESULTS: Eligible patients (N = 35,444) and matched controls (N = 65,467) had a mean age of 76.6 (± 6.8) years; 70% were women in NTMLD vs. 71% in controls. The Charlson index was 3.0 (± 2.5) in NTMLD vs. 1.5 (± 2.0) in controls. NTMLD patients had substantially more respiratory disorders (44.6% vs. 0.6% bronchiectasis, 81.1% vs. 17.7% COPD, 19.4% vs. 3.7% empyema, 0.1% vs. 0.0% cystic fibrosis, 54.5% vs. 6.6% pneumonia, 8.5% vs. 0.2% hemoptysis, 9.5% vs. 0.1% tuberculosis). Mean follow-up time was 3.1 (± 2.2) years for NTMLD vs. 3.3 (± 2.2) years for controls. Observed yearly all-cause hospitalization rates were 21.2% in NTMLD vs. 13.6% in controls (rate ratio [RR] = 1.6; 95% CI: 1.5-1.6); COPD-related hospitalization rates were 11.0% in NTMLD and 2.4% in controls (RR = 4.6, 95% CI: 4.5-4.8); pneumonia-related hospitalization rates were 7.7% in NTMLD and 2.6% in controls (RR = 2.9, 95% CI: 2.8-3.0). After adjusting for covariates, NTMLD was associated with higher risk/shorter time-to-hospitalization relative to controls by 32% (HR = 1.32, 95% CI: 1.29-1.36) for all-cause, 22% (HR = 1.22, 95% CI: 1.19-1.25) for COPD-related, and 17% (HR = 1.17, 95% CI: 1.14-1.20) for pneumonia-related hospitalizations.

CONCLUSIONS: NTMLD is associated with shorter time-to-hospitalization (all-cause, lung-related) relative to controls.

SPONSORSHIP: Insmed.

B1 Analyzing Hepatitis C Treatment Completion Rates in Patients with Substance Use Disorders in a New York State Health Plan

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BACKGROUND: Injection drug use is a common mode of hepatitis C virus (HCV) acquisition. Centers for Disease Control (CDC) data showed significant increases in HCV and opioid injection from 2004 to 2014 in people aged 18 to 39 years. In 2016, nearly 149,000 cases of chronic HCV were reported by the CDC; New York State (NYS) accounted for 8,985 (6%) of those cases. With a strong correlation between injection drug use and the incidence of HCV infection, treatment of this population is critical. Health plans previously restricted treatment for active drug users due to potential adherence concerns. Fidelis Care's case management program works with members and providers to proactively address potential barriers to successful treatment. This review analyzes HCV treatment completion rates of members of a NYS health plan with a documented history of substance use and/or substance use treatment.

OBJECTIVE: To determine completion rates of HCV treatment of NYS health plan members with or without a substance use history.

METHODS: A review of medical claims, pharmacy claims, and clinical notes identified members at least 18 years of age who initiated HCV treatment from October 2017 to September 2018. Members were sorted into groups: (1) No documented history of substance use disorder (SUD) and (2) Documented current, or history of, SUD. The SUD group was divided into sub-groups: (a) Documented substance dependence or abuse; (b) Methadone maintenance program participation; (c) Use of substance use deterrents; and (d) Receipt of Narcan (naloxone).

RESULTS: There were 2,058 unique regimens for HCV treatment. The treatment completion rate for all regimens was 85.8%. Completion rates for each defined subgroup were: (a) 84.2%, (b) 84.1%, (c) 85.3%, and (d) 84.2%. Members who did not have a documented history of substance use or substance use treatment had a completion rate of 87.3%.

CONCLUSIONS: Treatment completion rates for the 4 subgroups were similar to the overall completion rate and a reasonable correlation can be made to an effective case management strategy. Fidelis Care HCV case management works to maximize the potential for successful treatment by working with providers and members during the HCV treatment process, including selection of clinically appropriate therapies and member education for optimal adherence. The data further support the value of treating all patients infected with HCV through collaboration between health plans, providers, and members, including populations that may have previously been considered at risk for adherence issues.

SPONSORSHIP: Fidelis Care.

B2 Predictive Modeling of Fibrosis Scores for Patients Diagnosed with Chronic Hepatitis C in a State Medicaid Program

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BACKGROUND: Liver fibrosis is frequently used to prioritize hepatitis C virus (HCV) patients for treatment. Real-world evidence assessing case-mix severities and disease sequelae may assist in prioritizing patients to receive treatment with newer direct acting antivirals (DAA).

OBJECTIVE: To assess a multivariable predictive model of HCV METAVIR fibrosis score using clinical and administrative claims data among adult Medicaid members.

METHODS: This historical, cross-sectional cohort study used comprehensive administrative claims from Oklahoma Medicaid for adult members (aged 18-64 years old) diagnosed with chronic HCV from 07/01/14-10/31/17. Additional clinical data (e.g., fibrosis scores, HCV genotypes) were merged from a management program to analyze METAVIR fibrosis score. Proportional-odds ordered logit models were used, reporting odds ratios (OR) and controlling for demographic, clinical, and extra-hepatic comorbid factors, including extensive HCV-related sequelae and year of treatment. Sensitivity analyses included stepwise regressions and application of machine learning via support vectors to predict METAVIR classification.

RESULTS: Of 1,096 eligible Medicaid members in this study, cases averaged 48.8 ± 10.6 years and 43.3% were male. Some 194 (17.7%) had cirrhosis and 50 (4.6%) involved decompensated cirrhosis diagnosis. Physician reported METAVIR scores included 11.2% F0, 18.3% F1, 25.6% F2, 16.0% F3, and 28.9% F4. Multivariable analysis across all cases indicated significant associations ($P < 0.05$) between more severe METAVIR scores and several factors including male sex (OR = 1.82), age (OR = 1.05), genotype other than 1 (OR = 1.67), DAA treatment length (OR = 1.19), diabetes (OR = 1.69), hepatocellular carcinoma (OR = 5.45), cirrhosis (OR = 21.23), varices (OR = 7.55), and GERD (OR = 1.42). Most clinical associations were consistent among non-cirrhotic cases. Pseudo R2 values were 24.0% overall and 9.5% among non-cirrhotic cases only. Stepwise results were also generally consistent with main analyses, but with significant differences in year, ascites, and GERD. Machine learning predictions observed that 47.7% were support vectors across all cases and 75.3% for non-cirrhotic when tuned ($\geq 93.2\%$ and $\geq 79.8\%$, respectively, when untuned).

CONCLUSIONS: This investigation observed numerous multivariable clinical associations with METAVIR fibrosis scores in Medicaid members, machine learning suggesting potentially moderate to strong predictive capabilities when tuned. Disease severity prediction may assist policymakers with appropriate resource allocation and benefit design.

SPONSORSHIP: AbbVie.

B3 Impact of a Smartphone-Based Artificial Intelligence Platform on Hepatitis C Adherence in a Real-World Population

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BACKGROUND: Digital tools, including those leveraging artificial intelligence, offer a new means to both accurately measure and improve adherence. However, there is limited research available on the impact of such tools on adherence in a real-world population. To help answer this question, a pilot program was initiated in members initiating oral hepatitis C (HCV) therapy, in which members had the choice to use an AI platform (AIP) that visually and automatically confirmed participant identity, the medication, and medication ingestion.

OBJECTIVE: To compare adherence to HCV drugs in members who agreed to use smart-phone-based AIP compared to non-participants.

METHODS: The pilot was conducted from January 2018 to December 2018 in a self-funded commercial population. Participants who opted-in to use the AIP at the time of therapy initiation were eligible to earn small monetary incentives for each daily dose taken. Members in the eligible sample were excluded if their first HCV claim was dated after August 31 to ensure members had adequate time to complete treatment. Adherence, measured as the proportion of days covered (PDC), was calculated for each member. The index date for the PDC calculation was the date of the first HCV claim, while the end date was the first claim date plus the recommended therapy duration. Statistical significance was calculated using a Wilcoxon-Mann-Whitney test. Baseline medication adherence characteristics and Chronic Disease Score were also compared for members that had at least 6 months of continuous enrollment prior to index date.

RESULTS: The eligible sample consisted of 91 members, including 35 participants and 56 non-participants. Both the participants and non-participants were similar across all tested demographic (gender, age, and Chronic Disease Score) and baseline medication adherence characteristics. The observed PDC for HCV drugs was statistically higher in participants (mean 0.962) compared to non-participants (mean 0.876; $P = 0.02$).

CONCLUSIONS: Members utilizing a smart-phone-based AIP demonstrated a statistically significant higher PDC to HCV drugs than non-participants. Although cure rate data was unavailable at the time of this analysis, it is reasonable to infer that higher adherence would lead to less treatment failures. It is also possible that monetary incentives may have contributed to increased adherence rather than use of AIP solely. Further study is warranted to determine the impact of the AIP independent of monetary incentives, as well as in additional chronic disease states.

SPONSORSHIP: Magellan Rx Management.

B4 Long-Term Benefits of Rapid Antiretroviral Therapy Initiation Among Medicaid-Covered Patients with Human Immunodeficiency Virus

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BACKGROUND: New treatment guidelines for human immunodeficiency virus (HIV-1) advocate for rapid initiation of antiretroviral treatment (ART), which could reduce morbidity and mortality, improve patient health, and reduce long-term healthcare costs (HCC).

OBJECTIVE: To describe HCC over 6, 12, 24, and 36 months (6M, 12M, 24M, and 36M) post-HIV-1 diagnosis based on time to ART initiation in Medicaid-covered patients.

METHODS: Multi-state Medicaid data (01/2012-03/2017) was used to identify ART-naïve adults with HIV-1, $\geq 6M$ of continuous eligibility pre-diagnosis, and ART initiation ≤ 360 days of first diagnosis. ART regimen had to include a protease, integrase, or non-nucleoside reverse transcriptase inhibitor, with ≥ 2 nucleoside reverse transcriptase inhibitors. Cohorts were formed based on time to ART initiation post-HIV-1 diagnosis: rapid initiators (RI; ≤ 14 days), moderately rapid initiators (mRI; 15-60 days), moderately delayed initiator (mDI; 61-180 days), or delayed initiators (DI; 181-360 days). Total accumulated and per-patient-per-month (PPPM) HCC (sum of medical costs

[MC] and pharmacy costs [PC]) over 6M, 12M, 24M, and 36M post-diagnosis were described among patients with at least 6M, 12M, 24M, and 36M of Medicaid coverage, respectively.

RESULTS: Among 974 patients, 347 (35.6%) were excluded (initiated ART > 360 days post-diagnosis) and 627 eligible patients were analyzed; mean age was 40.1 years (SD = 12.3; median = 40.7), 42.7% were females, and 53.9% were black; 20.4% were RI, 36.4% were mRI, 26.0% were mDI, and 17.2% were DI. Overall, average time to treatment was 88.8 days (SD = 94.8). Over 6M (N = 571), 12M (N = 471), 24M (N = 283), and 36M (N = 162) post-diagnosis, total MC increased for RI and DI, but were always greater for DI (6M: $7,757 [RI] vs. $9,124 [DI]; 12M: $10,836 vs. $15,989; 24M: $16,220 vs. $27,797; 36M: $23,447 vs. $43,067); conversely, PC were always lower for DI. Over the same periods, MC generally accounted for > 50% of HCC for mDI and DI and for 30%-40% of HCC for RI and mRI. Over 36M, total HCC increased with delayed ART initiation (RI: $74,093; DI: $83,157). HCC PPPM decreased over time for RI (from $3,222 at 6M to $2,058 at 36M), mRI (from $3,475 to $2,143), and mDI (from $2,668 to $2,224), but increased for DI (from $1,553 to $2,310).

CONCLUSIONS: Over time, PPPM HCC and MC decreased for RI. Lower MC from 6M to 36M post-HIV-1 diagnosis were also observed for RI. Over 36M post-diagnosis, HCC were lower for RI (increased PC were offset by reduced MC), highlighting the long-term economic benefits of rapid ART initiation post-HIV-1 diagnosis.

SPONSORSHIP: Janssen Scientific Affairs.

B5 Estimating Costs of Health Resource Utilization for Patients Living with Human Immunodeficiency Virus

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BACKGROUND: Few studies estimate modern unit costs of health resource utilization (HRU) for people living with human immunodeficiency virus (PLWHIV) in the United States (U.S.). Estimated cost inputs for HRU can be used to determine cost of care for patients in clinical studies, since these studies often collect HRU data without payments for such services.

OBJECTIVE: To develop HRU cost estimates applicable to data collected in ongoing U.S. clinical studies of PLWHIV.

METHODS: Multi-state Medicaid data combined with a targeted literature review (TLR) was used to estimate HRU costs in PLWHIV. Mean, standard deviation (SD), and median costs were calculated for all-cause claims from the most recent year of Medicaid data (ranging from 2013 to 2016). Main components were costs per inpatient (IP) day (i.e., total IP cost per admission divided by length of stay) and costs per emergency room (ER) and outpatient (OP) visit. OP visits included general professional services (GPS; general practitioner, nurse/nurse practitioner, and physician assistant services), specialist professional services (SPS; specialist, therapist, psychiatrist, and dental services), HIV care (i.e., HIV-related follow-up visit or sexually transmitted disease test), and procedural and social services. The TLR was used to identify a range of HRU costs and included the following search terms: HIV, economic burden, cost(s), and United States. All costs represented amounts paid by Medicaid in 2017 U.S. dollars.

RESULTS: A total of 21,513 Medicaid PLWHIV (516,179 claims) were included in the analysis. Mean age was 43.6 (SD = 15.0; median = 46.4) years, 50.7% were female, and 53% were black. Mean costs were $2,035 (SD = $7,764; median = $515) per IP day, $212 (SD = $268; median = $130) per ER visit, and $85 (SD = $138; median = $51) per OP visit. Specifically, mean OP costs were $69 for GPS, $97 for SPS, $71

for HIV care, $106 for procedure services, and $74 for social services. Seven studies were identified from the TLR with data from 1995 to 2009; mean costs ranged from $1,849-$3,451 per IP day, $704-$828 per ER visit, and $130-$417 per OP visit. Mean costs for OP and ER visits were lower in Medicaid than in the TLR, but similar for IP days.

CONCLUSIONS: Administrative claims data provided updated cost estimates that were generally consistent with the TLR. Combining both sources provided a robust range of costs for PLWHIV, which is important for decision-makers. Changes in treatment guidelines and increased availability of single-tablet regimens could explain lower ER and OP costs in Medicaid, but further research is needed to confirm.

SPONSORSHIP: Janssen Scientific Affairs.

B6 Rapid Initiation of Antiretroviral Treatment Following Diagnosis of Human Immunodeficiency Virus Among Commercially Insured Patients in the United States

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BACKGROUND: New treatment guidelines for human immunodeficiency virus (HIV) advocate for rapid initiation of antiretroviral therapy (ART) as early as ≤ 7 days of diagnosis with agents that have high genetic barrier to resistance, good tolerability, and convenient dosing.

OBJECTIVE: To describe characteristics, time to ART initiation, and healthcare costs (HCC) in commercially insured patients living with HIV in the United States and treated ≤ 60 days of diagnosis.

METHODS: Truven Health MarketScan Research Databases (2012-2017) were used to identify ART-naïve adults with HIV-1, ≥ 6 months of continuous eligibility before first HIV-1 diagnosis, and ART initiation ≤ 60 days of first diagnosis. ART regimen had to include a protease inhibitor (PI), integrase strand transfer inhibitor (INSTI), or non-nucleoside reverse transcriptase inhibitor (NNRTI), with ≥ 2 nucleoside reverse transcriptase inhibitors. Cohorts were formed based on time to ART initiation post-diagnosis: rapid initiators (RI; ≤ 7 days) or moderately rapid initiators (mRI; 8-60 days).

RESULTS: Among 9,351 patients, median time to treatment was 31.0 days. Patients initiating ART > 60 days after HIV-1 diagnosis were excluded (2,608 [27.9%]), while 6,743 (72.1%) initiated ART ≤ 60 days of diagnosis and were analyzed; 18.3% were RI and 81.7% were mRI. For all analyzed patients, mean age was 38.1 (SD = 12.0; median = 37.0) years and 13.2% were females; 12.7%, 56.2%, and 31.1% initiated a PI-, INSTI-, or NNRTI-based regimen, respectively. Elvitegravir (EVG; 32.9%), efavirenz (EFV; 20.9%), dolutegravir (18.5%), and darunavir (DRV; 8.5%) were the most commonly used antiretrovirals; most patients (74.3%) were initiated on single-tablet regimens. PI-based regimens were more common for RI (PI = 17.7%, DRV = 11.0%) than mRI (PI = 11.5%, DRV = 7.8%). INSTI-based regimens were more common for mRI (INSTI: 57.7%, EVG: 33.8%) than RI (INSTI: 48.8%, EVG: 29.1%). NNRTI-based regimens were as common for RI and mRI. Total HCC (i.e., sum of medical and pharmacy costs) over 36 months post-HIV diagnosis were lower for RI ($109,456) than mRI ($116,870).

CONCLUSIONS: Although 72.1% of patients initiated ART ≤ 60 days of HIV-1 diagnosis, an opportunity remains to initiate ART sooner; only 18.3% initiated ART ≤ 7 days. Many RI used suboptimal agents such as EFV and EVG with low rather than high genetic barrier to resistance, demonstrating a need to optimize HIV treatment with antiretrovirals having high genetic barrier to resistance. RI showed lower HCC relative to mRI, highlighting the potential long-term benefits of rapid ART initiation.

SPONSORSHIP: Janssen Scientific Affairs.

B7 Characteristics of Early Adopters of a Two-Drug Regimen (Dolutegravir/Rilpivirine) for Treatment of Human Immunodeficiency Virus Type 1 in the United States

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BACKGROUND: In 2017, Juluca (dolutegravir/rilpivirine; DTG/RPV), the first complete treatment regimen containing only two drugs in a single tablet to treat human immunodeficiency virus type 1 (HIV-1) was approved for use in antiretroviral (ARV) treatment-experienced patients currently suppressed on a stable regimen with no history of treatment failure or resistance to either DTG or RPV.

OBJECTIVE: To characterize the early utilization of DTG/RPV in the United States.

METHODS: This is an ongoing cohort study of HIV-1 infected adults prescribed DTG/RPV in the Observational Pharmaco-Epidemiology Research and Analysis (OPERA) cohort, the product of a collaboration of HIV caregivers in 84 clinics across 18 states, District of Columbia, and Puerto Rico following over 90,000 people living with HIV through their prospectively-collected electronic medical records. Baseline demographic, clinical and laboratory characteristics of patients who initiated DTG/RPV between January 1 and June 30, 2018 were analyzed using descriptive statistics. Study index date was the start date of the first prescription for DTG/RPV.

RESULTS: A total of 456 patients were prescribed DTG/RPV during the study window; 55% of whom were ≥50 years of age, 83.8% male, 31.8% African American, and 28.7% Hispanic. DTG/RPV was most often administered as a stand-alone two-drug regimen (72.4%, n = 330) but was also administered in regimens containing other ARV agents, most frequently darunavir/cobicistat (n = 24) and emtricitabine/tenofovir alafenamide (n = 24). Twelve patients (3%) were ART naïve at index, 338 (74%) were ART experienced with undetectable viral loads (VL) at initiation (VL < 50 copies/mL), 42 (9%) had VL ≥ 50 to < 200 copies/mL while another 9% (n = 40) had VL ≥ 200 copies/mL. VL was unavailable at initiation for 21 (5%) patients. Most patients were previously on elvitegravir (21.4%), efavirenz (7.2%) or other RPV- or DTG- (21.0%) based regimens. A majority (78.5%) of patients initiated DTG/RPV with CD4 counts > 350 cells/mm3; 63.4% > 500 cells/mm3. Overall, a third of patients had a history of AIDS. Comorbidity was prevalent: 60% of patients had ≥1 endocrine disorder; 43% hypertension, 36% a mental health disorder and 29% renal disease. Median (IQR) VACS 5-year mortality score was 18 (10-29).

CONCLUSIONS: Early initiators of DTG/RPV, the first approved complete HIV-1 treatment regimen containing only two drugs, are primarily treatment-experienced individuals older than 50 years of age with virologic and immunologic control and high rates of comorbid conditions.

SPONSORSHIP: ViiV Healthcare.

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

C1 Physician Treatment Choice in Treating and Managing Patients with Advanced Hepatocellular Carcinoma in U.S. Community Oncology Practices

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BACKGROUND: With the rapid expansion of recent approvals for advanced hepatocellular carcinoma (aHCC; 3 targeted therapies, 2 immuno-oncology therapies, and many more new entities in phase 3 trials) the landscape of prescribing practices and provider attitudes are evolving and largely unknown. Given the dearth of routine practice data on these newer therapies, it is important to understand how providers adopt contemporary therapies for aHCC.

OBJECTIVE: To describe physician treatment selection and patterns of systemic therapy (ST) in aHCC, estimate the proportion of aHCC patients eligible for ST, define criteria for ST eligibility, and understand factors influencing ST selection.

METHODS: Oncologists completed a questionnaire evaluating how they assess whether to treat with ST or best supportive care and what contributes to their treatment selection decision making for patients with aHCC. Oncologists who had managed or treated >2 patients with aHCC over the past 2 years in a community practice setting were eligible. Physician characteristics were collected, and descriptive statistics were used to summarize responses.

RESULTS: Among 50 oncologists completing the survey, mean practice time was 17 years, 38% participated in the oncology care model, 20% were rural, and there was broad U.S. geographic representation. Participating oncologists managed a mean of 22 aHCC patients over the past 2 years. Most common characteristics rendering a patient a good candidate for ST were ECOG performance status (74%), Child-Pugh grade A or B (34%), and "fewer or no comorbidities" (18%). Physicians reported that most (91%) patients considered eligible for ST would be treated with ST. Typical management of a newly diagnosed HCC patient reported by 38% of oncologists is initiating loco-regional therapy (LRT) followed by ST, while 20% of oncologists initiate and conduct sequential LRT until exhausted. When asked about factors influencing ST selection, most (78%) oncologists ranked "efficacy of regimen/agent" highest, whereas "affordability of regimen/agent" and "patient choice" were ranked lowest among 34% and 24% of physicians, respectively.

CONCLUSIONS: The extensive and early (20% exhausting LRT) use of ST by oncologists in this survey, if more broadly representative, has significant implications for the rapidly expanding arsenal of drug therapies for aHCC. Understanding the comparative effectiveness of these new drugs, optimum sequencing, healthcare resource use and costs will be critical to their use in a patient centric and value-based healthcare delivery model.

SPONSORSHIP: Bristol-Myers Squibb.

C2 Treatment Patterns and Unmet Need in Advanced Hepatocellular Carcinoma: Analysis of U.S. Department of Defense Military Health System Data

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BACKGROUND: Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer, and its incidence is projected to grow due to increasing prevalence of chronic liver diseases. Treatment options for advanced HCC patients were limited until recent U.S. Food and Drug Administration (FDA) approvals, which has expanded systemic therapeutic options.

OBJECTIVE: To describe systemic treatment patterns, survival, and costs in Military Health System beneficiaries with advanced HCC.

METHODS: Adult patients with ≥2 claims indicating diagnosis of primary HCC (International Classification of Diseases [ICD]-9: 155.0 or ICD-10: C22.0, C22.2, C22.7, C22.8) receiving systemic therapy from January 1, 2014 to June 30, 2017 in the Department of Defense Military Health System were identified. Patients with a diagnosis for another primary cancer or intrahepatic cholangiocarcinoma within 1 year prior to start of first-line (1L) therapy were excluded. Costs and overall survival (OS) were assessed from 1L start until death, end of study, or health plan disenrollment. OS was analyzed using the Kaplan-Meier method.

RESULTS: During enrollment, 266 patients identified with advanced HCC were treated with 1L systemic therapy. The mean age was 69.9 years and 67.7% were male; 62.0% had a modified (excluding liver diseases) Charlson Comorbidity Index (CCI) score ≥3. The most frequently used 1L therapy classes were tyrosine kinase inhibitors [TKI] (71.4%) and chemotherapy (15.4%). Given the timing of the study, nearly all patients (190/191) receiving 1L TKI were treated with sorafenib. Only 47 (17.7%) patients went on to receive second-line (2L) therapy; nivolumab (29.8%) and regorafenib (17.0%) were the most commonly used agents. Patient characteristics for those receiving 1L sorafenib were similar to the broader 1L systemic cohort, except those on 1L sorafenib had a higher median CCI and a lower proportion of patients underwent liver transplant during the year prior to 1L. The 1-year survival probability was 49.2% for overall 1L (median: 350 days) and 35.7% for 1L sorafenib (median: 180 days). Unadjusted total per patient per month (PPPM) costs were numerically higher for 1L sorafenib relative to overall 1L ($8,612 vs. $7,475); this was driven primarily by increased pharmacy costs for 1L sorafenib ($4,253 vs. $2,935).

CONCLUSIONS: Advanced HCC patients initiating 1L systemic therapy had poor prognosis and less than 20% received 2L therapy. Most 1L HCC patients used sorafenib. There is an unmet need in 1L HCC for therapies that prolong survival and reduce cost.

SPONSORSHIP: Bristol-Myers Squibb.

C3 A Targeted Approach to Reducing Rates of Discontinuation and Dose Reduction in Patients Receiving Sorafenib or Regorafenib

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BACKGROUND: Sorafenib and regorafenib are oral multikinase inhibitors used to treat some cancers, but adverse events for both drugs are common and often cause patients to discontinue therapy or reduce their dose within several months of initiating therapy. Pharmacists have the potential to prevent discontinuation by closely monitoring and addressing patients' adverse reactions.

OBJECTIVE: To assess whether a pharmacist-initiated tailored intervention reduced patient discontinuations and dose reductions due to adverse reactions form sorafenib and regorafenib.

METHODS: We conducted a historically controlled intervention to detect and address adverse events in patients prescribed sorafenib and regorafenib. All patients who initiated therapy after August 2017 were in the intervention group (IG); at treatment initiation, IG patients received initial pharmacist counseling and a welcome kit containing educational materials, urea based creams, therapeutic socks, and pill container (sorafenib only). During the 90 days after initiating treatment, pharmacists called IG patients six times to conduct assessment questionnaires, designed to detect common adverse reactions at each interval. Pharmacists addressed adverse events by providing additional counseling, referring patients for clinic appointment, or requesting ancillary medications. The comparison group (CG) patients

initiated therapy between September 2016 and August 2017. CG patients only received pharmacist counseling at treatment initiation. We collected patient demographics and treatment indication, and compared how many patients discontinued or reduced dose in the IG vs. CG.

RESULTS: We assessed 33 patients (16 IG vs. 17 CG). Most were female (61%) and white (88%); median age 53 years. Common indications were Hepatocellular Carcinoma (36%), Acute Myeloid Leukemia (30%), and Desmoid Tumor (21%). In the 90-day follow-up, IG had lower rates of treatment discontinuation (13% vs. 29%) and dose reduction due to side effects (13% vs. 18%) than CG. Combined events of either discontinuation or dose reduction due to side effects were less frequent in the patients in the IG than CG (25% vs. 65%).

CONCLUSIONS: After initiating a pharmacist-led phone intervention, patients treated with sorafenib or regorafenib were less likely to discontinue therapy or reduce doses due to adverse reactions. Findings suggest tailored phone assessments is effective in detecting and treating adverse reactions, thus enabling patients to remain on therapy longer and without dose modification.

SPONSORSHIP: None.

C4 Patients' Preferences for Treatment Attributes Associated with Ribociclib and Abemaciclib in Women with Advanced or Metastatic Breast Cancer: A Discrete Choice Experiment

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BACKGROUND: Patients' preferences for treatments are subject to trade-offs between treatment attributes.

OBJECTIVE: To evaluate the extent to which patients with advanced/metastatic breast cancer (mBC) value treatment attributes and how it translates into preferences for treatment with ribociclib vs. abemaciclib, two newly approved CDK inhibitors.

METHODS: A survey-based discrete choice experiment was conducted among adult women with mBC in the U.S., stratified by menopausal status. Participants were asked to select the scenario that best reflected their preferences from a series of treatment choice cards, each displaying a pair of hypothetical treatment scenarios. Treatment attributes included progression-free survival (PFS), adverse events (AEs; abdominal pain, alopecia, fatigue, vomiting, non-severe diarrhea, severe diarrhea, severe anemia, severe neutropenia), and frequency of treatment administration and monitoring (blood tests and electrocardiograms [ECG]). The relative importance of each attribute was estimated using conditional logistic regression. Patients' preference for treatment profiles that approximated ribociclib and abemaciclib were reconstructed based on information from pivotal clinical trials, product labels, and guidelines.

RESULTS: A total of 300 post-menopausal and 277 pre-menopausal women were surveyed (mean age: 55 and 41 years, respectively). PFS positively impacted preference, while AEs, especially severe AEs, and more frequent monitoring (i.e., 6-8 vs. 2 blood tests in the first 6 months, or 3 vs. 0 ECG in the first month) negatively impacted preference (all $P<0.01$). Low frequency monitoring (i.e., 3 vs. 2 blood tests, or 1-2 vs. 0 ECG) was not a determinant of preference (all $P>0.05$). Post-menopausal women did not differentiate between once daily or twice daily administration, but a varying number of pills per day (e.g., 2 pills once daily for 21 days followed by 1 pill once daily for 7 days) negatively impacted preference ($P=0.01$). For pre-menopausal women, frequency of administration was not a determinant of preference (all $P>0.05$). Based on studied preference weights and reconstructed treatment profiles, among both post- and pre-menopausal women,

ribociclib treatment profile was preferred to that of abemaciclib, mainly driven by higher risk of diarrhea and abdominal pain for abemaciclib.

CONCLUSIONS: Clinical decision making should balance efficacy, tolerability, and other treatment attributes that may impact patient preferences and consequently satisfaction and medication adherence.

SPONSORSHIP: Novartis Pharmaceuticals.

C5 Estimating the Value of Bone-Targeting Agents Treatment in Patients with Bone Metastases from Solid Tumors from the U.S. Healthcare System Perspective

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BACKGROUND: bone-targeting agents (BTAs), denosumab and zoledronic acid (ZA), are commonly used in bone metastases (BM) from solid tumors (ST), to manage skeletal-related events (SRE). In many patients with BM, BTA is not initiated or delayed. High SRE burden has been reported in BTA-naïve patients.

OBJECTIVE: To estimate the number of potential SREs avoided and total value (TV) by increasing BTA treatment rates in patients with BM from ST, in the U.S.

METHODS: A lifetime, cohort model was developed using the same structure, clinical, and economic inputs from a published denosumab cost-effectiveness model to estimate TV from the U.S. healthcare system perspective. Key clinical inputs were tumor type; BM annual incidence; SRE rates for BTAs in phase 3 clinical trials comparing denosumab to ZA, adjusted for real-world SRE rates; adverse events (AE); and disutility related to SREs, administration route, and AEs. Key economic inputs were direct medical costs of SREs, BTA acquisition and administration costs, and costs of AEs. The net monetary benefit (NMB) per patient was estimated using quality-adjusted life-years (QALY) gained, monetized at $150,000 per QALY, and total cost difference between treated and untreated patients. In the base-case, 36% of the incident BM population was assumed to be on BTAs (70% denosumab, 30% ZA). SREs avoided and TV (NMB*BTA-treated patients) in the BM population in 2018 was estimated by varying BTA treated rates from 0-100%. Cumulative value was estimated using NMB and projected annual BM incidence (2018-2030).

RESULTS: The NMB of BTA therapy across tumor types was $69,416 per patient. Increasing BTA use by an additional 10% could avoid 20,692 SREs in 83,265 incident BM patients. In the base-case, treatment of BM with BTAs yielded a net direct cost savings of $540M, and a TV of $2.1B when QALY gain was monetized. This included $1.2B in direct medical costs from SREs prevented, $1.6B from QALYs gained, $601M in BTA acquisition costs, $39M for administration, and $1M for AEs costs. TV with 10% increased BTA use would be $2.7B, including $178M increase in BTA and AE costs, and $756M economic gain from prevented SREs and additional QALYs. Thus, every 10% increase in BTA use would result in $578M net savings. Cumulative value with 10% increased BTA use through 2030 would be $38.7B.

CONCLUSIONS: BTA therapy in BM has a substantial potential economic benefit for the U.S. healthcare system, driven by SREs prevented and improved health (QALY). Increasing treatment rate would further improve health and result in additional cost savings.

SPONSORSHIP: Amgen.

C6 Budget Impact Analysis of Abemaciclib in HR-Positive, HER2-Negative Advanced or Metastatic Breast Cancer

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BACKGROUND: Cyclin dependent kinase 4 & 6 (CDK4 & 6) inhibition is effective in the treatment of patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer (ABC). Abemaciclib is one of three CDK4 & 6 inhibitors approved in combination with endocrine-based therapy for treatment of ABC. It is the only CDK4 & 6 inhibitor approved as monotherapy for treatment of ABC with disease progression after hormone therapy and prior chemotherapy. In the U.S., SEER estimates 70% of all breast cancers are HR+, HER2-.

OBJECTIVE: To assess the budgetary impact of abemaciclib for the treatment of HR+, HER2- ABC in patients from U.S. commercial (COM) and Medicare (MED) perspectives.

METHODS: A budget impact model (BIM) was developed to estimate the annual costs of abemaciclib for COM or MED health plans. The BIM accounted for number of patients eligible for treatment [source: SEER and U.S. census data], projected market shares that consider the introduction of CDK4 & 6 inhibitors, adverse event incidence [clinical trial data], AE costs [HCUP], and treatment costs [RED BOOK]. Results are presented for the use of abemaciclib in combination with an aromatase inhibitor (AI) as initial therapy in ABC; individual results can also be estimated for all three indications.

RESULTS: For a 1 million-member COM plan, the BIM estimates 177 HR+, HER2- ABC patients will be treated annually. One-year incremental cost savings of $10,890 (per member per month [PMPM] $0.001) was estimated for Year 1 (2018) based on an abemaciclib market share of 1.9%. For Year 3 (2020), $718,356 incremental cost savings (PMPM $0.060) was estimated based on a 21.5% market share. For a 1 million-member MED plan, the BIM estimates 575 HR+, HER2- ABC patients will be treated annually. One-year incremental cost savings of $42,576 (PMPM $0.004) was estimated for Year 1 (2018) based on an abemaciclib market share of 1.9%. For Year 3, a $2,214,834 incremental cost savings (PMPM $0.185) was estimated based on a 21.5% market share. The BIM was most sensitive to the changes in respective market shares of abemaciclib and palbociclib due to their drug costs.

CONCLUSIONS: Based on the projected size of the target population and market share uptake of abemaciclib, budget impact analysis indicated slight cost-savings for a health plan when abemaciclib in combination with an AI is added as a treatment option as initial endocrine therapy for women with HR+, HER2- ABC.

SPONSORSHIP: Eli Lilly.

C8 Comparison of Olaparib Versus Bevacizumab in the Second-Line Maintenance Setting Using Value Frameworks

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BACKGROUND: In response to rising costs in oncology care, several organizations have developed frameworks to systematically assess the value of oncology drugs. These frameworks include the ASCO Value Framework, ESMO Magnitude of Clinical Benefit Scale, ICER Value Assessment Framework, and NCCN Evidence Blocks.

OBJECTIVE: To assess the value of olaparib and bevacizumab as second line (2L) maintenance treatment in ovarian cancer using these 4 value frameworks.

METHODS: Eleven expert panelists (4 gynecological oncologists, 3 other physicians, 3 pharmacists, and 1 non-physician health services researcher) were provided published clinical data on olaparib and bevacizumab, and detailed instructions on how to use each framework. Panelists completed the 4 value framework assessments for olaparib and bevacizumab. Mean value scores produced by each of the 4 frameworks (overall and by subdomain) were calculated. Scores were standardized on a 0-100 scale for ease of comparison. Results were also stratified by type of panel member specialty (gynecologic oncologist: yes/no).

RESULTS: Olaparib received higher mean value scores than bevacizumab across all 4 frameworks. Panelists gave olaparib a mean score of 63.1 on the ASCO framework (vs. 52.7 for bevacizumab); 45.5 on the ESMO framework (vs. 34.0); 75.0 on the ICER framework (vs. 68.3); and 71.0 on the NCCN framework (vs. 62.5). By subdomain, olaparib received higher mean scores for clinical benefit and lower scores for toxicity. Results were consistent after stratification by specialty; on the ICER framework, all gynecologic oncologists gave the highest possible score to olaparib.

CONCLUSIONS: The panel consistently rated olaparib higher than bevacizumab using 4 value frameworks. While clinical decisions should be based on individual patient needs as determined by physician assessment, this study showed real-world application of these frameworks.

SPONSORSHIP: AstraZeneca.

C9 Understanding Oncologist and Patient Preferences of Maintenance Therapy for Ovarian Cancer

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BACKGROUND: Historically, recurrent ovarian cancer has been associated with a poor prognosis and a high recurrence rate. Newly approved maintenance therapies have shown improvements in progression-free survival, but little is known about how these options are viewed.

OBJECTIVE: To understand U.S. oncologist (ONC) and patient (PT) perceptions of ovarian cancer treatments.

METHODS: In October 2018 (prior to the release of SOLO-1 data), in-depth interviews were conducted with 12 ONCs (6 GYN ONCs) and 12 PTs diagnosed with recurrent epithelial ovarian cancer, who had previously received chemotherapy (6 received maintenance therapy). A trained interviewer used a semi-structured interview guide that focused on factors in maintenance treatment decision-making. A standardized coding procedure was used to identify key themes emerging from the interview responses.

RESULTS: PTs reported that typically their ONC will recommend one specific treatment from multiple treatment options. ONCs reported that PARPs have shown the best advances in ovarian cancer but mostly in BRCA+ or HRD+ PTs. ONCs perceive PARPs to have similar efficacy to each other and are generally comfortable with dose adjustments. Most PTs did not express concern over dose reductions, although some questioned whether dose reductions impact effectiveness. More influential to ONCs in treatment selection are PARP-related toxicities (thrombocytopenia, nausea, fatigue, and anemia) and bevacizumab-associated toxicities (hypertension, gastrointestinal events, and proteinuria). PTs recognized the potential for extended duration with

maintenance and favored attributes that causes the least disruption to quality of life. PTs highlighted nausea and pain/body aches as most disruptive; other bothersome toxicities include hematological toxicities, diarrhea, fatigue, vomiting, organ damage, and brain fog. Most PTs reported a preference for the convenience of oral over intravenous therapy; however, several patients would sacrifice convenience for better efficacy. Several PTs noted concerns about toxicities that are life-threatening or result in treatment discontinuation. PTs varied in their willingness to accept these risks in exchange for potential treatment benefits, although most PTs describe efficacy as the most important treatment decision-making factor.

CONCLUSIONS: The current qualitative research identified treatment attributes that are valued among ONCs and PTs, thereby likely to influence selection of maintenance therapy.

SPONSORSHIP: AstraZeneca.

C10 The Economic Impact of Olaparib Used as a First-Line Maintenance Therapy for Women with BRCA-Mutated Ovarian Cancer

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BACKGROUND: Although budget impact analyses typically focus on short term costs (1-3 years), new oncology therapies associated with extended progression-free survival (PFS) require a longer time horizon to understand their full value. Olaparib is a first line (1L) maintenance treatment (MTX) for women with BRCA mutated (BRCAm) ovarian cancer which showed PFS in the SOLO1 trial (60% of olaparib vs. 27% of placebo patients were progression free at 3 years).

OBJECTIVE: To estimate the economic impact of olaparib (vs. watch and wait [WW]) as a 1L MTX for women with BRCAm ovarian cancer.

METHODS: The 4-year budget impact of olaparib was estimated for a commercial plan of 1M members. Patients entered the model at the time of 1L MTX initiation. Based on SOLO1, median PFS of 13.9 months was used for WW; as median PFS was not met for olaparib, we assumed 41 months (median follow-up at database lock). As per SOLO1 design, 95% of modelled patients discontinued olaparib at 24 months. Olaparib uptake was assumed to be 60%, 70%, 80%, 85% in years 1-4. Four lines of therapy post-progression were modelled. U.S. Census, SEER, and published literature informed the number of eligible patients for olaparib, as well as the sequence and duration of subsequent therapies. Costs for 1L MTX included drug acquisition, monitoring, adverse events (AEs). For subsequent therapies, only drug acquisition costs were considered (progression costs such as AEs, surgery, and routine follow up were not included). Sources included MediSpan Price Rx database, Healthcare Bluebook, CMS Fee Schedule and other literature. Model outcomes were total expenditure and cost per member per month (PMPM).

RESULTS: The model estimated that 7 women would be eligible for olaparib. Within the 4-year time horizon, olaparib patients received 7 months (up to 2L MTX) and WW patients received 34 months (up to 4L) of subsequent treatment. Total costs associated with WW were $0, $0.7M, $1.5M and $2.1M in years 1 to 4. Incremental costs for olaparib were $0.8M, $1.2M, $1M and $0.9M, resulting in incremental costs PMPM of $0.06, $0.10, $0.09 and $0.07, respectively. Increasing the olaparib market share to 80% in years 1-2, resulted in higher incremental costs PMPM in years 1-2($0.09, $0.13) but lower incremental costs in years 3-4 ($0.08, $0.06).

CONCLUSIONS: Access to olaparib as a 1L MTX for women with BRCAm ovarian cancer implies a budget impact increase in the first 2

years but is associated with substantial reductions in long-term costs of subsequent treatment.

SPONSORSHIP: AstraZeneca.

C12 Budget Impact of Enzalutamide for Non-Metastatic Castration-Resistant Prostate Cancer

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BACKGROUND: Prostate cancer is the most common cancer and second leading cause of cancer death among men in the United States. Prostate cancer poses a large economic burden, increasing with progression from localized to metastatic disease. Newly approved treatments for non-metastatic castration-resistant prostate cancer (nmCRPC) delay disease progression and reduce the risk of metastatic disease. Quantifying the potential budget impact of these new treatments is of interest to health care decision-makers.

OBJECTIVE: To estimate the budget impact of enzalutamide for the treatment of patients with nmCRPC in the United States over a 3-year time horizon.

METHODS: An Excel-based model was developed to estimate the budget impact to a U.S. health plan of enzalutamide as an add-on to androgen deprivation therapy (ADT) for the treatment of high-risk nmCRPC patients (prostate-specific antigen doubling time of ≤ 10 months). Comparators include apalutamide+ADT, bicalutamide+ADT, and ADT only. The analysis includes treatment costs for nmCRPC and after progression to metastatic castration-resistant prostate cancer (mCRPC). The treated population size was estimated from epidemiological data and literature. Dosing, duration of therapy, and adverse event rates were based on package inserts and pivotal studies. REDBOOK, Centers for Medicare & Medicaid Services fee schedules, and literature were used to obtain costs of drugs, adverse events, and health care visits. Market shares were estimated for each comparator before and after enzalutamide adoption. A one-way sensitivity analysis was performed to quantify the impact of parameter uncertainty.

RESULTS: In a hypothetical 1-million-member plan with 3% annual growth, it was estimated that there would be approximately 19 eligible incident nmCRPC patients in year 1, increasing to 20 eligible incident patients in year 3. With an assumed market share of approximately 6% for enzalutamide in year 1, the budget impact would be $106,074 ($0.009 per member per month [PMPM]) and, with 26% enzalutamide share in year 3, the budget impact would be $632,729 ($0.048 PMPM). Cumulative budget impact to the health plan over 3 years is estimated to be $1,082,095 ($0.028). The increased cost of the treatment regimen is partly offset by reduced post-progression costs.

CONCLUSIONS: Treatment of nmCRPC patients with enzalutamide has a modest budget impact that is partly offset by delaying progression to mCRPC.

SPONSORSHIP: Astellas Pharma and Medivation, a Pfizer company.

C13 Characteristics and Treatment Patterns for Non-Metastatic Castration-Resistant Prostate Cancer Patients in the United States

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BACKGROUND: The treatment goals for non-metastatic castration resistant prostate cancer (nmCRPC) are to delay time to metastasis while maintaining the quality of a patient's survival. Treatment

options have traditionally included first-generation androgen receptor inhibitors (ARis) or active surveillance. The recent approval of second-generation ARis (abiraterone and enzalutamide) in nmCRPC is anticipated to change the treatment landscape.

OBJECTIVE: To describe U.S. nmCRPC patients' clinical and demographic characteristics, their physicians' characteristics, and historical treatment patterns as a baseline to an evolving nmCRPC treatment landscape.

METHODS: Descriptive analyses were conducted using the 2015-2017 Ipsos Global Oncology Monitor Database, a physician-extracted cross-sectional patient record dataset. The analytic cohort included nmCRPC patients who received any pharmacotherapy.

RESULTS: 442 nmCRPC patients (median age: 78 yrs; Caucasian: 58.1%; median BMI: 29.2 Kg/m2; ECOG ≤ 1: 75.6%) were included in the analytic cohort. Most were treated by urologists (74.0%) and in an office-based setting (80.1%). A plurality (46.4%) were stage II at initial diagnosis, 28.1% had a Gleason score between 8-10, and 53.7% had a PSA doubling time of st, 2nd, and 3rd nmCRPC regimen (R) were: 1R, leuprolide (15.2%) and triptorelin (9.0%); 2R, nilutamide (13.2%) and combination of bicalutamide/leuprolide (7.9%); 3R, abiraterone/prednisone combination (15%) and bicalutamide/leuprolide/nilutamide combination (10.0%). The proportion of patients receiving abiraterone and enzalutamide were relatively low: 91 (20.6%) and 65 (14.7%) overall; 79 (17.9%) and 47 (10.6%) in 1R; 7 (18.4%) and 11 (28.9%) in 2R; and 5 (25%) and 7 (35%) in 3R, respectively. Median durations of 1R, 2R, and 3R for all therapies (and 2nd-generation ARis) were 360 (150), 168 (60), and 42 (140) days, respectively. The most common treatment discontinuation reasons were related to disease progression, treatment resistance, and side effects.

CONCLUSIONS: These data represent real-world treatment patterns in nmCRPC and may be reflective of a reticence to introduce pharmacotherapy in a disease state largely considered to be asymptomatic. Future studies should evaluate utilization patterns after more experience with 2nd-generation ARis has accumulated and explore any putative relationship between tolerable pharmaco-therapy and extent of utilization.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals.

C14 Health Care Resource Utilization and Costs Associated with Corticosteroid Use in Patients with Castration-Resistant Prostate Cancer: An Administrative Claims Analysis

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BACKGROUND: Corticosteroids (CSs) are used in the management of castration-resistant prostate cancer (CRPC) to reduce tumor-related symptoms and as a consequence of CRPC therapies. Because CSs are associated with toxicities, the economic impact of CS use among patients with prostate cancer should be evaluated.

OBJECTIVE: To assess the impact of cumulative CS use on health care resource utilization (HRU) and costs among men with CRPC.

METHODS: Adult chemotherapy-naïve patients who initiated a CRPC treatment following surgical or medical castration were identified from the MarketScan administrative claims database (2007-2016). Four patients cohorts were defined, based on the cumulative CS dose during the 1 year before CRPC treatment initiation: no CS (0 g); low CS (2.0 g). All-cause HRU and costs (in 2017 USD) were compared between cohorts during the 12-month study period following CRPC

treatment initiation, with "no CS" as the reference group. Multivariable regression models were used to adjust for baseline covariates, including age, region, index year, Charlson Comorbidity Index, presence of bone metastases, baseline all-cause HRU, and CS-related clinical events during baseline.

RESULTS: This study included 9,425 patients: 6,765 in no-CS; 1,660 in low-CS; 655 in medium-CS; and 345 in high-CS cohorts. Patients in the no-CS cohort were older on average and had a lower baseline HRU and comorbidity burden than patients in the other three cohorts. During the study period, patients with CS exposure (across all categories) had significantly more inpatient admissions (comparing the high-CS vs. no-CS cohorts, adjusted incidence rate ratio [IRR] = 1.56; $P < 0.001$), emergency department visits (adjusted IRR = 1.30; $P = 0.001$), and outpatient visits (adjusted IRR = 1.11; $P < 0.001$). In addition, patients in the low-, medium-, and high-CS cohorts had significantly higher monthly total costs (comparing the high-CS vs. the no-CS cohort, adjusted difference = $2,600; $P < 0.001$), including medical service costs (adjusted difference = $,1564; $P < 0.001$), and pharmacy costs (adjusted difference = $825; $P < 0.001$), compared with the no-CS cohort.

CONCLUSIONS: Cumulative CS exposure was associated with a significantly higher HRU and cost burden among men with CRPC. This increase in economic burden was more prominent among patients with annual cumulative CS doses of more than 2.0 g. The avoidance of CS use, when possible, may result in lower economic burden among men with CRPC.

C15 An Economic Analysis of Overall Survival with Abiraterone Acetate, Enzalutamide, and Sipuleucel-T in the Treatment of Metastatic Castration-Resistant Prostate Cancer

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BACKGROUND: Prostate cancer is the most common cancer and the second leading cause of cancer-related death among U.S. men. Per National Comprehensive Cancer Network Guidelines, 1st-line treatment options for metastatic castration-resistant prostate cancer (mCRPC) include sipuleucel-T (SIP-T), enzalutamide (ENZA), and abiraterone acetate plus prednisone (ABI). Data directly comparing these agents are not available.

OBJECTIVE: To indirectly compare treatment effects of 1st-line mCRPC treatment options (SIP-T, ENZA, and ABI), by analyzing the number needed to treat to benefit (NNTB) for overall survival (OS) at 1 and 2 years. Median and total drug cost estimates for these clinical benefits are also calculated.

METHODS: The reciprocal of the absolute risk reduction (ARR), NNTB is the average number of patients needed to be treated to prevent an adverse outcome (death) in one additional patient compared to control. The 12- and 24-month NNTB values were derived from published Kaplan-Meier curves for OS from three randomized controlled trials of 1st-line therapies for mCRPC (IMPACT, PREVAIL, and COU-AA-302). Total drug expenditures to achieve these incremental OS benefits (i.e., cost per NNTB) were calculated as the product of the drug cost (2018 Medicare Part-B or Part-D drug price), the drug's NNTB; and its median treatment duration. For SIP-T, where a full course of therapy consists of 3 biweekly infusions, the total drug costs were averaged over the 24-month. ENZA and ABI are taken daily until disease progression or unacceptable toxicity; with total drug cost based off of median treatment durations.

RESULTS: Estimated NNTB to prevent one additional mCRPC patient death at 12-months were: SIP-T = 12, ENZA = 15, and ABI = 100. At 24-months, NNTB were estimated at: SIP-T = 10, ENZA = 12, and ABI = 16. Median treatment costs were: SIP-T = $130,258, ENZA = $194,343, and ABI = $151,438. Total drug costs for an additional patient alive at 12-months was $1,563,099 for SIP-T; $2,107,332 for ENZA; and $13,168,560 for ABI. At 24-months, drug costs for these NNTB ranged from $651,291 for SIP-T, to $2,332,114 for ENZA, and $2,423,015 for ABI. SIP-T had $0 (zero) incremental costs in year-2 of treatment.

CONCLUSIONS: This analysis shows the OS benefit in mCRPC patients treated 1st-line with SIP-T compares favorably to ENZA and ABI over 2-years. Estimated total drug cost to achieve an additional OS benefit is lower for SIP-T and declines over time compared to ENZA or ABI, whose costs increase with continued therapy for a similar clinical outcome.

C17 Pattern of Disease Management Costs for Advanced Bladder Cancer Patients Receiving Chemotherapy

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BACKGROUND: Significant cost burden has been reported for advanced bladder cancer patients receiving chemotherapy. However, the pattern of disease management costs over time for advanced bladder cancer patients is not well studied, but important when evaluating the economic impact of new treatment with prolonged PFS and OS.

OBJECTIVE: To estimate the disease management costs for advanced bladder cancer patients receiving chemotherapy over time by health state.

METHODS: Patients who received chemotherapy for advanced bladder cancer were identified using the SEER-Medicare linked data from January 1, 2007 to December 31, 2011. Disease management costs (2018 USD) were calculated by deducting drug costs, drug administration costs, and AE costs from all-cause costs. The per-patient-per-month (PPPM) disease management costs among patients receiving 1L chemotherapy were summarized over time (0-<12, 12-<24, and 24+ months) from treatment initiation during 1L (proxy for progression-free state) and subsequent lines (proxy for progressive disease state). The calculation during the progression free state excluded costs and time incurred within the last 3 months from death or loss to follow-up. All-cause costs incurred during the last 30 days of death were considered as terminal care costs and summarized separately. Additional analysis was conducted for costs with bladder cancer as the primary diagnosis. All analyses were repeated in the 1L cisplatin-ineligible population and the 2L+ setting, respectively.

RESULTS: Among patients receiving 1L chemotherapy, PPPM disease management costs during 0-<12, 12-<24, and 24+ months from 1L initiation were $4,916 (N = 341), $2,587 (N = 74), and $1,364 (N = 23) during the progression-free state, and $5,468 (N = 145), $3,552 (N = 94), and $4,407 (N = 44) during the progressive disease state. Terminal care costs were $11,228 (N = 366). Similar patterns were observed for costs with bladder cancer as the primary diagnosis, in the 1L cisplatin-ineligible population, and in the 2L+ setting.

CONCLUSIONS: Disease management costs for advanced bladder cancer patients receiving chemotherapy were relatively high throughout the progressive disease state and were relatively low in the progression-free state. Disease management costs decreased over time in the progression-free state. The highest disease management costs after disease progression incurred within the first 12 months of 1L initiation and remained high over time. These patterns of disease management costs over time should be considered when evaluating the economic impact of new treatment.

C18 Lifetime Costs of Urothelial Carcinoma by Stage at Diagnosis

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BACKGROUND: Urothelial carcinoma (UC) is generally diagnosed early and may incur significant costs over a patient's lifetime. Assessing the lifetime costs by stage will help understand the economic burden of UC.

OBJECTIVE: To estimate lifetime UC costs by stage at diagnosis.

METHODS: This retrospective Surveillance, Epidemiology, and End Results (SEER)-Medicare database analysis identified patients who were ≥66 y and newly diagnosed with UC from 2004-2013. Patients were followed from UC diagnosis to death/last follow-up to estimate lifetime costs. Costs were allocated to 3 phases: diagnosis (≤3 mo. after diagnosis), terminal (≤3 mo. before death), and continuation (mo. between diagnosis and terminal phases). Survival-adjusted lifetime costs (total and major UC-related) were estimated by stage at UC diagnosis. Lifetime costs were also reported based on whether the patient received ≥1 systemic line of chemotherapy (LoC vs. no LoC). In the LoC vs. no LoC analysis, the no LoC group excluded patients who had received prior (neo-)adjuvant chemotherapy, whereas LoC patients may or may not have received prior (neo-)adjuvant therapy.

RESULTS: The sample included 15,588 patients: 3,446 stage 0 (8% ≥1 LoC; median [IQR] follow-up in months: 44 [23-71]); 3,902 stage I (12% ≥1 LoC; 33 [15-62]); 4,301 stage II (26% ≥1 LoC; 17 [7-39]); 1,612 stage III (25% ≥1 LoC; 17 [7-42]); and 2,327 stage IV (33% ≥1 LoC; 8 [3-18]). Mean age was 78 y and 72% were male. Mean lifetime costs were lowest for stage IV patients versus other stages ($151,626 stage 0; $150,123 stage I; $149,728 stage II; $190,996 stage III; $117,503 stage IV). Hospitalizations unrelated to cystectomy contributed 48-53% of lifetime costs ($73,903 stage 0; $73,249 stage I; $72,709 stage II; $100,356 stage III; $59,494 stage IV). Cystectomy contributed 2-13% of lifetime costs ($3,356 stage 0; $7,011 stage I; $11,855 stage II; $25,509 stage III; $11,693 stage IV). UC-related office visits contributed 8-15% of lifetime costs ($11,717 stage 0; $14,611 stage I; $19,882 stage II; $21,480 stage III; $17,820 stage IV). Except for stage III, no LoC patients had lower lifetime costs than LoC patients ($126,118 vs. $147,260 stage 0; $141,604 vs. $169,561 stage I; $131,055 vs. $159,219 stage II; $178,401 vs. $166,851 stage III; $74,319 vs. $138,274 stage IV).

CONCLUSIONS: Stage IV patients had the lowest lifetime costs, while stage III patients had the highest. Non-cystectomy hospitalizations were the major cost driver. Treatment plans that require shorter and fewer hospitalizations may lessen the economic burden of UC.

SPONSORSHIP: AstraZeneca.

C19 Healthcare Utilization and Cost by Phase of Treatment in Metastatic Bladder Cancer Patients

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BACKGROUND: There are no current data on burden of illness in patients with metastatic bladder cancer, particularly on patterns of cost across phase of treatment.

OBJECTIVE: To examine health care cost and utilization prior to and after initiation of systemic anti-cancer treatment among patients with metastatic bladder cancer.

METHODS: The study used medical and pharmacy claims from a U.S. database (January 2011-March 2017). Subjects were commercial (COM) and Medicare Advantage (MA) adults with ≥2 claims ≥30 days apart for bladder cancer. Index diagnosis date was first claim for bladder cancer. Subjects had: enrollment for 24 months pre- and ≥1 month post-index; no bladder cancer in the 12 months pre-index date; diagnosis of metastases (metastatic diagnosis index date) after index bladder cancer diagnosis date; anti-cancer systemic treatment (STX) after metastatic diagnosis; and ≥1 month of follow-up after start of metastatic treatment. Outcomes measured over variable follow-up included line of therapy (LOT) for metastatic STX, and all-cause and bladder cancer-related utilization and costs during phases of care for metastatic disease, including from metastatic diagnosis and prior to STX, during STX (entire period and during LOT), and post-STX. Descriptive and multivariable analyses were performed.

RESULTS: Among 8,896 bladder cancer patients identified, 652 patients were metastatic (62% MA). Mean (SD) count of LOT were COM 1.8 (1.20) and MA 1.6 (1.05); mean (SD) length of therapy ranged from 79 (49) to 105 (73) days for the first 3 LOT, with longer first LOT. In LOT1, mean (SD) all-cause cost were COM $72,703 ($76,684) and MA $26,224 ($23,849); LOT1 mean (SD) bladder cancer-related costs were COM $44,478 ($53,853) and MA $14,834 ($16,513). Non-bladder cancer health services contributed roughly 40-50% of the costs incurred during the LOT periods. COM had higher mean costs in LOT1 than LOT2 or 3. Kaplan-Meier estimates showed 76% of COM/75% MA had an ER visit and 81% of COM/76% MA had an inpatient visit within 1 year after metastatic diagnosis. Generalized linear models showed mean adjusted all cause cost from metastatic diagnosis until start of STX were $48,688/$16,585 (COM/MA); during STX were COM $145,303 ($81,390 for bladder cancer) and MA $46,698 ($23,706 for bladder-cancer); post-STX costs were $10,020 and $3,780 per month (COM/MA).

CONCLUSIONS: While costs were highest during systemic treatment, non-bladder cancer costs contributed substantially. Monthly costs remained high after the end of systemic treatment.

SPONSORSHIP: AstraZeneca.

C20 Budget Impact Analysis of Larotrectinib for 8 Tumors in the United States

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BACKGROUND: Larotrectinib is an oral tropomyosin receptor kinase (TRK) inhibitor indicated for tumors that express neurotrophic tyrosine receptor kinase (NTRK) gene fusions.

OBJECTIVE: To estimate the budget impact of adding larotrectinib in a U.S. context. The analysis assessed financial implications of larotrectinib in 8 tumor types: colorectal, non-small cell lung, melanoma, thyroid, gastrointestinal stromal tumor, infantile fibrosarcoma, soft tissue sarcoma, and salivary gland cancer.

METHODS: We developed a budget impact model for a hypothetical U.S. health plan with a 1-year time horizon. The analysis simulated fiscal impact for 1,000,000 members aged similar to the U.S. commercial population and separately evaluated a Medicare population. The treated population for each tumor was estimated utilizing data from SEER, estimated TRK fusion testing rates, frequencies of NTRK gene fusions, and treatment uptake. Current treatments for each tumor were abstracted from the NCCN guidelines. Drug costs were based on

wholesale acquisition or average sales price. Genetic testing, treatment administration and monitoring, as well as adverse event costs also were included in the model. The budget impact was estimated for each tumor type and then aggregated, calculated as total costs and also per member per month (PMPM) cost.

RESULTS: In the base case, it was estimated that less than one patient would be treated with larotrectinib across the eight tumor types in the first year after accounting for the frequency of NTRK gene fusion in each tumor type. In the scenario without larotrectinib, the total treatment costs in year 1 were $41,300 compared to $68,000 with the first year of larotrectinib uptake. This equates to an increase of $26,700 or a less than $0.001 change in PMPM. Across a three-year time horizon, an estimated 1 patient was treated with larotrectinib, a PMPM increase of $0.01. The cost increase was due to the higher costs of genetic testing and the addition of larotrectinib. In the Medicare population, approximately one treated patient was estimated in the first year (six patients for the three-year time horizon). The incremental costs in year 1 in the Medicare population was almost $200,000, or a PMPM increase of $0.02. And over the three-year time horizon, the total incremental costs were almost $1.8 million, or $0.05 PMPM.

CONCLUSIONS: Adding larotrectinib to formulary for treatment of 8 tumor types has a minimal impact on health care budgets.

SPONSORSHIP: Bayer U.S.

C22 Real-World Healthcare Resource Costs in Patients with Chronic Lymphocytic Leukemia: Differences Between Patients Treated with First-Line Ibrutinib or Bendamustine+Rituximab

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BACKGROUND: Chronic lymphocytic leukemia (CLL) is the most common type of leukemia in the Western world. In the U.S., there was an estimated 20,940 new cases of CLL and 4,510 deaths due to CLL in 2018. Two standard treatment options include Ibrutinib (IbM) or Bendamustine with Rituximab (BR).

OBJECTIVE: To examine the real-world differences in healthcare costs in CLL patients treated with either first-line IbM BR therapy using U.S. administrative claims data.

METHODS: The MarketScan Research Databases were used to identify patients aged 18 years or older with commercial or Medicare supplemental insurance plans based on their first prescription (index date) of either IM or BR therapy between 02/01/2014 and 08/30/2017. Patients were required to be diagnosed with CLL and be treatment naïve, as well as be continuously enrolled (CE) for 6 months prior to and at least 30 days following the index date. Patients were followed for as long as they remained continuously enrolled. All-cause and CLL-related mean healthcare costs were evaluated for a subset of patients with 12-months of follow-up and were reported per-patient per-month (PPPM). Differences between the IbM and BR cohorts were estimated using chi-squared test for categorical variables and t-test for continuous variables.

RESULTS: The PPPM all-cause total costs were comparable between IbM patients and BR patients ($12,767 vs. $12,268; $P = 0.34$). IbM patients had higher PPPM all-cause inpatient costs than BR patients ($1,383 vs. $722; $P = 0.03$). CLL-specific total costs were comparable between IM and BR patients ($11,042 vs. $10,407; $P = 0.16$). IbM patients had higher CLL-specific inpatient costs than BR patients ($1,257 vs. $466; $P = 0.01$). Due to differences in the route of administration, IM patients had higher PPPM outpatient pharmacy prescriptions costs, while BR patients had higher PPPM outpatient medical costs. IbM patients had higher CLL-specific treatments costs compared to BR patients ($8,358 vs. $7,530; $P = 0.004$).

CONCLUSIONS: All-cause and CLL-specific total healthcare costs were comparable between the two treatment groups; however, IbM patients had significantly higher inpatient costs and CLL treatment costs than BR patients. These real-world findings highlight the importance of considering the healthcare resource utilization of CLL patients which may be associated with their first-line therapy.

SPONSORSHIP: Teva Pharmaceuticals.

C23 Real-World Healthcare Resource Costs in Patients with Indolent Non-Hodgkin's Lymphoma: Differences Between Patients Treated First-Line with Ibrutinib or Bendamustine+Rituximab

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BACKGROUND: Non-Hodgkin lymphoma (NHL) encompasses a diverse group of cancers that generally develop in the lymph nodes and lymphatic tissue. In the U.S., there was an estimated 74,680 new cases of NHL and 19,910 deaths due to NHL in 2018. Indolent NHLs (iNHLs) primarily affect the older population as the median age of diagnosis ranges between 65 and 72 years. Two standard treatment options include Ibrutinib (IbM) as single agent monotherapy or the combination of Bendamustine with Rituximab (BR).

OBJECTIVE: To examine the real-world differences in healthcare costs in iNHL patients treated with either first-line IbM or BR therapy using U.S. administrative claims data.

METHODS: The MarketScan Research Databases were used to identify patients aged 18 years or older with commercial or Medicare supplemental insurance plans based on their first prescription (index date) of either IM or BR therapy between 02/01/2014 and 08/30/2017. Patients were required to be diagnosed with iNHL and be treatment naïve, as well as be continuously enrolled (CE) for 6 months prior to and at least 30 days following the index date. Patients were followed for as long as they remained continuously enrolled. All-cause and CLL-related mean healthcare costs were evaluated for a subset of patients with 12-months of follow-up and were reported per-patient per-month (PPPM). Differences between the IbM and BR cohorts were estimated using chi-squared test for categorical variables and t-test for continuous variables.

RESULTS: All-cause total healthcare costs were comparable between IbM ($N = 110$) and BR ($N = 745$) patients ($14,634 vs. $15,487; $P = 0.50$) during the 12-month follow-up period. IbM patients had higher all-cause inpatient costs than BR patients ($2,309 vs. $1,125; $P = 0.08$). The iNHL-specific total costs were similarly comparable between the two cohorts. Due to differences in the route of administration, IbM patients had higher outpatient pharmacy prescription costs, while BR patients had higher outpatient medical costs. The iNHL-specific inpatient costs ($1,269 vs. $672; $P = 0.25$) and the NHL treatment costs ($9,738 vs. $8,425; $P = 0.06$) were higher in the IbM BR patients.

CONCLUSIONS: The IbM cohort had a trend of higher all-cause inpatient costs and higher iNHL-specific inpatient and treatment costs. These real-world findings highlight the importance of considering the healthcare resource utilization of iNHL patients which may be associated with their first-line therapy.

SPONSORSHIP: Teva Pharmaceuticals.

C24 Impact of Oral Oncolytic Initiation on Medication Adherence in Comorbid Chronic Conditions

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BACKGROUND: Oral oncolytic therapies have improved survival in hematological cancers like chronic myeloid leukemia (CML), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), and multiple myeloma (MM). However, it is unclear whether initiation of these therapies impacts adherence to oral therapies for pre-existing comorbid chronic conditions.

OBJECTIVE: To assess the impact of initiation of and adherence to oral oncolytics on chronic medication use in patients with CML, CLL/SLL, or MM and select pre-existing comorbid chronic conditions.

METHODS: Adult patients diagnosed with and prescribed oral therapy for CML, CLL/SLL, or MM between 2013-2016 and with continuous eligibility 6 months before and after oral oncolytic initiation were identified from the Truven Health MarketScan Databases. Among those identified, patients with pre-existing diabetes, hypertension, and/or hyperlipidemia with ≥1 fill for oral therapies were selected to examine changes in adherence to medications indicated for these conditions after oral oncolytic initiation. Adherence to oral oncolytics and therapies for comorbid conditions was measured using the proportion of days covered (PDC) metric. Following oral oncolytic initiation, Wilcoxon signed rank tests assessed changes in comorbid therapy adherence, Pearson correlation coefficients assessed linear relationships of oral oncolytic and comorbid condition therapy adherence, and unadjusted difference-in-difference models assessed the impact of oral oncolytic adherence on changes in comorbid therapy adherence.

RESULTS: A total of 551 (CML), 476 (CLL/SLL), and 324 (MM) patients had at least one pre-existing comorbid condition and ≥1 fill for oral comorbid therapy. Significant reductions in PDC post-oncolytic initiation were observed across the included comorbid chronic therapies and were highest for patients taking lipid-lower agents (10.8%-18.8%). Unadjusted difference-in-difference models revealed consistent and significantly smaller reductions in adherence for those taking anti-hypertensives (CML: $P = 0.03$; CLL/SLL: $P = 0.01$; MM: $P = 0.04$) who were adherent to oncolytic therapy. Oral oncolytic adherence was moderately and positively correlated with adherence to oral anti-diabetic therapy in the follow-up period (CLL/SLL cohort [rho = 0.23; $P = 0.02$]).

CONCLUSIONS: Oral oncolytic initiation may negatively impact adherence to oral therapies for pre-existing comorbid chronic conditions. Medication management strategies may be necessary to help patients remain adherent to their entire medication regimen when oral anticancer therapy commences.

SPONSORSHIP: None.

C25 A Systematic Literature Review of Clinical Evidence in Cutaneous T-Cell Lymphoma

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BACKGROUND: Cutaneous T-cell lymphoma (CTCL) is a rare form of non-Hodgkin lymphoma that results in compromised quality of life for patients.

OBJECTIVE: To examine current clinical evidence from randomized clinical trials in CTCL to help inform CTCL treatment decisions.

METHODS: Literature was systematically searched using OVID Medline, Embase, EconLit, PsycINFO, Evidence-based medicine (EBM) review, ACP Journal Club, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews (CDSR), Cochrane Methodology Register, Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment, and NHS Economic Evaluation databases. Abstracts and full-text publications were examined to identify studies (phase II or higher) reporting efficacy and safety of pharmacological or phototherapy interventions for the treatment of patients with Stage I-IV CTCL, including subtypes mycosis fungoides (MF) and Sézary syndrome (SS). Pooled or observational analyses were excluded.

RESULTS: A total of 673 citations were retrieved as of February 2, 2018 (no date limiters) and 36 were included. Of the 36 trials, 2 were phase I/II; 21 were phase IIa-b, and 12 were phase III or II/III. Most trials had 1 to 2 treatment arms, but 4 studies had 3 arms, and one study had 4 arms. Overall, 67% of the trials (24/36) were open label. A total of 22 treatments at different doses were assessed. The majority of studies included patients with MF, and 5 studies reported data for patients with SS. The main efficacy outcomes included overall response rate (ORR), overall survival (OS), and progression-free survival (PFS). Complete response (CR) and partial response (PR) rates were also reported. ORR was measured based on varying criteria, including response in skin only or a composite response score involving multiple disease compartments. A total of 4 studies presented compartment response data. Blood ORR data were reported in 2 studies, skin ORR data were reported in 4 studies, and lymph node data were reported in 2 studies. OS and PFS data were reported as secondary endpoints in 4 and 9 publications, respectively.

CONCLUSIONS: The majority of identified publications were from small, open-label, phase II trials of MF, with ORR measured using differing criteria. Compartment response in CTCL was not frequently reported. Conclusions across studies in CTCL are difficult to draw due to the heterogeneity of patient populations, the varying response criteria, and the lack of consistent treatment paradigms.

SPONSORSHIP: Kyowa Kirin.

C26 Health Care Utilization and Economic Burden of Multiple Myeloma Among Patients in the U.S. Department of Defense Population

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STATinMED Research

BACKGROUND: Multiple myeloma is a fatal hematologic malignancy formed by malignant plasma cells—accounting for 1% of all cancers—and is the second most common hematologic disorder. Complexities and complications from the disease are associated with high health care expenditure.

OBJECTIVE: To examine the health care utilization and economic burden of multiple myeloma in the U.S. Department of Defense (DoD) population.

METHODS: This was a retrospective case-control study using the U.S. DoD database from October 1, 2011 through September 30, 2016. Patients were included as cases if they had ≥1 claim for multiple myeloma (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] diagnosis code 203.0x or ICD-10-CM: C90.0) during the study period. The first diagnosis during the identification period (October 1, 2012-September 30, 2015) was designated as the index date. A comparison cohort was created for patients without multiple myeloma but with similar baseline Charlson Comorbidity Index (CCI) scores and identical age, sex, and index year, and the index date was randomly chosen to minimize selection bias. Patients were required to have continuous health plan enrollment for 1 year pre- and post-index date. Generalized linear models (GLMs) were applied to compare health care utilization and costs, adjusting for patient clinical characteristics.

RESULTS: A total of 996 patients were included in the study. The mean age was 59 years, and 51% of the patients were male. After adjusting

for clinical characteristics in the GLM, multiple myeloma patients incurred higher all-cause health care utilization including inpatient admissions (0.9 vs. 0.2, $P<0.001$), ambulatory visits (58.5 vs. 22.0, $P<0.001$), emergency room (ER) visits (1.1 vs. 0.6, $P<0.001$), and pharmacy visits (27.0 vs. 14.3, $P<0.001$) compared to control patients. Patients with multiple myeloma had a longer hospitalization length of stay (10.5 vs. 1.2 days; $P<0.001$) compared to patients without multiple myeloma. As a result, case patients incurred much higher follow-up all-cause health care costs related to inpatient ($19,293 vs. $2,050; $P<0.001$), ambulatory visit ($48,558 vs. $6,432; $P<0.001$), ER visit ($833 vs. $357; $P<0.001$), pharmacy ($16,053 vs. $1,238; $P<0.001$), and total costs ($84,830 vs. $10,116; $P<0.001$).

CONCLUSIONS: During a 12-month period, DoD beneficiaries who were diagnosed with multiple myeloma had higher health care utilization and incurred higher costs than matched control patients.

SPONSORSHIP: None.

C27 Budget Impact Analysis of Venetoclax Combinations in Treatment of Newly Diagnosed Acute Myeloid Leukemia in Adults Who Are Ineligible for Intensive Induction Chemotherapy

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BACKGROUND: Treatment and management of newly diagnosed acute myeloid leukemia (ND AML) patients ineligible for intensive induction chemotherapy (IIC) is associated with poor outcomes. Venetoclax (VEN), in combination with azacitidine (AZA), decitabine (DEC), or low dose cytarabine (LDAC), was recently FDA approved for the treatment of ND AML in adults who are age 75 years or older, or who have comorbidities that preclude use of IIC.

OBJECTIVE: To assess the budget impact of the adoption of VEN combinations for the FDA-approved AML indication from a U.S. payer perspective.

METHODS: A model was developed to estimate the three-year budget impact in a hypothetical U.S. plan with 1 million members (60% commercial and 40% Medicare). The number of eligible patients was estimated based on epidemiologic data of age distribution and AML incidence. Upon market entry, VEN combination therapies were assumed to draw market share from existing comparators: AZA, DEC, LDAC, gemtuzumab ozogamicin, and best supportive care. The model considered the costs of treatment and its administration, adverse events, hospitalization, disease monitoring, and blood transfusions. Clinical inputs included observed rates of complete remission (CR) and CR with incomplete hematologic recovery, duration of treatment, and ≥56 days of transfusion independence. The incremental total budget and per-member-per-month (PMPM) costs (2018 USD) were calculated, comparing the scenarios with vs. without VEN combination therapies for the treatment of ND AML. One-way sensitivity analyses were performed.

RESULTS: The model estimated 49 patients with ND AML who are ineligible for IIC in a health plan with 1 million members per year. The adoption of VEN was calculated to have an initial annual impact on the incremental total budget of $1,395,553. The annual incremental PMPM was $0.12, $0.17, and $0.17 for Year 1, 2, and 3, respectively. Overall, with the introduction of VEN for ND AML into a formulary, there were cost offsets from hospitalization and monitoring costs. The increase was primarily attributed to factors affecting drug cost of VEN combination therapies which included longer duration of treatment. The model results remained robust in sensitivity analyses.

CONCLUSIONS: The adoption of VEN combinations for the treatment of the FDA-approved indication of ND AML had a small incremental budget impact from a U.S. payer perspective. The use of VEN combinations provides the potential to avoid costly hospitalizations, partially offsetting the drug cost, while offering longer duration of treatment.

SPONSORSHIP: AbbVie and Genentech.

D1 Impact of Hemoglobin Normalization on Healthcare Resource Utilization in Patients Receiving Parenteral Iron Therapy

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BACKGROUND: Iron deficiency is the most common cause of anemia in the United States. Parenteral iron therapy is often necessary for patients who are intolerant or unresponsive to oral iron. Prior research has demonstrated the importance of timely and sufficient iron replacement on improving hemoglobin (Hgb) normalization.

OBJECTIVE: To assess the impact of Hgb normalization on healthcare resource utilization.

METHODS: Data were obtained from the Decision Resources Group (DRG) Real World Evidence Data Repository U.S. database. Study population were adults (≥ 18 years of age) who received parenteral iron therapy between 3/1/2015 and 2/28/2017, with below-normal baseline Hgb level recorded within 30 days prior to or on the date of index (first) parenteral iron therapy claim and did not receive parenteral iron therapy 6 weeks before index injection. The proportions of patients with normalized Hgb levels within 8 weeks and 1 year of index iron injection were assessed. Negative binomial regression was used to compare the adjusted mean number of all-cause inpatient admissions, outpatient and ER visits during 6 months and 1 year following index injection between patients with and without normalized Hgb while controlling for gender, age, comorbidities, and use of prescription oral iron therapy.

RESULTS: A total of 2,966 patients were assessed, of whom 58.4% were ≥65 years old (68% females, 60% CKD, 51% CHF, 39% IBD, 59% cancer). Overall, 20% (n=582) patients had normalized Hgb levels within 8 weeks of index injection and 54% (n=1,430) had normalized Hgb levels within 1 year after index.

Patients who had Hgb normalization within 8 weeks of index iron injection had fewer outpatient visits (6.0 v 6.9, $P=0.01$), similar number of hospitalization (2.9 vs. 3.1, $P=0.64$) and ER visits (2.2 vs. 1.9, $P=0.14$) in the 6 months following index iron injection compared to patients who did not have Hgb normalization in the same time period. Patients who had Hgb normalization within 1 year of index injection had fewer outpatient visits (9.7 vs. 10.6, $P=0.05$), fewer inpatient admissions (3.2 vs. 4.3, $P=0.009$), and similar number of ER visits (2.6 vs. 2.5, $P=0.3$) in the 1 year following index injection compared to patients who did not have Hgb normalization in the same time period.

CONCLUSIONS: The results of this analysis suggest that prompt achievement of normal Hgb may provide the opportunity to reduce healthcare resource utilization in patients receiving parenteral iron therapy.

SPONSORSHIP: Daiichi Sankyo.

D2 Association Between Hydroxyurea Adherence and Persistence and Vaso-Occlusive Crises Among Texas Medicaid Recipients with Sickle Cell Disease

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BACKGROUND: Among the 100,000 Americans with sickle cell disease (SCD), vaso-occlusive crises (VOCs), which are unpredictable attacks of acute pain, are the most common manifestation. VOCs typically lead to costly emergency department (ED) visits and hospitalizations and negatively impact quality of life. Hydroxyurea (HU) is used to prevent VOC events; however, adherence and persistence have been suboptimal. While SCD causes significant burden, little is known about HU treatment patterns associated with VOCs.

OBJECTIVE: To determine if HU adherence and persistence are associated with number of VOC events.

METHODS: This Texas Medicaid retrospective study of medical and prescription claims between 9/1/11-8/31/16 included: patients (2-63 years) who were continuously enrolled during 12-months post-index with at least 1 inpatient or 2 outpatient SCD diagnoses and at least 1 HU prescription. The index date was the first HU prescription. The primary outcome was the number of VOC events, while the independent variables were: HU adherence (medication possession ratio [MPR]) and persistence using 90 days of continuous HU without a 60-day gap. Covariates included age, gender, pain medication use, non-study SCD-related medication (penicillin and folic acid) use, evidence of blood transfusions, number of SCD-related complications, number of SCD-related comorbid conditions, and Charlson Comorbidity Index. Negative binominal regression analysis was used to address the study objectives.

RESULTS: Of included patients (N = 1,190), 889 (74.7%) had at least one VOC event with a mean ± SD of 4.1 ± 5.0 VOCs. Overall, HU adherence was 48.1 ± 29.4 and 19.7% were adherent (MPR ≥ 80%). Patients persisted 179.4 ± 141.8 days and 60.2% were persistent. The regression showed that compared to those who were adherent, those who were not adherent had 26% more VOC-related events (incidence rate ratio [IRR] = 1.259, 95% CI: 1.064-1.491; $P < 0.05$). Similarly, compared to non-persistent patients, persistent patients were expected to have 11.8% fewer VOCs (IRR = 0.882, 95% CI: 0.784-0.993; $P < 0.05$). In both analyses, significant covariates associated with a higher number of VOC events included: older age, female gender, greater number of pain medications, and greater number of SCD-related complications.

CONCLUSIONS: HU adherence and persistence were suboptimal and non-adherence and non-persistence were significantly associated with increased risk of VOC events. Healthcare professionals should encourage HU adherence and persistence among patients with SCD.

SPONSORSHIP: Novartis.

D3 Affordability Problems Among Medicare Beneficiaries Using Erythropoiesis-Stimulating Agents

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BACKGROUND: Out-of-pocket (OOP) cost is a significant concern for patients to use erythropoiesis-stimulating agents (ESAs), which are expensive. To use ESAs, Medicare beneficiaries are more likely to have affordability problems and spend less on basic needs.

OBJECTIVE: To provide national estimates on the prevalence of affordability problems and identify predictors of affordability problems among Medicare beneficiaries using ESAs.

METHODS: The linked Medicare Current Beneficiary Survey (MCBS) and Medicare claims data were used in the study. Medicare beneficiaries were included in the study if they had a diagnosis of chronic kidney disease or cancer in Medicare Part A or B claims and had at least one prescription of darbepoetin alfa or epoetin alfa in Medicare Part B or D claims. Survey participants were considered as having affordability problems if they spent less money on basic needs (e.g. food or heat) to afford medications. We used survey sampling weights to generate national estimates and weighted logistic regressions to identify predictors of affordability problems.

RESULTS: Among 7,841 Medicare beneficiaries with chronic kidney disease or cancer, 828 (11.00%, weighted percentage) were ESAs users. Compared to ESAs non-users, ESAs users had a higher prevalence of affordability problems (9.14% vs. 5.53%; $P = 0.0058$). ESAs users who had $500 to $1,000 annual OOP costs of ESAs (OR: 3.51; 95% CI: 1.10-11.20), had more than $1,000 annual OOP costs of ESAs (OR: 3.41; 95% CI: 1.23-9.45), were 18 to 64 years of age (OR: 3.18; 95% CI: 1.05-9.63), were female (OR: 3.93; 95% CI: 1.73-8.91), and were Hispanic (OR: 3.25; 95% CI: 1.01-10.40) were more likely to report affordability problems. In addition, ESAs users who had some college education (OR: 0.31; 95% CI: 0.12-0.83) and were single (OR: 0.25; 95% CI: 0.08-0.76) were less likely to report affordability problems.

CONCLUSIONS: Affordability problems were more prevalent among Medicare beneficiaries using ESAs and were found to be associated with OOP costs of ESAs and some sociodemographic characteristics. It is important and urgent for Centers for Medicare and Medicaid Services and health plans to adopt new reimbursement strategies to address affordability problems due to high OOP costs.

SPONSORSHIP: None.

D4 A Budget Impact Analysis of Roxadustat for the Treatment of Anemia of Chronic Kidney Disease

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BACKGROUND: In the United States, approximately 15% of the adult population has chronic kidney disease (CKD), and up to 15% experience anemia. Guidelines recommend considering erythropoietin stimulating agents (ESAs) in patients with severe anemia who have hemoglobin (Hb) < 10 g/dL. However, ESAs are associated with significant safety concerns and black box warnings, and up to 11% are hyporesponders. Despite these concerns, ESAs were blockbuster agents with a combined revenue of almost $3 billion in 2017. Roxadustat is an investigational agent for the treatment of anemia of CKD in non-dialysis-dependent (NDD) and dialysis-dependent (DD) populations. As an oral agent, roxadustat would offer greater convenience to patients, and studies indicate a potentially improved safety and clinical profile. In addition, differences in Medicare reimbursement may incentivize roxadustat utilization in dialysis patients. Where Medicare is the primary payer, ESAs given in dialysis are reimbursed as part of a bundled payment by Medicare Part B. However, roxadustat as an oral-only agent would be reimbursed outside of the bundle by Medicare Part D. Given these advantages and differences in reimbursement, roxadustat may be poised to take on significant market share from ESAs in anemia of CKD.

OBJECTIVE: To estimate the budget impact of roxadustat for the treatment of anemia of CKD from a commercial and Medicare Part D perspective.

METHODS: We estimate the budget impact of roxadustat's approval in anemia of CKD for both NDD and DD populations over a one-year time horizon. The eligible patient population is modeled based on the prevalence of CKD Stages 3-5, end-stage renal disease (ESRD), dialysis, anemia of CKD and ESA use. Drug costs are derived from pharmacy claims data. Pricing and uptake assumptions are based on expert opinion. For the Medicare Part D perspective, ESA costs in dialysis patients are assumed to be zero, as they would fall under a Medicare Part B bundled payment.

RESULTS: We estimate that the incremental budget impact would be $0.06 per member per month (PMPM) to a commercial plan, and $1.22 PMPM for a Part D plan. In one-way sensitivity analyses, our results varied most with cost of roxadustat, prevalence of dialysis, and market uptake assumptions.

CONCLUSIONS: The launch of roxadustat may result in significant budget impact to health plans, especially Medicare Part D plans. Estimating the budget impact of new agents ahead of launch, such as roxadustat, may help managed care pharmacists prepare for and appropriately manage costs and utilization.

SPONSORSHIP: None.

D8 Rate of Sickle Cell Pain Crises in Patients Who Previously Participated in the SUSTAIN Trial in the United States: The SUCCESSOR Study

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BACKGROUND: SUSTAIN was a phase 2 randomized, double-blind, placebo-controlled, 52-week study that compared the effect of crizanlizumab, a P-selectin inhibitor, at 2.5 or 5 mg/kg versus placebo on the frequency of sickle cell pain crises (SCPCs, or vaso-occlusive crises [VOCs] leading to a health care visit) in patients with any genotype of sickle cell disease. Crizanlizumab 5 mg/kg significantly reduced the median annual rate of VOCs versus placebo (1.6 vs. 3.0, $P = 0.01$), leading to a decrease in health care visits by 45%, and increased the time to first VOC (4.1 vs. 1.4 months, $P = 0.001$). Adverse events (AEs) and serious AEs were similar across all treatment arms. SUCCESSOR is a multicenter, retrospective, non-interventional follow-up study in U.S. patients up to 52 weeks following their completion of SUSTAIN. Patient consent was obtained prior to data collection if required by local and/or central research ethics review.

OBJECTIVE: To assess additional cases of VOCs, health care resource utilization (HCRU), including hospitalizations, and emergency department and clinic visits upon completion of crizanlizumab treatment.

METHODS: Medical records were reviewed for patients who completed SUSTAIN and were no longer on study drug. Patients who received at least 12 of the 14 planned drug doses, completed a visit at least 14 days after the final dose, and had no major protocol violations that impacted efficacy assessments were included. The study identification period was September 2015 to March 2017. Descriptive analyses of patient demographics, time to VOC, and VOC and HCRU rates were performed.

RESULTS: Of 125 patients who met the SUCCESSOR inclusion criteria (41, 44, and 40 on placebo, crizanlizumab 2.5 mg/kg, and 5 mg/kg, respectively), data for 19 patients were available for analysis by Sept 2018 (7, 4, and 8, respectively). All patients but 1 were African American. Three patients, 1 from each SUSTAIN treatment arm, had HbSC; all remaining patients had HbSS. In the 52 weeks following completion of SUSTAIN, VOCs were reported by 5 patients in the former placebo group, 4 who received crizanlizumab 2.5 mg/kg, and 7 who received crizanlizumab 5 mg/kg. Median time to first VOC after SUSTAIN was 3.2 months, 2.2 months, and 5.4 months, respectively. Most patients did not require blood transfusions but demonstrated an increase in HCRU versus pre-SUSTAIN. There were no deaths.

CONCLUSIONS: In SUCCESSOR, although some patients experienced high rates of VOC and HCRU, the time to first SCPC appeared to be delayed in the crizanlizumab 5 mg/kg arm.

SPONSORSHIP: Novartis Pharmaceuticals.

D9 Assessing Patient Preferences for Rare Disease Treatment: Qualitative Development of the Paroxysmal Nocturnal Hemoglobinuria Patient Preference Questionnaire

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BACKGROUND: Paroxysmal nocturnal hemoglobinuria (PNH) is a rare disease of uncontrolled complement activation. Two phase 3 clinical trials demonstrated that ravulizumab, a new C5 inhibitor administered every 8 weeks, was non-inferior to eculizumab (administered every 2 weeks) for all efficacy parameters in patients with PNH. However, eculizumab's more frequent dosing regimen may adversely affect quality of life; thus, patient preferences may aid in treatment selection.

OBJECTIVE: To develop a patient preference questionnaire (PPQ) assessing eculizumab and ravulizumab treatment for PNH.

METHODS: The development of the PNH-PPQ was consistent with Federal Drug Administration guidelines for the development of patient reported outcomes, and included: (a) a targeted literature review to investigate PNH patients' experiences with eculizumab, and factors that influence treatment and dosing preferences; (b) PNH expert clinician input on treatment preferences collected as part of a Delphi survey; (c) concept elicitation interviews with 8 PNH patients who received eculizumab and/or ravulizumab. Interview participants were recruited through a United Kingdom PNH patient advocacy group and a Canadian clinical site involved in clinical trial ALXN1210-PNH-302. The resulting Paroxysmal Nocturnal Hemoglobinuria Patient Preference Questionnaire (PNH-PPQ) was reviewed for translatability, then refined via cognitive interviews with 5 patients.

RESULTS: Themes identified as most relevant to the PNH treatment experience from the concept elicitation interviews included: disease symptoms (n = 8/8); treatment frequency (n = 7/8); quality of life impact of treatment/disease (n = 7/8); treatment burden (n = 7/8); treatment efficacy (n = 5/8); and treatment side effects (n = 5/8). An initial list of 88 preference questions was created. After removing redundant items, the resulting PNH-PPQ consists of 11 questions reflecting the 6 themes. In cognitive interviews, 5 PNH patients unanimously agreed that the PPQ instructions were clear; response options were understandable, easy to use, and provided enough choices; and the questions captured the factors that inform their treatment preferences.

CONCLUSIONS: The PNH-PPQ was developed from literature, expert input, and multiple sources of patient input including qualitative concept elicitation and cognitive interviews. This tool provides a patient-centered approach for evaluating preferences for the treatment of PNH. Currently, the PNH-PPQ is being assessed in the clinical trial sub-study ALXN1210-PNH-302s.

SPONSORSHIP: Alexion Pharmaceuticals.

D10 Patient Preferences for the Treatment of Paroxysmal Nocturnal Hemoglobinuria: Interim Results of a Patient Survey of Ravulizumab (ALXN1210) and Eculizumab

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BACKGROUND: Eculizumab inhibits complement-mediated hemolysis and thrombosis and improves quality of life (QoL) in patients with paroxysmal nocturnal hemoglobinuria (PNH). However, eculizumab has a treatment burden associated with every 2-week dosing. Ravulizumab, a new C5 inhibitor for PNH administered every 8 weeks, was shown to be non-inferior to eculizumab in 2 phase 3 trials. In the presence of multiple treatment options, patient preference should be considered when selecting a treatment plan.

OBJECTIVE: To evaluate patient treatment preference for eculizumab or ravulizumab in clinical sub-study ALXN1210-PNH-302s.

METHODS: ALXN1210-PNH-302 sub-study aims to enroll at least 95 PNH patients. Patients were enrolled from the ALXN1210-PNH-302 extension study, had received at least 2 doses of ravulizumab and provided informed consent. All patients were on stable eculizumab therapy prior to entering the trial. Patient treatment preference was evaluated at one time point by using an 11-item PNH specific patient preference questionnaire (PNH-PPQ).

RESULTS: To date, 52 completed PNH-PPQs have been analyzed. Mean age was 50 years (range: 28-78) and sex was equally distributed (~50%). Mean time since diagnosis was 15 years (range: 2-48) and the mean number of days between the last randomized study treatment and the survey was 278. Overall, 94% of patients (n=49) preferred ravulizumab vs. 6% (n=3; $P<0.001$) who preferred eculizumab (n=1) or had no preference (n=2). When asked for drug preference, ravulizumab was preferred based on frequency of infusions (98%), ability to plan activities (98%), convenience of receiving treatment (92%), overall QoL (88%), and effectiveness of medication until the next infusion (79%). When asked for the most important characteristic for treatment preference, the most common choice was frequency of infusions (42%). Moderate to large effect sizes were observed for factors differentiating ravulizumab and eculizumab, including the frequency of infusions disrupting everyday life (–1.43, $P<0.001$), feeling fatigued after infusions (–0.61, $P<0.001$), and being able to enjoy life while receiving treatment (0.96, $P<0.001$).

CONCLUSIONS: This interim analysis provides insights into PNH patient treatment preferences, and indicates that the vast majority of patients surveyed preferred ravulizumab due to reduced infusion frequency, ability to plan activities, effectiveness of medication, and convenience of treatment compared to eculizumab.

SPONSORSHIP: Alexion Pharmaceuticals.

D11 Humanistic Cost Impacts Associated with Immunoglobulin Replacement Therapy Among Patients with Primary Immunodeficiency Disease in the United States

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BACKGROUND: Primary immunodeficiency disease (PID) is a genetic condition characterized by a nonexistent or nonfunctioning part of the immune system. Individuals with PID are at risk for repeated and severe infections that are difficult to treat and may be fatal, if untreated. Immunoglobulin replacement therapy (IGRT) is a commonly used treatment for some types of PID, and can be administered at home or at a medical facility, either intravenously (IV) or subcutaneously (SC).

OBJECTIVE: To understand the humanistic impact associated with IGRT within a broader study that developed and evaluated a novel patient-reported outcome measure of overall patient experiences with IGRT (the Ig Patient Experience with Treatment [IgPET]).

METHODS: Researchers conducted phone interviews of English-speaking individuals aged ≥ 17 years who received IGRT for PID in the United States. The interviews included concept elicitation focused on participants' experiences with IGRT and cognitive debriefing of the IgPET. Interviews were audio recorded and transcribed for qualitative analysis.

RESULTS: Twenty-one interviews were conducted. Patients were mostly female (n=19, 90.5%), white (n=20; 95.2%), and college educated (n=14, 66.6%). The mean age was 42.5 (range 17-70) years, and mean time since PID diagnosis was 8.3 (range 1-26) years. Approximately half of the patients received IV treatment and half received SC treatment; 76.2% received IGRT at home. Although patients overwhelmingly stated that they did not consider their IGRT to be burdensome, many described economic and humanistic impacts associated with their care. These included obtaining or maintaining health insurance coverage; skipping treatments due to costs and lapses in health insurance coverage; interference with work and productivity due to frequency of treatments and side effects of IGRT; time required to order, prepare, set up, and schedule infusions; and time required to travel to a medical facility for IGRT. Worries about insurance coverage were similar regardless of IGRT mode of administration.

CONCLUSIONS: This qualitative study suggests that patients generally considered IGRT to be lifesaving rather than burdensome. Nevertheless, patients described humanistic implications associated with IGRT, including worries about insurance coverage, productivity loss, and time spent planning and receiving infusions; these responses suggest areas for improvement in IGRT.

SPONSORSHIP: Shire.

D12 Cost-Effectiveness Model for On-Demand Treatment of HAE Attacks

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BACKGROUND: Hereditary angioedema (HAE) is a rare C1-inhibitor deficiency that involves recurrent attacks of severe swelling occurring in areas such as the limbs, face, GI tract, and throat. If not treated promptly and effectively, attacks can result in hospitalization or death. Agents targeting the specific physiological pathway of HAE attacks can offer improved outcomes with limited side-effects compared to non-specific therapies. However, these agents are typically more expensive so managing treatment costs for HAE patients is crucial.

OBJECTIVE: To estimate the expected cost and utility per HAE attack when treated on-demand with HAE-specific therapies to help better clarify and control expenses related to disease management.

METHODS: A decision tree model was developed using TreeAgePro software. Four comparators were included: Berinert (pdC1INH), Firazyr (icatibant), Kalbitor (ecallantide), and Ruconest (rhC1INH). The model incorporated probabilities for self-administration versus healthcare-provider administration, re-dosing, and hospitalization risk. Costs within the model comprised the HAE therapies and various healthcare system expenses. Utility during attacks (0.51) and no-attack baseline (0.83) were considered for effectiveness, as was the time to attack resolution. Overall cost and effectiveness per attack were calculated and used to estimate cost-per-QALY. Probabilistic sensitivity analyses were performed to establish ranges for cost-effectiveness. A budget impact model was also developed for a health plan of 1M covered lives.

RESULTS: Base case analysis show costs and utility per attack at $12,342 and 0.804 for rhC1INH, $13,611 and 0.762 for icatibant, $13,993 and 0.759 for pdC1INH, and $20,315 and 0.786 for ecallantide. At a mean annual attack rate of 26.9, cost-per-QALY are calculated as $403k for rhC1INH, $449k for icatibant, $462k for pdC1INH, and $666k for ecallantide. Sensitivity analyses indicate re-dose rates (from 3% for rhC1INH, up to 44% for icatibant) as a primary driver of cost-effectiveness variability, while bodyweight can affect costs for weight-based therapies (pdC1INH, rhC1INH). The budget impact model reveals annual cost to the plan of $6.6M for rhC1INH, $7.3M for icatibant, $7.5M for pdC1INH, and $10.9M for ecallantide.

CONCLUSIONS: The model developed here accounts for patient well-being and downstream costs of HAE attacks. Findings indicate rhC1INH is the most cost-effective while ecallantide the least, and that cost-effectiveness is influenced by re-dosing rates and the ability to self-administer.

SPONSORSHIP: Pharming Group NV.

D13 A Budget Impact Model for Lanadelumab Treatment for the Prevention of HAE Attacks Among Patients with Type I or II HAE: Estimates of Yearly Savings for a U.S. Commercial Health Plan

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BACKGROUND: Hereditary angioedema (HAE) is a rare disease characterized by recurrent, painful, and potentially life-threatening swelling attacks; laryngeal edema is the major cause of angioedema-related mortality. Attacks can result in hospitalizations or emergency department (ED) visits, imposing a costly burden. Takhzyro (lanadelumab), a fully human monoclonal antibody targeting plasma kallikrein, was recently FDA-approved for prevention of HAE attacks in patients ≥12 years old.

OBJECTIVE: To estimate budgetary impact of adding lanadelumab to a U.S. commercial insurance plan's formulary.

METHODS: The budget impact model was developed per ISPOR guidelines. Number of HAE patients (type I or II) and patterns of acute and prophylactic HAE treatments were estimated for a U.S. commercial health plan with 1 million members (age [years] based on U.S. national statistics: 12-17 = 9%, 18-64 = 72%, and ≥65 = 19%). Impact for a plan that includes lanadelumab in the formulary for prophylaxis (in addition to plasma-derived CI-INH agents) was compared to a formulary with plasma-derived CI-INHs as the only prophylactic options. Budgetary impact of adding lanadelumab was modeled based on clinical trial efficacy data. Wholesale acquisition cost for drugs, cost of treatment administration, cost of hospitalization, ED visit,

physician office visit, as well as costs related to severe adverse events were included. Sensitivity analyses were performed to evaluate budget impact of varying influential parameters by ±10% from base value.

RESULTS: A total of 17 patients with HAE type I or II were estimated to be present in a health plan of 1 million members, 40% of whom were estimated to use a prophylactic treatment in 2018. Based on the model, if 15% of all prophylactically treated patients with type I or II HAE received lanadelumab, estimated total annual saving was $289,878 (or $17,019 per patient per year [PPPY]). By year 2020, 44% of HAE patients were estimated to receive prophylactic treatment; if 40% of all prophylactically treated patients received lanadelumab, total annual saving was $914,779 (or $52,175 PPPY). This results in savings of $0.024 per member per month (PMPM) in year 2018, and $0.076 in year 2020. Per sensitivity analyses, PMPM savings after introduction of lanadelumab were $0.020 to $0.029 for year 2018 and $0.067 to $0.089 for year 2020.

CONCLUSIONS: An increasing use of treatments for prophylaxis of HAE attacks in general, and specifically treatment with lanadelumab, provide yearly savings to a U.S. commercial health plan.

SPONSORSHIP: Shire.

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

E1 A Retrospective Database Analysis Evaluating the Association Between Pharmacy Quality Alliance Antidiabetic Medication Measure Adherence, Healthcare Use, and Expenditures Among Commercially Insured Patients

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BACKGROUND: Medication nonadherence is associated with decreased clinical outcomes and increased healthcare use and costs among diabetic patients. The Centers for Medicare and Medicaid Services adopted Pharmacy Quality Alliance (PQA) adherence measures to evaluate Medicare health plan performance. The impact of these measures in other populations is warranted.

OBJECTIVE: To determine the association between adherence and economic outcomes (use and costs) among commercially insured patients using antidiabetic medications.

METHODS: This one-year retrospective study used a cohort of individuals from Truven Health MarketScan Research Databases (2009-2015) who used antidiabetic medications (except insulin). Generalized linear models with log link and gamma distribution (costs) or negative binomial distribution (use) assessed relationships between adherence (≥80% proportion of days covered) and healthcare use and costs (adjusted to 2015 U.S. dollars) while adjusting for covariates (e.g., age, gender, Charlson Comorbidity Index). Cost ratios (CR) and rate ratios (RR) were computed using beta coefficients. Cohort characteristics were compared using t-tests, Wilcoxon rank sum tests, or chi square tests with an alpha level of 0.001 set a priori.

RESULTS: A total of 1,576,112 individuals were eligible and 1,028,176 (65.2%) were classified as adherent. Differences in demographics were observed between adherent and non-adherent groups (P<0.001). Multivariable analyses showed adherence was associated with: fewer inpatient (RR=0.834, 95% CI=0.819-0.850) and more outpatient visits (RR=1.036, 95% CI=1.032-1.039); and lower inpatient (CR=0.833, 95% CI=0.829-0.836) and total (CR=0.958, 95% CI=0.954-0.962)

costs. Adherence was associated with lower incremental per member per month costs for inpatient ($31.74) and total ($30.82) costs compared to nonadherence.

CONCLUSIONS: Adherence to antidiabetic medications was associated with more outpatient but fewer inpatient visits, and lower total costs compared to nonadherence.

E2 Reduced Healthcare Utilization in Patients Using Empagliflozin: An Interim Analysis from the EMPagliflozin compaRative effectIveness and SafEty (EMPRISE) Study

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BACKGROUND: The efficacy of Empagliflozin (EMPA) for reducing the risk of cardiovascular (CV) death (HR: 0.62; 95% CI: 0.49-0.77) and hospitalization of heart failure (HHF; HR: 0.65; 95% CI: 0.50-0.85) was demonstrated in the EMPA-REG OUTCOME trial in adults with type 2 diabetes (T2D) and established CV disease. EMPRISE is a study program on the comparative effectiveness, safety and health care resource utilization (HCRU) of EMPA for T2D patients in routine care across a spectrum of CV risk in 2 U.S. commercial (Optum and MarketScan) and Medicare claims datasets (2014-2019).

OBJECTIVE: To compare HCRU among EMPA versus dipeptidyl peptidase-4 inhibitor (DPP4i) users observed during the first two years of EMPRISE (08/2014-09/2016).

METHODS: In this interim analysis, we identified a 1:1 propensity-score-matched cohort of T2D patients ≥ 18 years initiating either EMPA or a DPP4i, and assessed balance on ≥ 140 covariates including clinical, HCRU, and cost related covariates at baseline using absolute standardized differences (aSD). We compared risk of first hospitalization, risk of first emergency department (ED) visit, hospital length of stay (LOS), and number of hospital admissions, office visits, and ED visits in EMPA and DDP4i users.

RESULTS: We identified 17,549 matched pairs in the three data sets with mean follow-up of 5.4 months. All baseline characteristics were well balanced (with aSD < 0.1) after propensity matching. The mean age was 59 and 47% were female. Approximately 24% of patients had history of CV disease and mean HbA1C was 8.6%. Risk of first hospitalization [Hazard ratio (HR) = 0.84; 95% CI: 0.76-0.92] and ED visit (HR = 0.83; 0.73-0.94) was lower in EMPA than DDP4i users as was the number of all hospital admissions (12% and 15% PMPY; Incidence rate ratio (IRR) = 0.78; 0.72-0.86). LOS was 0.52 days per member per year (PMPY) in EMPA compared to 0.75 days in DDP4i group (Diff = -0.23, 95% CI = -0.38 - −0.08). Number of ED visits (0.07 and 0.09 PMPY; IRR = 0.80; 0.71-0.89), and number of office visits (8.03 and 8.39; IRR = 0.96; 0.95-0.98) were also lower in EMPA than DPP4i initiators. Our findings in the pooled data were consistent across individual databases; however, rate ratios for risk of first hospitalization and first ED visit only reached statistical significance in Medicare databases in this first analysis.

CONCLUSIONS: We observed significant lower HCRU in EMPA compared to DDP4i initiators in the pooled dataset within the first two years of EMPRISE. The findings in each individual database were consistent with the overall results in the pooled analysis.

E3 Healthcare Costs in Patients Using Empagliflozin: An Interim Analysis from the EMPagliflozin compaRative effectIveness and SafEty (EMPRISE) Study

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BACKGROUND: The efficacy of Empagliflozin (EMPA) for reducing the risk of cardiovascular (CV) death (HR: 0.62; 95% CI: 0.49-0.77) and hospitalization of heart failure (HHF; HR: 0.65; 95% CI: 0.50-0.85) was demonstrated in the EMPA-REG OUTCOME trial in adults with type 2 diabetes (T2D) and established CV disease. However, little is known about the impact of EMPA on health care cost.

OBJECTIVE: To estimate inpatient and outpatient cost among EMPA and dipeptidyl peptidase-4 inhibitor (DPP4i) users observed in 2 U.S. commercial and Medicare claims datasets from 08/2014 to 09/2016.

METHODS: We analyzed healthcare cost in the first two years after marketing of EMPA as part of EMPRISE, a non-interventional real world evidence study program on the comparative effectiveness, safety and health care resource utilization of EMPA for T2D patients in routine care across a spectrum of CV risk in 2 U.S. commercial (Optum and MarketScan) and Medicare claims datasets (2014-2019). We identified a 1:1 propensity-score-matched cohort of T2D patients ≥ 18 years initiating either EMPA or a DPP4i, and assessed the balance on ≥ 140 covariates including clinical, health care resource utilization, and cost related covariates at baseline using absolute standardized differences (aSD). Per member per year (PMPY) cost were estimated including both the payer and patient costs captured in claims data. We estimated overall and CV related inpatient and outpatient costs among EMPA and DDP4i initiators.

RESULTS: After propensity score matching, we identified 17,549 matched pairs in the three datasets (mean follow-up of 5.4 months). All baseline characteristics were well balanced (with aSD < 0.1). The mean age was 59, 47% were female, 24% had history of CV disease, and mean HbA1C was 8.6%. Mean baseline inpatient costs ($1,765 vs. $1,905, aSD = 0.01) and outpatient costs ($5,698 vs. $5,760, aSD = 0.01) were balanced between EMPA and DPP4i initiators. During follow-up, both inpatient costs ($2,418 vs. $2,859 PMPY; Diff = -441, 95% CI = -1,089, 253) and outpatient costs ($6,513 vs. $6,870 PMPY; Diff = -356, 95%CI = -1,069, 356) tended to be lower among EMPA initiators compared to DDP4i initiators. CV-related inpatient costs ($624 vs. $756 PMPY; Diff = -132, 95%CI = -462, 225) and CV-related outpatient costs ($2,321 vs. $2,455 PMPY; Diff = -134, 95%CI = -556, 287) tended to be lower in EMPA initiators during follow-up.

CONCLUSIONS: Results observed in the first analysis of EMPRISE trend toward lower inpatient and outpatient costs among patients initiating EMPA compared to DDP4i initiators.

E5 Comparative Healthcare Costs and Medication Burden in Real-World Patients Augmenting Metformin Monotherapy with Empagliflozin from the EMPagliflozin compaRative effectIveness and SafEty (EMPRISE) Study

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BACKGROUND: The EMPA-REG OUTCOME trial showed that empagliflozin (EMPA) reduces the risk of cardiovascular (CV) death and hospitalization for heart failure in adults with type 2 diabetes (T2D) and established CV disease. However, the impact of EMPA add-on therapy to metformin monotherapy on healthcare resource utilization (HCRU) and costs in routine care has not been evaluated yet.

OBJECTIVE: To assess healthcare costs and medication burden among metformin monotherapy users initiating EMPA vs. dipeptidyl peptidase-4 inhibitor (DPP4i) in Medicare and 2 U.S. commercial claims datasets from 08/2014 to 09/2016.

METHODS: We identified a 1:1 propensity-score (PS)-matched cohort of T2D patients ≥ 18 years on metformin monotherapy starting either EMPA or DPP4i, controlling for ≥ 140 baseline covariates including clinical, HCRU, and cost-related covariates, measured during the 1 year before add-on treatment initiation. We evaluated total (inpatient, outpatient and pharmacy) cost and medication burden among EMPA vs. DDP4i initiators, and measured per member per year (PMPY) costs during the follow-up period.

RESULTS: We identified a total of 2,928 1:1 PS-matched pairs from the three datasets, with well-balanced baseline characteristics, as measured by absolute standardized differences (aSD) < 0.1. Mean age was 57 years, 45% were female, 19% had history of CV disease, and mean HbA1C was 8.2%. During the 1-year baseline period, mean total ($8,698 vs. $8,980, aSD = 0.01), inpatient ($1,265 vs. $1,369, aSD = 0.01), outpatient ($5,161 vs. $5,222, aSD = 0.00), and pharmacy ($2,239 vs. $2,362, aSD = 0.02) costs were balanced among EMPA vs. DPP4i initiators, as well as mean number of distinct medication prescriptions (10.8 in both groups). During follow-up (mean 168 days), the PMPY total costs tended to be lower among EMPA vs. DDP4i initiators ($13,547 vs. $14,902; Diff = -$1,355, 95% CI: -3,922, 991), as were inpatient ($1,502 vs. $2,140 PMPY; Diff = -$638, 95% CI: -1,864, 484) and outpatient ($5,570 vs. $6,300 PMPY; Diff = -$730, 95% CI: -2,500, 643) costs. Pharmacy costs ($6,442 vs. $ 6,416 PMPY; Diff = $26, 95% CI: -914, 795) tended to higher in EMPA group. CV-related medical costs also tended to be lower (Diff = -$242, 95% CI: -1,641, 902) in EMPA initiators. The number of distinct medication prescriptions was similar (15.5 PMPY in both groups; Incidence rate ratio = 1.01; 95% CI: 0.99-1.03).

CONCLUSIONS: Results from the first analysis of EMPRISE showed trend towards lower total cost of care, driven by medical costs, and similar medication burden among metformin monotherapy users initiating EMPA vs. DPP4i.

SPONSORSHIP: Boehringer Ingelheim.

E6 The Clinical and Financial Impact of Active and Passive Dipeptidyl Peptidase-4 Medication Switch Programs

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BACKGROUND: Active switch (AS) programs, in which healthcare providers and patients work together to implement lower-cost pharmaceutical regimens, have shown success in reducing costs in various settings, including within academic health systems and accountable care organizations. However, limited evidence exists regarding the impact of AS programs compared to passive switch (PS) programs, wherein patients are encouraged via messaging to switch to lower-cost generic alternatives with no consequence in coverage. The purpose of this cost-minimization study was to quantify the clinical and economic impact in converting patients from a branded dipeptidyl peptidase-4 (DPP-4) product to generic alogliptin within a self-funded prescription drug plan.

OBJECTIVE: To assess the clinical and economic effectiveness of parallel AS and PS programs. The primary clinical endpoint was change from baseline HbA1c compared to months 3, 6 and 9 post-switch. The primary economic endpoints included costs avoided within the drug class and overall drug spend six months pre- and post-switch, from both plan and member perspectives. A secondary objective was to assess patient and provider acceptance of the switch programs.

METHODS: In November 2017, all active plan members receiving a branded DPP-4 product from a Michigan Medicine (MM) provider were assigned to the AS program. A MM pharmacist reviewed each patient and, if appropriate, worked with the provider and patient to transition therapy to generic alogliptin. Members receiving a branded DPP-4 product from a non-MM provider were assigned to the PS program and were sent a one-time letter from the plan informing them of the opportunity to switch to generic alogliptin.

RESULTS: A total of 430 members were identified for the study, with 201 (46.7%) assigned to the AS program and 229 (53.3%) assigned to the PS program. Of those assigned to AS, 68 (33.8%) successfully switched to generic alogliptin, whereas one member successfully switched in the PS program. No adverse clinical outcomes were identified in those who successfully switched to generic alogliptin. In the twelve months post initiation, the AS program led to a projected plan savings of up to $0.17 PMPM.

CONCLUSIONS: Active switch programs may be a reasonable cost-containment strategy for reducing plan costs in lieu of changes to plan design. The success of switching products in both programs was lower than anticipated; however, this study provided useful data and insights that will be instrumental in the development of future programs.

SPONSORSHIP: University of Michigan Prescription Drug Plan.

E7 Evaluating the Effect of a Medication Adherence Tracker on Adherence and the Implications on HgA1c Among Medicare Advantage Prescription Drug Plan Members with Diabetes

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BACKGROUND: Optimizing medication adherence has the potential to prevent serious complications, reduce morbidity and mortality, and is critical in the management of chronic disease states. Therefore, understanding and implementing approaches to enhance medication adherence is vital in providing quality care to patients. A tool called the Medication Adherence Tracker (MAT) has previously been shown to increase rates of paid Rx claims, proportion of days covered (PDC) rates, and overall adherence. However, the initiative's influence on clinical outcomes has yet to be evaluated.

OBJECTIVE: To examine the MAT's impact on PDC rates and HgA1c among patients with diabetes.

METHODS: A retrospective analysis of Medicare Advantage Prescription Drug Plan (MAPD) beneficiaries in South TX included in the MAT initiative July-December 2016 was conducted. The MAT involved an interdisciplinary care team who worked together to improve patients' medication adherence. Health plan reports identifying patients that met CMS's Part D triple weighted star measures were sent to primary care physician offices. The offices contacted patients to identify barriers to care, with the intention of optimizing medication adherence. The MAT patients with diabetes and at least 1 oral antidiabetic agent were selected. Rx claims were tracked and effect on PDC was evaluated. Change in HgA1c was determined by comparing pre-intervention HgA1c to post-intervention HgA1c, measured 3-12 months after

the intervention. The goal PDC was defined as > 0.8 and the goal HgA1c was defined as <9.0%, using CMS benchmarks. Changes in mean HgA1c values were assessed using paired t-tests and goal PDC achievement was assessed using McNemar chi-square test.

RESULTS: A total of 152 patients were included in the analysis, with 76 (50%) having a pre-intervention PDC rate ≤0.8 and 25 (16.4%) having a pre-intervention HgA1c>9.0%. McNemar chi-square test revealed a significant net increase in adherent patients of 32% post-intervention. Paired t-tests demonstrated a significant reduction in mean HgA1c values from 7.7% to 7.1% ($P < 0.0001$). Only 10 (6.6%) patients were observed to have an HgA1c>9.0% and 27 (17.8%) had a PDC≤0.8 in the assessments following the MAT.

CONCLUSIONS: The results of this study indicate the MAT not only improves medication adherence but also clinical outcomes. After the MAT, patients were more likely to achieve goal PDC and HgA1c values. The ability to extrapolate the MAT's positive effect on adherence and clinical outcomes validates the MAT initiative and supports further expansion and implementation.

SPONSORSHIP: None.

E8 Evaluating the Impact of a Diabetes Self-Management Education and Support Service on Medication Adherence and Glycemic Control Within a Texas Medicare Advantage Population

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BACKGROUND: Glycemic control in patients with diabetes is highly dependent upon medication adherence, yet 45% of patients fail to achieve glycemic control as measured by attaining HgA1c goals. Oral and injectable diabetes medication adherence and glycemic control are focal points in Medicare quality of care metrics. Diabetes self-management education and support service (DSMES) programs have demonstrated effectiveness in improving clinical outcomes. However, the impact of such programs on medication adherence as well as their effectiveness in varying TX regions within a MAPD population has not been adequately explored.

OBJECTIVE: To assess the impact of DSMES along with clinical and demographic factors on diabetes medication adherence and glycemic control.

METHODS: A longitudinal analysis of pharmacy claims was conducted among Medicare Advantage beneficiaries from South and East Texas enrolled in a DSMES program from June 2016-June 2017. Patients were referred and enrolled into the program utilizing DSMES inclusion criteria: diagnosis of diabetes, HgA1c>8.5%, new onset or prior history of poor control, or on >3 oral medications or >2 oral medications plus incretin mimetics or on insulin therapy. Two-hour DSMES courses facilitated by health plan staff were offered locally for six weeks. Patients were considered to have completed the course if they attended at least five sessions. After course completion, health plan staff members conducted three- and six-month follow-ups by telephone. Three- or six- month change in HgA1c after DSMES participation was assessed using paired t-tests. The effect of DSMES participation on improvement in medication proportion of days covered (PDC), with PDC≥0.8 considered adherent was analyzed using McNemar Chi-square test.

RESULTS: Seventy-nine participants were included in the DSMES evaluation. No significant relationship between DSMES participation

and mean PDC was found; however, 64.7% of those who did not begin the course with a PDC at goal (≥0.8) achieved PDC at goal after DSMES participation. Participation was significantly associated with improved glycemic control; mean HgA1c decreased from 10.1% at baseline to 9.0% ($P < 0.0001$). Patients in the East TX region experienced a greater mean HgA1c reduction (1.25%, $P < 0.0001$) as compared to patients in South TX (0.65%, $P < 0.01$).

CONCLUSIONS: The results indicate that participants that complete DSMES are more likely to attain glycemic control. Reasons for geographic difference in glycemic control among patients attending DSMES need further investigation.

SPONSORSHIP: None.

E9 Health Care Utilization and Economic Burden of Type 2 Diabetes Among Patients in the U.S. Department of Defense Population

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BACKGROUND: Type 2 diabetes mellitus (T2DM) affects millions of people and is associated with high mortality and morbidity, resulting in high health care costs.

OBJECTIVE: To examine the health care utilization and economic burden of T2DM in the U.S. Department of Defense (DoD) population.

METHODS: This was a retrospective case-control study using the U.S. DoD database from October 1, 2011-September 30, 2016. Patients were included as cases if they had ≥1 claim for T2DM (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] diagnosis codes 250.x0 or 250.x2, or ICD-10-CM: E11) during the study period. The first diagnosis during date the identification period (October 1, 2012-September 30, 2015) was designated as the index date. A comparison cohort was created for patients without T2DM, but with similar baseline Charlson Comorbidity Index (CCI) scores and identical age, sex, and index year. The index date was randomly chosen to minimize selection bias. Patients were required to have continuous health plan enrollment for 1 year pre- and post-index date. Generalized linear models (GLMs) were applied to compare the health care utilization and costs, adjusting for patient clinical characteristics.

RESULTS: A total of 236,590 patients were included in the study. The mean age was 53 years, and 51% were female. Patients with T2DM had higher CCI scores (0.7 vs. 0.3, $P < 0.001$) compared to controls. After adjusting for patients' clinical characteristics in the GLM, T2DM patients had higher all-cause health care utilization including inpatient admissions (0.19 vs. 0.09, $P < 0.001$), ambulatory visits (24.8 vs. 17.3, $P < 0.001$), emergency room (ER) visits (0.63 vs. 0.39, $P < 0.001$), and pharmacy visits (16.4 vs. 11.0, $P < 0.001$ and longer hospitalization length of stay (1.3 vs. 0.6 days; $P < 0.001$) compared to those without T2DM. As a result, case patients incurred higher follow-up all-cause health care costs related to inpatient ($2,442 vs. $1,113; $P < 0.001$), ambulatory visit ($6,841 vs. $4,794; $P < 0.001$), ER visit ($453 vs. $266; $P < 0.001$), pharmacy ($1,480 vs. $956; $P < 0.001$), and total costs ($11,220 vs. $7,134; $P < 0.001$).

CONCLUSIONS: During a 12-month period, DoD beneficiaries diagnosed with T2DM had higher health care utilization and incurred higher costs than matched control patients.

SPONSORSHIP: None.

E10 All-Cause and Diabetes-Related Costs in Patients with Type 2 Diabetes and Substance Use Disorders

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BACKGROUND: Patients with type 2 diabetes (T2D) and a comorbid substance use disorder (SUD) face self-management challenges, which could put them at risk for poor outcomes and higher medical costs.

OBJECTIVE: To determine all-cause and diabetes-related medical and pharmacy costs in commercially insured adults with T2D.

METHODS: A retrospective cohort study (January 2006-June 2015) of adults with T2D and comorbid SUD was conducted in a national commercial insurance claims database. SUD included abuse of opioids, alcohol, and other abused substances. Costs were based on payer amount paid for medical services and prescription drugs. Costs were calculated per person per year (PPPY) separately for SUD and non-SUD groups by summing paid costs per patient divided by the total number of follow-up days in the group, multiplied by 365, and adjusted to 2014 dollars. Bootstrap sampling was conducted to generate descriptive statistics. Non parametric tests were performed to compare cost between two groups.

RESULTS: A total of 155,594 patients with T2D were included. Of these 1.1% (n = 1,760) had a concurrent SUD diagnosis. The SUD group was younger at 50.9 (10.4) vs. 53.4 (11.2) years old and a higher proportion were male (69.3% vs. 54.1%) relative to the non-SUD group ($P < 0.001$ for both). Total PPPY all-cause medical costs were higher in the SUD group at $27,129 (54,209) than the non-SUD group ($13,951 [65,790]; $P < 0.001$) as were diabetes related medical costs PPPY ($1,651 [7,659] vs. $1,115 [4,228]; $P = 0.004$). Costs were significantly higher in the SUD group for inpatient, outpatient and emergency department services ($P < 0.01$). Total prescription drug costs PPPY were higher in the SUD group ($7,618 [19,243] than the non-SUD group ($4,862 [13,737]; $P < 0.001$), but diabetes related drug costs were lower ($915 [2,681] vs. $1,624 [3,930]; $P < 0.01$).

CONCLUSIONS: Patients with SUD had significantly higher all-cause and diabetes-related medical costs and all-cause pharmacy costs than those without SUD, but lower costs for diabetes-related medications. Future research will assess diabetes medication prescribing and glycemic control to identify if there is opportunity to improve diabetes drug treatment in commercially insured patients with T2D and SUD.

SPONSORSHIP: None.

E11 A Ready-to-Use Liquid Glucagon Rescue Pen for Severe Hypoglycemia Demonstrates Reduced Healthcare Payer Costs in a Budget Impact Model

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BACKGROUND: American Diabetes Association consensus guidelines recommend that glucagon should be prescribed for all individuals at increased risk of clinically significant hypoglycemia, defined as blood glucose < 54 mg/dL. However, a substantial number of persons with diabetes who are on insulin have not received nor filled a glucagon prescription. A ready-to-use, room-temperature stable liquid glucagon rescue pen auto-injector (GRP; Xeris Pharmaceuticals) has been developed for the treatment of severe hypoglycemia events (SHEs). GRP has a simple two-step process where, in simulated emergency settings, 99% of all users can successfully administer of a full dose of glucagon.

Conversely, for marketed glucagon emergency kits (GEK) only 0% to 31% of users were successful.

OBJECTIVE: To demonstrate the value of covering the GRP compared to GEK or no devices for the treatment of SHEs in insulin-dependent diabetic patients.

METHODS: We developed a budget impact model to estimate the economic impact of coverage of the GRP. Cost offsets from higher rates of successful administration of GRP incorporated EMS call, ambulance transport to ED, ED encounter, inpatient, and outpatient utilization. Diabetes prevalence and event probabilities were obtained from publicly-available sources and clinical literature, while costs were obtained from the 2018 Medicare Fee Schedules and adjusted to represent a commercial payer perspective.

RESULTS: Based upon the functional efficacy (i.e., rates of successful administration) of the GRP (99%) compared to GEK (31%), the resulting events following unsuccessful administration were higher among patients using GEK. Consequently, a hypothetical commercial health plan with 1,000,000 covered lives may achieve over 8% savings ($0.75 PMPM vs. $0.69 PMPM) for the treatment of SHE by covering GRP.

CONCLUSIONS: Our model suggests significant cost savings can be achieved with GRP. In tandem with the superior functional efficacy profile, the budget impact results illustrate the financial benefit of open coverage of the GRP, along with an incentive for physicians to increasingly prescribe and patients to fill glucagon prescriptions, in order to optimize patient outcomes.

SPONSORSHIP: Xeris Pharmaceuticals.

E12 Budget Impact of Adding the Omnipod DASH Insulin Management System for the Treatment of Type 1 Diabetes to the Pharmacy Benefit of a U.S. Third-Party Commercial Payer

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BACKGROUND: An estimated 1.25M people in the U.S. have type 1 diabetes (T1D) requiring daily insulin treatment by multiple daily injections or by continuous subcutaneous insulin injection using an insulin pump. The Omnipod DASH Insulin Management System (Insulet Corp., Billerica, MA) consists of a tubeless insulin pump (Pod) and a Personal Diabetes Manager (PDM), a handheld device used to wirelessly control the Pod. The Omnipod DASH System is available through the pharmacy benefit and has a lower upfront cost compared to durable tubed insulin pumps because there is no charge for the PDM with the initial purchase of pods.

OBJECTIVE: To evaluate the budget impact of adding the Omnipod DASH System to the pharmacy benefit of a U.S. third-party commercial payer formulary over a 4-year time period.

METHODS: The model included a cohort of adult T1D patients and considered Pharmacy Wholesale Acquisition Costs (WAC) for durable pumps, infusion sets, PDMs, Pods; daily insulin use and total inpatient hospitalization costs for patients with diabetes adjusted to 2018 USD. 25% of eligible patients were assumed to be at tubed pump warranty renewal or initiating insulin pump therapy each year. Cost inputs and patient churn rates were sourced from public pricing databases, medical literature, or data on file. Per-member, and per-patient-per-month (PMPM/PPPM) costs were calculated. A one-way sensitivity analysis was also conducted.

RESULTS: In a model plan of 1,000,000 patients, approximately 1,255 member patients with T1D receive treatment with an insulin pump. A 30% initiation of the Omnipod DASH System by the end of the fourth year is projected to result in cost savings for the treatment population, decreasing total treatment costs by $691,168. The acquisition cost of the Omnipod DASH System for the eligible population of patients is projected to be $1,764,737 which is offset by a reduction of $2,455,906 due to the partial avoidance of upfront durable pump acquisition costs. This translates to a savings of -$0.02 PMPM and -$16.47 per patients with T1D per month. In sensitivity analyses, the BI model was most affected by the cost of tubed pumps, the proportion of patients renewing annually, the future market share of the Omnipod DASH System, and the cost of Pods.

CONCLUSIONS: This budget impact model suggests that including the Omnipod DASH System for the treatment of T1D in the pharmacy benefit of a third-payer commercial formulary is associated with cost savings to payers, largely due to meaningful reductions in upfront device costs.

SPONSORSHIP: Insulet Corporation.

E32 Real-World Persistence, Healthcare Resource Utilization, and Costs of Octreotide and Lanreotide Among Patients with Carcinoid Syndrome

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BACKGROUND: Somatostatin analogues (SSAs) are recommended for the management of symptoms associated with carcinoid syndrome (CS) among NET patients (pts), but research assessing real-world treatment persistence and costs of long-acting octreotide and lanreotide is limited.

OBJECTIVE: To assess real-world persistence, healthcare resource utilization (HRU), and costs among NET pts with CS receiving long-acting octreotide vs. lanreotide.

METHODS: Retrospective claims data from Symphony Health Solutions were analyzed for NET pts who initiated octreotide or lanreotide (index date) between 01/2015-11/2017 for ≥90 days. Pts with continuous clinical activity (≥180 pre and ≥90 days post index date) and no prior non-surgical NET treatment were included. Pts with CS were identified from matched cohorts of pts receiving long-acting octreotide or lanreotide. We examined time to treatment discontinuation [TTD] using Kaplan-Meier and assessed all-cause and NET-related HRUs and costs using adjusted rate ratio (RR) and adjusted mean cost difference (CD) with 95% bootstrap confidence interval (CI), respectively. Adjusted results were estimated using multivariate models controlling for age, gender, region, insurance type, Charlson comorbidity index (CCI), metastatic disease, and all cause and NET-related HRU and cost at baseline.

RESULTS: Among 1,086 NET matched pts (N=543 for each SSA), 161 octreotide and 113 lanreotide pts had a CS diagnosis. Mean age was 66.4 and 64.8 years among octreotide and lanreotide CS pts, respectively, and baseline CCI was 5.3 in both cohorts. Median TTD was 21.4 months for octreotide and 15.9 months for lanreotide CS pts. Numerically lower and non-statistically significant hospitalization rates were observed among octreotide than lanreotide pts (all cause=0.043 and 0.045 per pt per month [PPPM]; NET-related=0.015 and 0.017 PPPM). Statistically significantly fewer NET-related outpatient visits (0.97 and 1.03 PPPM; RR [CI]: 0.93 [0.87, 0.99]) and lower total healthcare mean costs PPPM were observed for octreotide than lanreotide CS pts (CD [CI]: all cause=$3,736 [$1,225, $6,248]; NET-related=$4,256 [$2,075, $6,436]).

CONCLUSIONS: Among patients with CS in octreotide and lanreotide matched cohorts, octreotide was associated with significantly lower all-cause and NET-related total healthcare costs compared with lanreotide. The lower healthcare costs associated with octreotide may be driven by the combined trends of fewer NET-related inpatient and outpatient visits despite numerically longer median TTD.

SPONSORSHIP: Novartis Pharmaceuticals.

E33 Assessing Healthcare Resource Utilization Across Segments of Obesity: A Retrospective Claims Study

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BACKGROUND: Obesity is a disease that is caused and influenced by genes and the environment. Whether different etiologies or presentations of obesity result in homogeneous disease burden and/or cost is not well characterized.

OBJECTIVE: To determine whether there are distinct segments within the pool of patients who are obese that are differentiated by clinical characteristics, and quantify their healthcare resource utilization (direct healthcare costs [HCC]), using U.S. claims data.

METHODS: This retrospective, exploratory analysis uses the IQVIA adjudicated claims database. The cohort included patients of age <65 years with 1+ claim coded for obesity/morbid obesity in the most recent 12 months of continuous enrollment (January 2012-September 2017). A review of literature on clinical characteristics of obesity (including genetic obesity) informed the cluster analysis. A two-step cluster analysis was performed separately on two age groups: <12 years ("AG1") and 12-64 years ("AG2"). Mean annual HCC was compared.

RESULTS: Of the 4,694,296 individuals who met the inclusion criteria, 355,372 (8%) were classified into AG1 and 4,338,924 (92%) into AG2. Within AG1, three distinct clusters emerged: cluster A (17% of patients) characterized by high rates of cognitive/developmental disorders, visual/auditory impairments, and renal disease; cluster B (9%) with high rates of hormone replacement, lipid panel, and TSH testing; and cluster C (74%) with few signature characteristics. Within AG2, five distinct clusters emerged: clusters A' (11%), B' (11%), and C' (52%), which were clinically similar to AG1 clusters A, B, and C, respectively; cluster D' (12%) characterized by high rates of genitourinary disorders and visual impairments; and a distinct cluster E' (14%) characterized by sleep apnea-related conditions and treatments. Clusters A and A' exhibited the highest mean annual HCC ($4,215 and $26,406, respectively) within the respective age groups, while clusters C and C' where associated with the lowest mean costs ($1,262 and $6,746, respectively). In general, costs in AG2 segments were higher than in AG1.

CONCLUSIONS: Despite potential limitations inherent in claims data (lack of standardized coding practices and the fact that data are gathered for the purposes of billing and reimbursement), this study identified distinct patient clusters and HCC patterns based on clinical characteristics in a population with obesity. The underlying causes of obesity between these subgroups warrants further investigation.

SPONSORSHIP: Rhythm Pharmaceuticals.

E34 Reduced Renin-Angiotensin-Aldosterone System Inhibitors Use After Hyperkalemia-Related Hospitalization

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BACKGROUND: Renin-angiotensin-aldosterone system inhibitor (RAASi) therapy has beneficial effects in patients with heart failure (HF) and chronic kidney disease (CKD). However, due to the mechanism of action and underlying comorbidities, patients on RAASi are at increased risk for hyperkalemia (HK). The development of HK may alter RAASi prescribing patterns, which may impact quality metrics related to RAASi therapy.

OBJECTIVE: To compare post-discharge RAASi use between patients with HK-related hospitalization and matched patients with hospitalization unrelated to HK.

METHODS: Patients with at least one hospitalization with a HK diagnosis (ICD-9 276.7) were selected as cases from a large U.S. commercial claims database (1/1/2010-12/31/2014), with the first HK-related hospitalization as the index hospitalization. Patients with at least one hospitalization and with normal potassium lab results (≤ 5.0 mEq/L), no HK diagnoses, and no sodium polystyrene sulfonate prescriptions were selected as controls, with a randomly selected hospitalization as the index hospitalization. Continuous enrollment from 6 months prior to the index hospitalization admission (baseline period) to 12 months post discharge was required. All patients were required to have at least one RAASi prescription claim during the baseline period. Controls were exactly matched 1:1 to cases on age group, CKD stage, dialysis, HF, major diagnostic categories, and selected diagnosis-related groups. Kaplan-Meier analysis and adjusted Cox regression model were used to compare post-discharge RAASi use between matched cases and controls and among subgroups of patients with CKD, HF, and CKD and/or HF.

RESULTS: A total of 2,609 matched pairs of cases and controls were selected. Patients with HK-related hospitalization had a lower proportion of RAASi use during 30-day, 60-day and 90-day post-discharge periods compared with controls (37.4% vs. 41.7%, 54.7% vs. 59.9%, and 63.9% vs. 71.3%, respectively). The median time to first post-discharge RAASi use was 1.7 vs. 1.4 months among cases vs. controls (log-rank test $P < 0.001$). In multivariable Cox regressions, the hazard ratio of using RAASi was 0.84 (0.79-0.89) comparing cases vs. controls. All results were similar in the patient subgroups with CKD, HF, and CKD and/or HF.

CONCLUSIONS: HK-related hospitalization is negatively associated with post-discharge RAASi use among patients who may benefit from adherence to RAASi, in both the overall population and in subgroups of patients with CKD, HF, and CKD and/or HF.

SPONSORSHIP: AstraZeneca U.S.

E35 Evaluation of the Impact of Providing Drug-Drug Interaction Information of Statins on Physician Prescribing

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BACKGROUND: In South Korea, the DUR information is given to physicians and pharmacists via a concurrent DUR system when they prescribe or dispense drugs. Hospital and pharmacy computer systems are linked to the DUR system for checking patient`s medication history on a real-time basis including history from other hospitals and pharmacies.

OBJECTIVE: To evaluate the impact of providing drug-drug interaction information of statins by a nationwide drug utilization review (DUR) monitoring system on physician prescribing in South Korea.

METHODS: We used the National Health Insurance Service-National Sample Cohort from 2002 to 2015 which sampled about 1 million subjects. Monthly average number of concomitant prescriptions before and after providing drug-drug interaction information for statins and relative changes were calculated.

RESULTS: According to the 18 statin-interacting drug pairs in the Contraindicated Drug List by MFDS (Ministry of Food and Drug Safety), the interaction information has been provided to medical institutions and pharmacies through DUR system since March 2011. Among them, eight were excluded from the analysis because there was no concomitant prescription before and after March 2011. Monthly average number of concomitant prescriptions before March 2011 was 20.1 per 100,000 people, and it was significantly reduced to 7.0 per 100,000 people after March 2011. The relative change was -65.4% ($P < 0.05$). The co-prescribing rate of every single statin-interacting drug pair was reduced, and 9 of them were statistically significant. Only atorvastatin-itraconazole co-medication was not statistically significant (-35.7%, $P > 0.05$). The total prescription for atorvastatin was increased by 196.3%, and the total prescription for itraconazole was decreased by 14.5%.

CONCLUSIONS: This study showed that providing drug-drug interaction information of statins was effective in reducing contraindicated prescriptions. When assessing changes in medication use, we assessed not only the amount of prescriptions for relevant information, but also the increased use of health care services. In the case of atorvastatin-itraconazole, although the use of atorvastatin increased by 196.3%, the combined use of atorvastatin and itraconazole was reduced by 35.7%. Although not statistically significant, it seems to be also effective in reducing the combined use of atorvastatin-itraconazole. Changes in health care services such as prevalence of disease seem to be an important factor in evaluating the effectiveness of drug information.

SPONSORSHIP: None.

E36 Management of Hyperkalemic Patients in the Inpatient Setting by Hyperkalemia Severity

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BACKGROUND: There is limited real-world evidence on the inpatient (IP) management of hyperkalemia (HK).

OBJECTIVE: To compare the management and post-discharge events between patients with mild vs. moderate/severe HK event during an IP stay.

METHODS: This retrospective study used electronic medical record data from the Research Action for Health Network (2012-2018). Adult patients with a randomly selected HK-related IP stay (IP stay with ≥ 1 elevated potassium level (> 5.0 mEq/L)) were included. Patient characteristics, potassium levels, andtreatments were compared during the 6 months prior to and during the IP stay between patients with mild HK (> 5.0-5.5 mEq/L) and moderate/severe HK (> 5.5 mEq/L). After discharge, 30-day all-cause and HK-related IP admissions (admissions with an elevated potassium level), and 30-day HK recurrence (elevated potassium level) were compared using Chi-square and t-tests.

RESULTS: Among the 33,579 patients with an HK-related IP stay, 23,432 (70%) had mild HK and 10,147 (30%) had moderate/severe HK, with mild patients being slightly older than moderate/severe patients (64.7 vs. 63.4 years, IP use (22% vs. 23%). During the IP stay, the mean first potassium level was 5.2 vs. 6.1 mEq/L in mild vs. moderate/severe HK patients. The last potassium level during the stay was normalized to ≤ 5 mEq/L in most patients (mild = 88%, moderate/severe = 84%, $P < 0.001$). Moderate/severe HK patients received more

potassium-binding treatments (35% vs. 12%), diuretics (33% vs. 30%), albuterol (18% vs. 4%), calcium (12% vs. 4%), insulin/glucose (20% vs. 3%), sodium bicarbonate (22% vs. 10%), dialysis (17% vs. 10%), and telemetry (40% vs. 28%) during the IP stay than mild HK patients (all $P < 0.001$). Only 0.1% of patients received a potassium-binding treatment at discharge. Moderate/severe HK patients had slightly higher rates of 30-day IP readmission (all-cause: 20% vs. 19%; HK-related: 7% vs. 5%) and 30-day HK recurrence (14% vs. 11%) than mild HK patients (all $P < 0.05$).

CONCLUSIONS: Among patients with HK in the IP setting, potassium levels were successfully normalized in both mild and moderate/severe patients, with moderate/severe HK patients receiving more treatments. About one in five patients were re-hospitalized within 30 days, regardless of HK severity. HK recurrence rates were also similar by HK severity.

SPONSORSHIP: AstraZeneca.

E37 Patiromer and RAAS Inhibitor Utilization in U.S. Veterans with Hyperkalemia

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BACKGROUND: Guideline recommended renin angiotensin aldosterone system (RAAS) inhibitor therapy is imperative for patients (pts) with cardiorenal comorbidities. Patiromer (PAT) is a sodium-free, non-absorbed potassium (K+) binder approved for the treatment of hyperkalemia (HK).

OBJECTIVE: To describe the use of RAAS inhibitors in U.S. Veterans with HK following K+ binder initiation.

METHODS: RAAS inhibitor continuation was evaluated using the VA Corporate Data Warehouse (1/1/16-8/31/18). Among patients with 6 months continuous baseline RAAS inhibitor exposure, the percent of patients continuing a RAAS inhibitor was assessed 1, 3, and 6 months after the first PAT and sodium polystyrene sulfonate (SPS) dispensing (index date). All pts had a baseline K+ ≥5.1 mEq/L and heart failure, diabetes, or chronic kidney disease (CKD). Follow up (FU) began on index date and ended at first censoring event (K+ binder discontinuation or switch, death, end of FU or 6 months post index).

RESULTS: 102 and 4,410 hyperkalemic patients with 6 months of continuous baseline RAAS inhibitor utilization initiated PAT and SPS, respectively. Patient characteristics were (PAT/SPS): mean age 68/71 years, African-American race 27/17%, CKD 98/60%, diabetes 88/84%, heart failure 40/26%, eGFR 24/38 ml/min/1.73 m2, and median K+ 5.7/5.7 mEq/L. The percent of patients continuously exposed to patiromer was 83% (85/102) at 1 month, 31.3% (32/102) at 3 months and 16% (16/102) at 6 months. In these patients, the percent continuing a RAAS inhibitor was 89.4% (76/85) at 1 month, 87.5% (28/32) at 3 months, and 81.3% (13/16) at 6 months. The percent of patients continuously taking SPS was 23% (1,100/4,410) at 1 month, 2.7% (120/4,410) at 3 months and < 1% of patients at 6 months. Of these SPS patients, 92.1% (931/1011) continued a RAAS inhibitor at 1 month, 75% (90/120) at 3 months and 64.9% (24/37) at 6 months.

CONCLUSIONS: Greater than 80% of patients continuously exposed to PAT were maintained on a RAAS inhibitor at all time points (1, 3, and 6 months). In the SPS group, more than 80% of patients continued RAAS inhibitor therapy at 1 month and 65% or greater at 3 and 6 months. This descriptive and hypothesis generating analysis indicates that chronic use of PAT may allow a large percentage of patients to continue RAAS inhibitor therapy up to 6 months. These findings warrant additional investigation as PAT use increases.

SPONSORSHIP: Relypsa.

E39 Real-World Analysis of Disease Burden and Healthcare Utilization Among Medicaid and Commercially Insured Patients Living with Acute Hepatic Porphyria

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BACKGROUND: Acute hepatic porphyria (AHP) refers to a family of rare genetic diseases caused by mutations of enzymes involved in hepatic heme synthesis, with acute intermittent porphyria (AIP) as the most common subtype. These defects cause the accumulation of neurotoxic heme intermediates, aminolevulinic acid (ALA) and porphobilinogen (PBG) and can lead to potentially life-threatening attacks and debilitating chronic symptoms. Real-world data characterizing the economic and humanistic burden of AHP in the United States are lacking, especially in the Medicaid population.

OBJECTIVE: To characterize clinical characteristics, healthcare resource utilization (HCRU), and disease burden associated with AHP in a real-world setting amongst the Medicaid and commercially insured population in the United States.

METHODS: Physicians (n = 45) accepting Medicaid and/or commercial insurance who actively managed or treated AHP patients (with or without recurrent attacks) in the year prior were recruited from 9/2017-10/2017 to complete a chart review and online survey. Information collected included anonymized information on patient demographics, medical history, number of porphyria attacks, severity of patient symptoms, physician familiarity with AHP and diagnostic tests, symptoms important to diagnosis, referral patterns, and treatment preferences.

RESULTS: Of the charts (n = 119) reviewed, 41 were of Medicaid patients (MP; mean age: 42 years; 56% female; 39% African American; 78% with AIP) and 78 of commercially insured patients (CIP; mean age: 40 years; 49% female, 14% African American; 82% with AIP). Unemployment and disability status was 59% in MP and 9% in CIP. Fifty-six percent of MP and 36% of CIP reported limited functioning in activities of daily living requiring some level of assistance, and limited functioning was reported to be primarily due to porphyria in both groups (MP: 78%; PIP: 71%). Mean (SD) number of attacks in the past year was 1.8 (1.3) in MP and 1.6 (1.3) in CIP. The mean (SD) number of hospitalizations in the preceding year was 1.5 (1.3) in MP and 0.8 (1.0) in CIP. In both patient groups, 50% of attacks resulting in hospitalization required hemin treatment. In between attacks, abdominal pain and fatigue were the most common chronic symptoms reported by both MP and CIP.

CONCLUSIONS: Both MP and CIP experienced acute and chronic disease manifestations leading to substantial HCRU and disability. New therapeutic options are needed to address the unmet needs of AHP patients.

SPONSORSHIP: Alnylam Pharmaceuticals.

E40 Cystic Fibrosis Transmembrane Conductance Regulator Modulators: Current and Future Utilization and Spend Among 15 Million Commercial Lives

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BACKGROUND: Cystic fibrosis (CF) is a genetic disease affecting 30,000 people in the U.S. Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are indicated for 60% of CF mutations. There are three FDA approved agents with Symdeko approved most recently in Feb 2018. Kalydeco (ivacaftor, IVA) treats 14%, Orkambi (lumacaftor/ivacaftor, LUM/IVA) treats 36%, and Symdeko (tezacaftor/ivacaftor, TEZ/IVA) treats 27% of mutations, with some overlap. Annual costs approach $300,000 per member. Additional indications and a triple combination product are anticipated by the end of 2019. Little is known about real-world utilization, spend, and discontinuation rates.

OBJECTIVE: To examine current CF prevalence, modulator utilization and spend, discontinuation rates, and forecast future spend among commercially insured members.

METHODS: Integrated pharmacy and medical claims data among 15 million commercial members were queried between May 2017 and Apr 2018 to identify: (a) CF prevalence: members with 2 or more ICD-10 codes (E84.xx) in any field at least 30 days apart, or (b) members with a modulator pharmacy claim. To assess index modulator use and discontinuation, defined as greater than a 45-day gap in modulator therapy, we assessed a subset of modulator utilizers continuously enrolled 6 months before (pre-period) and after (post-period) the first claim (index). Modulator total paid per member per month (PMPM) cost trend from January 2015 through November 2018 and current treatment rate were used to forecast future utilization and spend.

RESULTS: 2,147 (14 per 100,000) CF members were identified, an estimated 1,288 (60%) CF patients are eligible to receive a modulator and 695 had a modulator claim, resulting in the current treatment rate among eligible members at 54%. 457 of 695 (66%) of members with a modulator claim were continuously enrolled with an index claim for IVA (26.9%), LUM/IVA (66.5%), or TEZ/IVA (6.6%). 65 of 457 (14%) discontinued modulator therapy. Modulator PMPM has increased from $0.08 in January 2015 to $0.96 in November 2018. PMPM for TEZ/IVA in November 2018 was $0.43. Based on utilization trend and current treatment rate, PMPM could reach $1.21 by December 2019. If the treatment rate among eligible members increases to 100%, PMPM could reach $2.07 by December 2019.

CONCLUSIONS: CF has a low prevalence; however, PMPM has dramatically increased with new modulator approvals and could double by the end of 2019. These costs will likely result in increased premiums for members. Continued enhancement of modulator clinical programs along with outcomes analyses are necessary to ensure the class is priced to value.

SPONSORSHIP: Prime Therapeutics.

E41 Adult Patient Perspectives While Traversing the Healthcare System: Research in Primary Mitochondrial Myopathy

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BACKGROUND: Primary mitochondrial myopathies (PMMs) are genetic disorders that impair normal mitochondrial function, ultimately affecting central and peripheral neurologic function, as well as musculoskeletal, gastrointestinal, and cardiovascular function. Because of skeletal muscle respiratory chain dysfunction, patients experience symptoms, such as muscle weakness. This leads to exercise intolerance and less physical activity ultimately compromising activities of daily living.

OBJECTIVE: To obtain a broader understanding of the adult PMM pathway to diagnosis to identify methods for improving patient lives through better access to care.

METHODS: Adult patients (N=29; aged 21-64 yrs) with a formal diagnosis of PMM entered into a 3-part study (web-assisted telephone interviews, symptom questionnaires and a 7-day journal) related to their experience prior to diagnosis and thereafter to the present. Patient average ages at the time of diagnosis were females (41 yrs) and males (36 yrs).

RESULTS: The 3 most common symptoms experienced by females (n=21) and males (n=8) were fatigue (90% and 88%, respectively), muscle pain (86% and 63%, respectively), and muscle weakness (86% and 75%, respectively) followed distantly by shortness of breath and eye problems. The majority of symptoms were severe to very severe in intensity; nerve pain was severe to very severe in females, and moderate in males. Neurologic symptoms (balance issues, dizziness/lightheadedness, and visual disturbance/blurry vision), were also noted. Patients reported there was no clear path to a PMM diagnosis; the avg length of time until diagnosis across genders was ~17 yrs, seeing an avg of 8 HCPs before diagnosis. The primary provider of care for PMM patients were neurologists. PMM patients often see other MDs more regularly (every 3 to 6 mo) depending on their health issues; although the referral process may take months. Patients report using physical therapy; however, issues with insurance coverage remain problematic. Patient organizations (MitoAction and UMDF) are also utilized.

CONCLUSIONS: New insights into the adult patient journey identified the most prominent symptoms and reinforced the need for a more timely diagnosis of PMM. PMM also takes an emotional toll on patients; signs of compensated depression, with underlying despair, may be present. In consideration of their physical, social, emotional and financial concerns, the future for PMM patients is fraught with worry, although the potential of a PMM treatment and more education raises hopes and improves their QoL.

SPONSORSHIP: Stealth BioTherapeutics.

E42 Barth Registry and Repository: Summary of Findings and Key Points for Moving Forward

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BACKGROUND: Barth syndrome (BTHS) is a rare X-linked genetic disorder caused by defects in the tafazzin gene (TAZ) on chromosome Xq28. Clinical features include early-onset cardiomyopathy, skeletal muscle myopathy, growth delays and neutropenia. The BTHS Foundation created the BTHS Registry and Repository (BRR) to accumulate global information to aid researchers.

OBJECTIVE: To conduct an analysis on the available BRR data captured through May 2018, in an effort to identify aggregate trends and increase the understanding of the BTHS participants.

METHODS: BTHS patients (N=82) and/or their caregivers responded to a profile survey to capture specific, categorized information regarding patient diagnosis and symptoms, disease management trends, and family history.

RESULTS: Approximately 90% of individuals with BTHS experienced symptoms at ≤1 year of age; however, only 45% of patients reported having received a formal diagnosis by the same age. Genetic testing to confirm a defect in tafazzin provided a definitive diagnosis in >80% of respondents. Delays in neurological and developmental capacities were the first recognized symptoms and included delays in motor development (i.e., learning to walk; 66.2%), and difficulty with physical activities such as running or rising from the floor (54.9%). Almost all patients and caregivers reported having largely sought treatment from pediatric specialty physicians (pediatric cardiologists for cardiomyopathy/heart failure), pediatricians, hematologists and nutritionists. Pediatric cardiologists were first health providers to address symptoms in 42/82 (51%) of patients; pediatricians in 15 patients (18%). Feeding difficulties were identified in 50% of patients.

CONCLUSIONS: The BTHS Registry and Repository has provided valuable insights into the diagnosis, care, and management of patients with BTHS. Although symptom onset in patients occurs early, delays in achieving a formal diagnosis are typical. Cardiomyopathy and feeding issues are the most identifiable symptoms necessitating frequent consults with pediatric cardiologists, pediatricians, and/or nutritionists/dieticians. The compilation of BRR data may potentially improve the lives of patients with BTHS by allowing researchers and clinicians to tailor treatment approaches to this patient population.

SPONSORSHIP: Stealth BioTherapeutics.

E43 Characterizing Treatment Experience Among Patients with Transthyretin Amyloidosis

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BACKGROUND: Transthyretin amyloidosis (ATTR) is a rare, systemic, progressive and fatal condition resulting from amyloid deposits of misfolded transthyretin proteins in peripheral nerves and organs. As new therapies emerge to treat the symptoms of ATTR amyloidosis, little is known about patients' experience and satisfaction across different therapies.

OBJECTIVE: To examine the treatment tolerability, hospitalizations, and satisfaction experienced by patients with ATTR amyloidosis.

METHODS: Adult patients with ATTR amyloidosis were enrolled in an online longitudinal observational study (n = 83). Survey items assessed patients' current treatment regimens; ability to tolerate their current treatment; hospitalizations due to treatment side effects; and current treatment satisfaction. Patients characterized their treatment tolerability using a single item, 4-point scale, and any treatment-related hospitalizations with a single "Yes/No" item. Treatment satisfaction was assessed using the Treatment Satisfaction Questionnaire for Medication (TSQMvII), an 11-item patient-reported instrument comprised of four domain scores: Side Effects, Effectiveness, Convenience, and Global Satisfaction; all scores range from 0 to 100, with higher scores representing more satisfaction. Responses for all outcomes were summarized descriptively by treatment.

RESULTS: Approximately 82% of patients were currently receiving treatment for their ATTR amyloidosis (n = 68). The 4 most prevalent treatments were: inotersen (n = 8), patisiran (n = 14), diflunisal (n = 25), and doxycycline + tauroursodeoxycholic acid (n = 11). Treatment duration was 0.91 to 2.8 years. Among patients receiving these treatments, tolerability was high (≥ 73% of patients reported they tolerated their current treatment "very well"). Treatment-related hospitalizations were uncommon with only 2 patients reporting a diflunisal-related hospitalization and 1 patient reporting a patisiran-related hospitalization. Patients receiving diflunisal reported high satisfaction with their treatment in terms of Side Effects (mean score = 94.1) and Convenience (75.2); whereas patients receiving inotersen reported high satisfaction in their treatment's Effectiveness (69.8) and Convenience (77.78). Across all treatments, patients receiving inotersen reported the highest Global Satisfaction (82.3); however, the ability to statistically compare the scores was limited by small sample sizes.

CONCLUSIONS: Patient treatment experience for available ATTR therapies showed high levels of tolerability and low incidence of hospitalizations. Overall, treatment satisfaction was highest with inotersen.

SPONSORSHIP: Akcea Therapeutics.

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

F1 Prevalence of Antipsychotic Prescribing Errors for Elderly Patients Based on Medicare Claims Data

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BACKGROUND: By the year 2060, it is projected that 25% of the U.S. population will be over the age of 65. This increase is expected to bring with it an increase in the frequency of neurological disorders, such as Alzheimer's, that have the ability to cause behavioral disturbances. While antipsychotics have been shown to aid with suppression of behavioral disturbances in these patients, their use is not recommended by the BEERS criteria due to an increased risk of stroke and mortality.

OBJECTIVE: To investigate the prevalence of inappropriate antipsychotic prescribing in elderly Medicare patients.

METHODS: Inappropriate antipsychotic prescribing was defined as an instance where either an ICD code was not present or another ICD code not consistent with a diagnosis of schizophrenia, bipolar disorder, or short-term therapy for chemotherapy-induced nausea and vomiting. Prevalence of inappropriate prescribing was evaluated via 2015 data from the Medicare Current Beneficiaries Survey (MCBS). Patient encounters where the patient was 65 years of age of greater and at least one antipsychotic medication was prescribed were extracted, and data regarding patient diagnosis was analyzed via chi-squared test for categorical variables and two-sample t-test for continuous variables.

RESULTS: It was found that only 0.53% (167 cases) of evaluated claims has a diagnosis consistent with appropriate use, while 99.47% of cases were considered to indicate inappropriate use. Patients prescribed antipsychotics inappropriately were more likely to be white (89.62% vs. 80.24%, $P = 0.000$) and female (70.39% vs. 53.89%, $P = 0.000$). The mean age of patients prescribed psychotherapeutic medication inappropriately was 78.7 years (95% CI: 78.6-78.8), about 6 years older than the average age of patients who were billed with appropriate ICD codes ($P = 0.0000$). For the encounters for which the specialty of the prescribing doctor was recorded (n = 12,773), medical doctors were responsible for 71.51% of claims without an ICD code indicating appropriate use (n = 9,057) while psychologists were only responsible for 4.22% of claims (n = 213).

CONCLUSIONS: Inappropriate prescribing of antipsychotics in the elderly remains a significant issue in the health care community despite the availability of resources that recommend against the use of these agents in this patient population.

SPONSORSHIP: Ferris State University Office of Research and Sponsored Programs.

F2 Quality of Life in Adult Outpatients with Opioid Use Disorder Treated with Long-Acting Subcutaneous Injection Buprenorphine Depot: Results from an Open-Label Multicenter Clinical Trial

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BACKGROUND: Depot partial agonist treatments for opioid use disorder (OUD) have emerged with potential to improve outcomes while reducing risks of opioid misuse and diversion. Given the implications

of this long-acting modality on patient monitoring and follow-up, understanding the relationships between traditional clinical endpoints (e.g., relapse rate) and longer-term, patient-focused endpoints such as quality of life (QOL) is critical.

OBJECTIVE: To assess the relationship between treatment response and (QOL) among OUD patients receiving long-acting subcutaneous injection buprenorphine depot (CAM2038).

METHODS: Investigational CAM2038 was evaluated in a 48-week, Phase 3, open-label clinical trial (NCT02672111) for adult outpatients with moderate-severe OUD. In this post hoc analysis, patients were categorized as "high responders" (≤50% months with illicit opioid use) or "low responders" (>50% months with illicit opioid use). Illicit opioid use was indicated by any urine toxicology test positive for illicit opioids or self-reported illicit use of opioids within a given month. QOL was assessed monthly beginning in Month 7 with the EQ-5D-5L: a validated, patient-reported outcome measure that evaluates QOL in 5 domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each with 5 levels of functioning ranging from 1 (no problems) to 5 (extreme problems). Quality-adjusted life-years simultaneously convey the quality and duration of life, and were generated based on utility index values derived from the domain scores. The EQ-5D-5L also included a visual analog scale (VAS), which ranges from 0 (worst health) to 100 (best health). Parametric and non-parametric methods analyzed the impact of treatment response on QOL among the full-exposure safety population.

RESULTS: Patients (N=156) were: 61% male, 88% white/Caucasian, median age 41 (±9.9) years, and 59% primarily heroin abusers. High responders (77%; n=120) accumulated significantly more QALYs over 6 months (+12.2%; 0.45 vs. 0.40, P<0.05). VAS values increased overall (81.1 to 83.8, +3.3%): moreso for high responders (+4.3% vs. +0.3%), but the difference was not significant. A similar trend was observed for the individual domain scores.

CONCLUSIONS: Significantly more QALYs in the high responder group demonstrated a meaningful link between objective treatment response and QOL. Domain-level and VAS evidence was inconclusive, perhaps due to key limitations of this study: lack of a true baseline QOL measurement and unequal administration of the EQ-5D-5L across time points.

SPONSORSHIP: Braeburn.

F3 Impact of Abuse-Deterrent Formulation Opioid Utilization on Healthcare Resource Use Among Managed Medicaid Patients

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BACKGROUND: Limited evidence exists regarding the impact of abuse-deterrent formulation (ADF) opioid utilization on health care resource use in real world setting.

OBJECTIVE: To compare rates of opioid abuse, healthcare resource use and costs between managed Medicaid patients taking ADF extended-release (ER) opioids and non-ADF ER opioids.

METHODS: Retrospective analysis was performed on claims data from managed Medicaid patients in Florida and Tennessee. Patients were included if they had at least one prescription (Rx) claim for an ER opioid anytime between 9/1/2010 and 9/30/2016 and were continuously enrolled for at least 180 days before and after the index ER opioid Rx. Patients with a prior diagnosis of opioid abuse before index Rx were excluded. Patients were assigned to the ADF and non-ADF cohort depending on their index Rx. Patients who switched between ADF and non-ADF ER opioids were excluded. Proportion of patients with

opioid abuse diagnosis; all-cause and opioid abuse related hospitalization and emergency department (ED) visits; and all-cause health care costs during 6 months after index ER opioid Rx were assessed. Results were adjusted using the CMS hierarchical condition categories score, calculated based on comorbidities before index ER opioid Rx.

RESULTS: Data from 12,519 patients (n=1,247 for ADF and 11,272 for non-ADF) [Mean (SD) age=48.77 (10.75) years; 53.43% females] were analyzed. Adjusted rate of opioid abuse diagnosis in the post-index period was 5.36% for the ADF cohort vs. 6.74% for non-ADF cohort (P<0.05). Post-index health care resource utilization rates were consistently lower for ADF than non-ADF: all-cause hospitalization (7.76% vs. 12.66%), opioid abuse related hospitalization (1.46% vs. 2.21%), all-cause ED visit (32.48% vs. 37.53%), opioid abuse related ED visit (0.34 vs. 0.55%; all adjusted P-values <0.05). Increase in pharmacy cost [mean (SD)=$3,753 (6,613) for ADF vs. $1,942 (4,228) for non-ADF, adjusted P<0.0001] was offset by medical cost reduction [mean (SD)=$4,887 (11,117) for ADF vs. $6,845 (14,510) for non-ADF, adjusted P=0.016]. There was no statistically significant difference in total all-cause healthcare costs [mean(SD)=$8,769 (14,438) for ADF vs. $8,930 (16,375) for non-ADF, adjusted P>0.05].

CONCLUSIONS: Use of ADF opioids was associated with lower rates of opioid abuse, healthcare utilization, and medical costs. Increased access to these products may present an opportunity to combat rising rates of opioid abuse and overdose.

SPONSORSHIP: Daiichi Sankyo.

F15 Reducing Psychiatric Medical Costs: Choice of Antipsychotics Matters

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BACKGROUND: Brexpiprazole is an oral atypical antipsychotic (OAA) for treatment of schizophrenia. This is the first real-world evidence study comparing the health economic impact of brexpiprazole and other U.S. FDA-approved OAAs.

OBJECTIVE: To compare psychiatric medical costs in adult patients with schizophrenia newly treated with brexpiprazole vs. other OAAs in a real-world setting.

METHODS: This retrospective cohort study analyzed data from: (a) Truven Health MarketScan Commercial, Medicare Supplemental, and Multi-State Medicaid Databases and (b) De-identified Optum Clinformatics Datamart. Adult patients were identified if they had schizophrenia and initiated either brexpiprazole or another OAA during the study identification period [7/1/15-9/30/16 for MarketScan Commercial and Medicare Supplemental; 7/1/15-6/30/16 MarketScan Medicaid; 7/1/15-9/30/16 Optum] and had ≥12 months of continuous enrollment before (baseline) and after (follow-up) the first treatment date. A linear regression model was conducted to test association between treatment group (brexpiprazole vs. another individual OAA) and psychiatric medical costs (total inpatient and outpatient service costs, as distinct from pharmacy costs) during follow-up, adjusting for baseline demographic and clinical characteristics.

RESULTS: The final study sample consisted of 6,254 patients with schizophrenia: 176 initiated brexpiprazole; 391 ziprasidone; 453 paliperidone; 523 lurasidone; 786 aripiprazole; 1,234 quetiapine; 1,264 olanzapine; and 1,427 risperidone. Controlling for baseline differences, brexpiprazole users had lowest mean psychiatric medical costs [$12,119 (95% confidence interval [CI]: $7,381-$16,857), P=0.002] among all OAA users. Using brexpiprazole as the reference

group, paliperidone and olanzapine users had $7,438 (95% CI: $1,892-$2,985; $P = 0.009$) and $6,590 ($1,527-$11,653; $P = 0.011$) higher psychiatric medical costs, respectively. Psychiatric medical cost was not statistically significantly lower for brexpiprazole than the remaining individual OAAs.

CONCLUSIONS: Initiators of brexpiprazole had lower psychiatric medical costs than paliperidone and olanzapine initiators. While treatment decisions are driven by a number of factors (e.g., clinical circumstances and drug costs), choice of OAA may affect healthcare costs. Payers may want to assess differences within their own data when making formulary decisions.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization and Lundbeck.

F16 Early Adoption of the Long-Acting Atypical Antipsychotic Aripiprazole Lauroxil in Schizophrenia Patients: Treatment Patterns, Healthcare Utilization, and Costs

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BACKGROUND: Aripiprazole lauroxil (AL) is a long-acting injectable (LAI) antipsychotic that was approved for the treatment of schizophrenia in the U.S. in October 2015. Real world resource use and costs associated with the use of AL has yet to be examined.

OBJECTIVE: To evaluate treatment patterns and changes in healthcare resource use (HCRU) and costs after AL initiation.

METHODS: We conducted a retrospective cohort study using the MarketScan Multi-State Medicaid Database. The study cohort included adults (18+ years) initiating therapy with AL between 10/5/2015 and 6/30/2017 with >1 claim for schizophrenia in the year prior to initiation and continuous enrollment during the study period. The index date was defined as the date of the first claim for AL. Descriptive analyses were conducted on treatment patterns, HCRU, and costs. Changes in HCRU and costs between baseline (6 months pre-index) and follow-up (6 months post-index) were assessed using two-sided Paired t-test or Mann-Whitney tests.

RESULTS: The study cohort (n = 485) had a mean age of 35.3 years and 58.1% were male. Compared with the 6 month pre-index period, during the 6 months after AL initiation, patients had fewer all-cause inpatient admissions (0.64 vs. 0.49, $P = 0.017$) and higher numbers of prescription fills (32.3 vs. 36.0, $P < 0.0001$). Changes in outpatient services, including ER visits, were not statistically significant. Patients initiated on AL had lower inpatient costs ($6,121 vs. $3,284, $P = 0.036$) in the 6-month post-index period compared to the pre-period, and higher medication costs ($5,443 vs. $9,565, $P < 0.0001$). Outpatient costs were not significantly different ($7,039 vs. $7,521, $P = 0.109$). Patients initiated on AL had no change in total health care costs between the pre- and post-index periods ($18,603 vs. $20,370, $P = 0.215$).

CONCLUSIONS: Patients with schizophrenia had lower inpatient costs and higher pharmacy costs in the 6-month period following initiation with aripiprazole lauroxil relative to the 6-month period prior to initiation, resulting in no difference in total health care costs.

SPONSORSHIP: Alkermes.

F17 The Cost-Effectiveness of PERSERIS: A Once-Monthly Long-Acting Injectable Antipsychotic in Patients with Schizophrenia

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BACKGROUND: PERSERIS a once-monthly extended-release injectable risperidone in the ATRIGEL delivery system was recently approved by the U.S. FDA for subcutaneous (SC) use in adults with schizophrenia.

OBJECTIVE: To evaluate the cost-effectiveness of SC risperidone.

METHODS: A 2-stage, 1-year, discrete-event Monte Carlo simulation model was developed to estimate total annual healthcare cost. At the beginning of Stage 1 (duration 2 months), each simulated patient was randomised to treatment with SC risperidone or 1 of 4 other long-acting injectable (LAI) atypical anti-psychotics. At the end of Stage 1, each LAI's treatment effectiveness (via Positive and Negative Syndrome Scale [PANSS] total score), total discontinuation rate, and discontinuation rate due to lack of clinical efficacy (LOE) were simulated. Possible outcomes were: (a) patient responded to initial LAI and progressed to maintenance therapy, (b) patient discontinued therapy due to LOE, or (c) patient discontinued therapy for other reasons. For patients not discontinuing initial treatment at the end of Stage 1, Stage 2 (duration 10 months) consisted of maintenance therapy with the initial LAI. At the end of Stage 2, effectiveness and discontinuation rates were simulated. Patients discontinuing initial LAI were assigned to another LAI, at the beginning of Stage 2. Treatment effect, discontinuation rates, and costs were then simulated. Paliperidone palmitate (PPIM) was selected as the primary comparator. Effectiveness and discontinuation rates were derived from published clinical trials. Utilities were based on SC risperidone trial EQ-5D and PANSS data, and disutility due to relapse was based on published research. Cost estimates were based on publicly available data. Primary economic endpoint was quality-adjusted life years (QALY).

RESULTS: Compared with PPIM, SC risperidone was associated with lower average total annual cost of treatment ($29,650 vs. $32,784) and lower average cost per QALY ($55,580 vs. $78,124).) Average cost per QALY was lower than LAI comparators (range $58,578 to $78,124). Differences were driven primarily by lower rates of discontinuation due to LOE over 1 full year of treatment (1.5% for SC risperidone vs. 4.1% to 7.8% for other LAIs). Sensitivity analyses using higher discontinuation rates for SC risperidone, supported the main findings.

CONCLUSIONS: SC risperidone was associated with lower cost per QALY than were PP1M and other LAIs. The lower cost per QALY was driven primarily by lower rates of discontinuation due to LOE.

SPONSORSHIP: Indivior.

F18 Real-World Outcomes Among Veterans Severely Affected by Schizophrenia Who Transitioned from Oral Risperidone or Paliperidone to Once-Monthly Paliperidone Palmitate

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BACKGROUND: Once-monthlypaliperidone palmitate (PP1M) has been associated with a reduction in hospitalizations and medical costs compared to oral atypical antipsychotics. Schizophrenia patients with a hospital admission may have more severe symptoms, poor disease management (i.e. non-adherence), and are at risk for readmission.

OBJECTIVE: To compare treatment patterns, healthcare resource utilization (HRU) and costs during the 12-months pre- and post-transition

to PP1M among U.S. veterans diagnosed with schizophrenia with ≥1 hospitalization.

METHODS: Patients with schizophrenia (aged ≥ 18 years) who initiated oral risperidone or paliperidone (ris/pali) and directly transitioned to PP1M during the identification period (January 1, 2015-March 31, 2017) were included in the study. The first PP1M transition date was identified as the index date. Patients were required to have had ≥ 1 all-cause inpatient stay, continuous health plan eligibility for 12 months pre- and post-PP1M transition, and no PP1M use in the pre-PP1M transition period. Outcomes were compared using the Wilcoxon-signed rank and McNemar's test, as appropriate.

RESULTS: A total of 319 patients (mean age [standard deviation]: 51.6 [14.2] years) were included in the study. Among those, the mean proportion of days covered (PDC) for antipsychotics was significantly lower in the pre- compared to the post-PP1M period (0.5 vs. 0.7, $P<0.0001$). Compared to the pre-PP1M period, the average all-cause inpatient length of stay was significantly lower during the post-PP1M period (43.4 vs. 18.3 days, $P<0.0001$), and so was the average number of inpatient stays (3.5 vs. 1.4, $P<0.0001$). The pre-PPIM period included significantly higher all-cause inpatient ($64,702 vs. $26,147), lower outpatient ($23,215 vs. $30,800), lower pharmacy ($3,263 vs. $12,159), higher total medical ($87,917 vs. $56,947), and higher total costs ($91,181 vs. $69,106)—all $P<0.0001$ compared to the post-PP1M transition.

CONCLUSIONS: Veterans diagnosed with schizophrenia with at least one hospital stay who transitioned from ris/pali to PP1M treatment had lower all-cause inpatient utilization, inpatient costs, medical costs, and total costs during the post-PP1M transition. Transition to PP1M among U.S. veterans diagnosed with schizophrenia with at least one hospitalization may lead to improved clinical outcomes resulting in potential cost savings.

SPONSORSHIP: Janssen Scientific Affairs.

F19 Lower Medical Cost Associated with Aripiprazole Once-Monthly Compared to Oral Atypical Antipsychotics in Patients with Schizophrenia

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BACKGROUND: Aripiprazole once-monthly (AOM 400) is one of the long-acting injectable atypical antipsychotics approved for acute and maintenance treatment of adult patients with schizophrenia. Limited real-world data exists comparing the economic impact of AOM 400 and oral atypical antipsychotics (OAAs).

OBJECTIVE: To compare medical and hospitalization costs in adult patients with schizophrenia newly initiating treatment with AOM 400 vs. OAAs.

METHODS: This retrospective cohort study analyzed data from: (a) Truven Health MarketScan Commercial, Medicare Supplemental, and Multi-State Medicaid Databases and (b) De-identified Optum Clinformatics Datamart. Adult patients were identified if they had schizophrenia and initiated either AOM 400 or an OAA during the study identification (ID) period (which varied by database: 01/01/14-09/30/16 for MarketScan Commercial and Medicare Supplemental; 01/01/14-06/30/16 for MarketScan Medicaid; 07/01/15-09/30/16 for Optum) and had at least 12 months of continuous enrollment before (baseline) and after (follow-up) the first date of treatment. In addition to univariate comparisons, a linear regression model and a two-part model were conducted to estimate all-cause medical costs and

all-cause hospitalization costs, respectively, adjusting for baseline patient demographic and clinical characteristics.

RESULTS: The final AOM 400 cohort included 361 individuals, and the OAA cohort included 3,737. AOM 400 users had lower unadjusted mean (SD) all-cause medical costs compared with OAA users [$26,708 ($35,800) vs. $36,530 ($53,642); $P<0.001$], as well as lower costs of hospitalizations [$10,834 ($22,896) vs. $13,722 ($34,855); $P<0.001$]. After adjusting for baseline differences, mean (95% confidence interval) all-cause medical costs remained significantly lower in AOM 400 users than OAA users [$29,639 (24,483-34,795) vs. $36,249 (34,666-37,831); $P=0.017$]. There was no statistically significant difference in adjusted all-cause hospitalization costs between AOM 400 and OAA users.

CONCLUSIONS: In a real-world setting, adult patients with schizophrenia who initiated AOM 400 had lower all-cause medical costs than OAA initiators. Payers may wish to assess their own costs when assessing the antipsychotic class for formulary placement.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization and Lundbeck.

F20 The Budget Impact of PERSERIS: A Once-Monthly Long-Acting Injectable Antipsychotic in Patients with Schizophrenia

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BACKGROUND: PERSERIS a once-monthly extended-release injectable risperidone in the ATRIGEL delivery system was recently approved by the U.S. FDA for subcutaneous (SC) use in adults with schizophrenia.

OBJECTIVE: To estimate the expected impact on expenditure of a health care system after adoption of SC risperidone.

METHODS: A prevalence-based budget impact model was developed from a U.S. payer perspective. The model assumed 500,000 covered members, 0.5% prevalence, and included only direct healthcare costs that would result from medical and pharmacy claims. Efficacy data for SC risperidone and 4 other long-acting injectable (LAI) atypical antipsychotic comparators were derived from Phase III trials. Direct medical costs and event rates (LAI, oral supplementation, office visits, injection procedures, relapse due to lack of clinical efficacy, and serious medication-related adverse events) were obtained from manufacturer data, publicly available data, and published research. Total annual healthcare cost estimates were derived from a 2 stage, discrete-event Monte Carlo simulation model. Analyses assessed the budget impact of SC risperidone under different levels of market share versus the "status quo" baseline which did not include SC risperidone. Baseline market share estimates were taken from MarketScan Commercial and Medicaid Databases.

RESULTS: The addition of SC risperidone to marketed and covered LAIs was associated with a reduction in total annual cost of treating adult patients with schizophrenia. At the lowest estimated market share of 2%, estimated budget impact for 1 year was a cost reduction of -$210,673, though the upper bound of the interquartile range (IQR) indicated a slight, positive budget impact of $40,729. At market share of 4% and above the estimated budget impact included cost reductions only, with expected budget impact of -$349,725 [IQR: -$362,714 to -$43,422]. Sensitivity analyses suggest that the primary driver of total budget impact was the per-dose cost of SC risperidone.

CONCLUSIONS: SC risperidone was associated with a slight reduction in direct cost of LAI treatment for adults with schizophrenia. Results suggest that as market share increased, cost reductions were greater. The budget impact was sensitive to parameter changes due to the low prevalence of schizophrenia and the high variability of individual

healthcare costs. Budget impact analysis by market share suggest greater reductions in total annual direct medical cost of LAI treatment as SC risperidone market share increases.

SPONSORSHIP: Indivior.

F21 Projecting the Long-Term Economic Impact of Once-Monthly Paliperidone Palmitate Versus Oral Atypical Antipsychotics in Medicaid Patients with Schizophrenia

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BACKGROUND: A prior decision-tree model demonstrated that over 12 months, pharmacy costs associated with switching patients from oral atypical antipsychotics (OAAs) to once-monthly paliperidone palmitate (PP1M) were offset by reduced relapse rates and schizophrenia-related healthcare costs, with earlier use of PP1M projected to generate greater cost savings.

OBJECTIVE: To extend the previous model to a 24- and 36-month timeframe in order to project the long-term economic impact when a proportion of non-adherent patients with a recent relapse switch from OAAs to PP1M.

METHODS: A 36-month decision-tree model with twelve 3-month cycles was developed from a Medicaid perspective. The population was non-adherent OAA patients with a recent relapse. At equal adherence, relapse risk was equal between PP1M and OAAs, and OAA patients were non-adherent until treatment switch. Event rates and cost inputs were based on literature and rates stayed constant over time. Outcomes included number of relapses, pharmacy costs, and relapse costs at years 1, 2, and 3.

RESULTS: Based on a hypothetical health plan population of 1 million members, 3,037 OAA patients were non-adherent with a recent relapse. Compared to continuing OAAs, switching 5% of patients (n = 152) to PP1M resulted in net cost savings of $674,975, $723,298, and $562,310 at the plan-level, $4,445, $4,764, and $3,703 per patient switched per year, and $0.0562, $0.0603, and $0.0469 per member per month in years 1, 2, and 3, respectively, resulting in total plan-level savings of > $1.9M over 3 years. A total of 221 relapses were avoided (year 1: 92; year 2: 72; year 3: 57). In years 1, 2, and 3, respectively, total annual plan-level schizophrenia-related costs were $114.1M, $107.2M, and $105.8M when all patients switched to PP1M before any subsequent relapse (n = 3,037), $123.4M, $109.6M, and $106.7M when patients switched to PP1M after a first subsequent relapse (n = 2,631), and $127.6M, $121.6M, and $117.0M when all patients continued OAAs. The cost per patient switched to PP1M was lower when all patients received PP1M before a subsequent relapse vs. after their first subsequent relapse at all years (year 1: $37,559 vs. $45,089; year 2: $35,288 vs. $36,321; year 3: $34,826 vs. $35,155).

CONCLUSIONS: Extending the model to 24- and 36-months showed that pharmacy costs associated with switching non-adherent OAA patients with a recent relapse to PP1M were offset by reduced relapse rates and healthcare costs at years 1, 2, and 3, with earlier use of PP1M resulting in increased cost savings.

SPONSORSHIP: Janssen Scientific Affairs.

F23 Healthcare Resource Utilization and Costs Associated with Postpartum Depression: Commercially Insured Households

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BACKGROUND: Postpartum depression (PPD) affects 8-20% of women in the U.S. (varied by state) following childbirth and can result in severe anxiety, agitation, suicidal thoughts, and lack of interest in the newborn.

OBJECTIVE: To quantify the economic burden of PPD that accrues to commercially insured households in the year following childbirth.

METHODS: The OptumHealth Care Solutions administrative claims database was used to identify households of women affected by PPD and matched comparison households of women not identified as suffering from PPD with similar baseline health, demographic characteristics, and no apparent prior history of depression. Study outcomes included direct total all-cause medical and pharmaceutical costs, and number of outpatient visits at the household level and stratified by household member. These costs were evaluated for the 6-month period following the PPD-identifican date and during the first year following childbirth. Data extracted for this study covered the period from January 1, 2009, to March 31, 2016.

RESULTS: Within our matched sample, households affected by PPD (N = 7,769) incurred 22% higher mean total all-cause medical and pharmaceutical spending, when compared to their matched non-PPD controls (N = 41,308) during the first year following childbirth ($36,049 vs. $29,448, P < 0.01). Households affected by PPD had an average of 16 more outpatient visits than unaffected households (P < 0.01). Mothers comprised the largest share (> 50%) of total all-cause spending. Mothers affected by PPD had significantly higher annual mean direct total all-cause medical and pharmaceutical spending than their non-PPD controls ($19,611 vs. $15,410, P < 0.01). Total all-cause and PPD-related spending for mothers is driven primarily by medical spending with mothers affected by PPD having an average of 11 more outpatient visits than unaffected mothers (P < 0.01).

CONCLUSIONS: Households affected by PPD incurred higher mean total all-cause medical and pharmaceutical spending during the first year following childbirth, when compared to their matched non-PPD controls, but not all costs are attributable to maternal treatment for PPD. These findings contribute to a better understanding of economic burden associated with PPD and demonstrated costs may extend beyond the patients.

SPONSORSHIP: Sage Therapeutics.

F24 Prevalence and Characteristics of Major Depressive Disorder (MDD)-Related Hospitalizations in Adolescents Diagnosed with MDD

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BACKGROUND: Major depressive disorder (MDD) is a chronic, relapsing, and burdensome disorder that can lead to hospitalization. The prevalence of MDD among adolescents aged 12 to 17 has been rising, with past-year episodes increasing from 9% in 2005 to 13% in 2016. While prevalence and characteristics of MDD-related hospitalizations among adults with MDD have been previously described, less is known about MDD hospitalizations in adolescents with MDD.

OBJECTIVE: To determine the prevalence and characteristics of MDD-related hospitalizations among adolescents with MDD in the United States.

METHODS: This retrospective analysis was conducted using healthcare claims from the Truven MarketScan Research Databases. Adolescents (12-17 years) with a prevalent MDD diagnosis between January 1, 2013 and December 31, 2013 were identified. The prevalence of hospitalizations with a primary diagnosis of MDD and rehospitalization patterns were calculated using patient-level data. Clinical

characteristics, length of stay, and costs of stay associated with MDD-related hospitalizations were analyzed using encounter-level data.

RESULTS: The MarketScan database covered 3,894,464 adolescent lives; 84,832 (2.2%) adolescents had a primary diagnosis of MDD. The prevalence of MDD-related hospitalizations among adolescents with MDD was 14.5% (12,301/84,832). Most hospitalizations for MDD were accompanied by comorbid anxiety (80%) or impulse control, adjustment, or other mental disorders (64%). Nearly half of MDD-related hospitalizations were associated with suicidal ideation or attempt (48%). Median (25th, 75th percentile) length of stay was 5.0 (4, 7) days and mean (SD) cost of stay was $8,367 ($6,863). Rehospitalization was common, with 8% of adolescents readmitted for MDD within 1 month and 22% readmitted within 1 year. Among patients with readmissions within 1 month, the mean time to readmission was 13 days.

CONCLUSIONS: In the U.S., the prevalence of MDD-related hospitalization is high among adolescents with MDD, with admissions associated with long stays and high costs. Readmissions for MDD among adolescents is common, often occurring within 1 month of discharge, which increased healthcare-related costs. Current medications approved to treat MDD have slow onsets, low remission rates, and a high side effect burden. Newer treatments with novel mechanisms that work faster, with proven efficacy in patients with MDD exhibiting suicidal ideation or behavior, may be able to reduce hospitalizations in adolescent patients with MDD.

SPONSORSHIP: Allergan.

F25 Healthcare Use and Associated Cost Among Patients with Treatment-Resistant Depression Across U.S. Payers: A Comprehensive Analysis

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BACKGROUND: Approximately 30% of Major Depressive Disorder (MDD) patients receiving oral antidepressants will develop treatment resistant depression (TRD). In addition to facing clinical burden, previous studies have shown consistent increases in healthcare resource use and costs among patients with TRD.

OBJECTIVE: To review the HRU and associated costs of TRD relative to non-TRD MDD and non-MDD patients across payers and systems: Medicare, Medicaid, commercial, U.S. Veterans Health Administration (VHA) and Integrated Delivery Networks (IDN).

METHODS: Similarly designed claims-based algorithms identified TRD, non-TRD MDD and non-MDD patients in U.S. databases including a 5% Medicare database (01/2012-12/2015), a multi-state Medicaid database (1/2010-3/2017), a database of privately insured employees and dependents (07/2009-03/2015), the U.S. VHA database (04/2014-03/2018), and IDN patients in an Optum Integrated Claims EHR de-identified database (07/2011-06/2017). Across the five studies, patients with a diagnosis of MDD were considered to have TRD if they had two antidepressant treatment regimens (including augmentation therapy) at adequate dose and duration and initiated a third. The index date was defined as the 1st antidepressant claim (TRD and MDD patients) or was randomly imputed (non-MDD patients). In each database, patients with TRD were matched 1:1 to non-TRD MDD and to randomly selected non-MDD patients based on demographic characteristics. Mean per-patient-per year (PPPY) healthcare costs were assessed in each cohort and database post-index.

RESULTS: Overall 32,790 patients with TRD were identified, including 178 (1%) Medicare, 14,170 (43%) Medicaid, 6,411 (20%) commercial, 10,449 (32%) VHA, and 1,582 (5%) patients from IDN setting. Patients with TRD consistently had higher PPPY HRU and costs post-index compared to matched non-TRD MDD and non-MDD patients. Costs in patients with TRD vs. non-TRD MDD and non-MDD were $24,543 vs. $16,059 and $8,058 (Medicare), $16,654 vs. $12,133 and $5,812 (Medicaid), $17,261 vs. $9,790 and $4,782 (commercial plans), $19,268 vs. $12,919 and $5,205 (VHA), and $25,807 vs. $13,701 and $8,500 (IDN) PPPY, respectively.

CONCLUSIONS: Healthcare resource use and costs of MDD are increased compared with other patients and concentrated among those with TRD. These results suggest improved treatment of TRD may result in improved economic outcomes as well as reduced clinical burden.

SPONSORSHIP: Janssen Scientific Affairs.

F26 Assessment Using Claims-Based and Patient-Reported Data to Identify Treatment-Resistant Depression: Implications for Research and Practice

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BACKGROUND: About 30% of persons suffering from Major Depressive Disorder (MDD) fail to respond to evidence-based treatment. This treatment resistant depression (TRD), defined as depression that does not respond to two or more consecutive treatments with two different antidepressant medications, used for sufficient length and at an adequate dose, can be particularly burdensome to patients. To date, studies of TRD have depended on claims-based pharmacy data to define TRD (traditional method). As awareness of the prevalence and impact of depression on populations has grown, NCQA and others have called for increased awareness and systematic screening particularly in managed care organizations. Depression screening tools, such as the Patient Health Questionnaire (PHQ-9), present an opportunity to incorporate patient reported symptoms in the identification of TRD.

OBJECTIVE: To explore the use of PHQ-9 data to refine identification of TRD and compares sample characteristics between those identified with TRD with a traditional approach and those identified with the addition of PHQ-9 data.

METHODS: This analysis is part of a larger case control study using data from the electronic medical records and administrative systems of the Kaiser Permanente Northwest (KPNW). The study includes all KPNW members aged ≥18 with a diagnosis of MDD. We compare TRD patients identified by traditional methods, with those identified with the traditional method plus PHQ-9 data. We describe how the groups differ by demographic, clinical, and treatment characteristics using generalized linear modeling.

RESULTS: Preliminary analyses identified 23,845 individuals using the traditional definition of TRD, 94% had PHQ-9 data. Of those with PHQ-9 data, 81% have ongoing depression symptoms (PHQ-9 scores ≥10). The remaining would be considered to have TRD by the traditional method, but not based on PHQ-9 scores. Significant differences in demographic and clinical characteristics for the subgroups were seen.

CONCLUSIONS: This analysis demonstrates that PHQ-9 data can refine identification of TRD. Using traditional identification of TRD may capture some persons whose depression has remitted, but who may be switching medications for other reasons (e.g., side effects). Refining identification of TRD could improve targeting of treatment to those with continuing depression symptoms despite indicators of adequate treatment. Additionally, use of PHQ-9 data allows researchers to incorporate patient perspectives in the definition of TRD.

SPONSORSHIP: Janssen Scientific Affairs.

F29 Humanistic Burden of Binge Eating Disorder: A Systematic Literature Review

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BACKGROUND: Binge eating disorder (BED) is the most common eating disorder in the U.S.

OBJECTIVE: To assess the humanistic burden of BED.

METHODS: A systematic literature review was conducted. The Embase Database (2014-2018) was searched for English language publications on the humanistic burden of BED among adolescents and adults in USA and EU-5 using NICE guidelines. General HRQoL scales included the Short Form (SF)-12 and -36 (range 0-100, higher scores=better HRQoL), the Yale-Brown Obsessive-Compulsive Scale-Binge Eating (YBOCS-BE; range 0-40, higher scores=greater severity of BED), the Barratt Impulsiveness Scale (BIS; range 0-120, high score=greater impulsiveness), and the Impact of Weight on Quality of Life-Lite (IWQoL-Lite; range 0-100, higher scores=better weight-related QoL). HRQoL scores were weighted by BED sample size for observational studies.

RESULTS: Of the 1,779 records retrieved, 525 full text publications were reviewed and 25 studies (14 randomized trials and 11 observational studies) met the inclusion/exclusion criteria. One observational study found that SF-12 total score was worse among BED patients vs. non-BED controls was 33.8 vs. 39.3 ($P < 0.001$). Mean SF-36 physical component score (PCS) and mental component score (MCS) from five observational studies of BED patients was 42.9 (36.8-45.2) and 42.5 (39.7-48.1), respectively. Only 1 of the 5 observational studies reporting SF-36 scores showed that BED patients experienced significant impairment compared to non-BED controls as reported by PCS (BED 40.3 vs. controls 47.3; $P < 0.01$) and MCS (BED 48.1 vs. controls 52.6; $P < 0.02$). Two of five observational studies showed that SF-36 total score decreased with increasing BED severity as assessed by the DSM-5 criteria. The YBOCS total score from 1 observational study of BED patients was 18.2 and correlated with increased symptom severity (11.7 for mild to 30.7 for severe). The BIS total score from 1 observational study was 72.5 for BED patients vs. 62.6 among obese/overweight patients without BED ($P < 0.001$). Mean IWQoL-Lite total score from 2 observational studies of BED patients was 87.5, one of which reported that BED patients had lower IWQoL-Lite total scores compared to non-BED patients (58.5 vs. 69.3, $P < 0.04$).

CONCLUSIONS: Few observational studies reported on humanistic burden of BED in the past 5 years. HRQoL was more impaired among BED patients with greater disease severity. The limited evidence suggests that further research is warranted to better understand the humanistic burden of BED.

SPONSORSHIP: Sunovion Pharmaceuticals.

F30 Factors Associated with the Healthcare Effectiveness Data and Information Set Follow-Up Measures in Medicaid-Insured Children with Attention-Deficit Hyperactivity Disorder

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BACKGROUND: Initiation rate and continuation and maintenance (C&M) rate are the two important Healthcare Effectiveness Data and Information Set (HEDIS) follow-up care performance measures for Attention-deficit hyperactivity disorder (ADHD) patients.

OBJECTIVE: To assess the factors associated with the C&M Phase follow-up in children with ADHD.

METHODS: A retrospective longitudinal observational study was conducted using 2013-2016 data from a large pediatric Managed Care Plan in Texas that covered more than 400,000 Medicaid enrolled children and adolescents. ADHD Children (aged 6-12 years) who received the ADHD diagnosis (ICD-9-CM code-314.XX or ICD-10 code-F90.9) and an index-prescription for ADHD were considered for the analysis. Initiation and C&M phase follow-up rates were measured as per the HEDIS specifications. A multivariable logistic regression model was performed, using SAS 9.4, to determine the factors associated with children who had C&M phase follow-up.

RESULTS: Among the 8,868 eligible children identified with ADHD diagnosis and prescription, 48.73% (n=4,321) had initiation follow-up. From those who had initiation follow-up, 3,083 children were continuously eligible through the C&M phase i.e. 10 months after the index ADHD prescription. Among which, 14.95% (n=461) of the patients had C&M phase follow-up. Children who had follow-up were significantly different in terms of race/ethnicity, provider specialty, and treatment category. The results of multivariable logistic analysis found that, compared to Caucasian children, Hispanic children were 66% (Odds ratio [OR]: 0.34, 95% confidence interval [CI]: 0.26-0.44) and African American children 67% (OR: 0.33, 95% CI: 0.25-0.45) less likely to fulfill C&M phase follow-up criteria, respectively. Further, patients who consulted psychiatrists were 1.78 times more likely to fulfill C&M phase follow-up criteria than those who consulted primary care physicians only (OR: 1.78, 95% CI: 1.41-2.24). Further, children who received combination therapy were 8 times more likely to fulfill C&M phase follow-up criteria than those who received monotherapy (OR: 8.20, 95% CI: 6.17-10.90).

CONCLUSIONS: Receiving combination therapy and consulting psychiatrist are positively associated with C&M phase follow-up. Whereas, Hispanic and African American race/ethnicity was negatively associated with C&M phase follow-up.

SPONSORSHIP: None.

F36 Multiple Stakeholder Evaluation of Issues, Barriers, and Needs for Substance Use Disorder in the United States

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BACKGROUND: Since 2000, more than 300,000 Americans have died from opioid overdose. In 2017, the opioid crisis was declared a public health emergency, but substantial unmet needs remain for patients with substance use disorder (SUD). In an effort to promote best practices for improving addiction services, the Academy of Managed Care Pharmacy's (AMCP) Addiction Advisory Group (AAG) aims to evaluate SUD treatment policies and practices by healthcare payers and providers.

OBJECTIVE: To understand and evaluate trends in treatment, coverage, policies, and challenges for SUD in order to inform AMCP activities in this area.

METHODS: An online survey containing multiple choice, open-ended, and Likert scale rating questions was fielded to 30 AMCP health plan members at healthcare organizations and addiction treatment providers (ATPs). The survey was launched in November 2018 and completed in December 2018.

RESULTS: A total of 30 responses were received from 15 AMCP members and 15 ATPs with 40% representing national health plans and provider organizations. 60% of the ATPs surveyed have been practicing medicine full-time for more than 10 years. Respondents reported high familiarity and knowledge with the SUD treatment and policy landscape (80%). 40% stated that negative connotations, stigma, or

bias have affected treatment or coverage decisions for individuals with SUD at their organization. Respondents identified multiple challenges/barriers to providing optimal care for individuals with SUD. Of the challenges/barriers to providing optimal care for individuals with SUD, lack of patient support systems was noted by 80% of respondents. Specifically, a majority of AMCP members and ATPs noted a lack of patient support systems (93% and 67%, respectively), with 73% of respondents overall anticipating high levels of usefulness of future information on naloxone co-prescribing.

CONCLUSIONS: SUD is a highly stigmatized condition, as validated by both provider and payer respondent groups, indicating that stigma has an impact on treatment or coverage decisions for individuals with SUD. By targeting identified barriers and addressing patient support systems, care can be optimally delivered and received by this patient group. Naloxone co-prescribing information is regarded as highly useful, therefore, opportunities exist for enhanced dissemination of new and existing resources. Further work is needed to identify ways for AMCP to address potential stigma in SUD coverage and treatment decisions.

SPONSORSHIP: Academy of Managed Care Pharmacy.

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

G1 Spinal Muscular Atrophy: An Integrated Medical and Pharmacy Claims Analysis of Nusinersen Uptake and Gene Therapy Forecast Among 15 Million Commercially Insured

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BACKGROUND: Nusinersen (Spinraza) is a novel therapy indicated for spinal muscular atrophy (SMA) in pediatric and adult patients. Nusinersen launched in January 2017 with an annual first year cost of $700,000. Internal commercial forecasted per member per month (PMPM) impact of nusinersen was $0.15 to $0.40. A gene therapy in development for SMA Type 1 (Zolgensma, onasemnogene abeparvovec) could cost $4 million per treated member. Health insurers need to understand the potential financial impact of existing and new to market SMA therapy.

OBJECTIVE: To describe utilization of nusinersen among SMA members using administrative medical and pharmacy claims and forecast potential impact of a gene therapy for SMA Type 1.

METHODS: Integrated medical and pharmacy claims data among 15 million commercial members were queried 1/1/17 through 8/30/18 to identify (a) members with at least one medical claim SMA ICD 10 code, or (b) members with a medical or pharmacy claim for nusinersen. Member distribution among the different SMA diagnosis codes is described. Nusinersen metrics include: claims, total paid (plan plus member allowed), and average age based on earliest claim (index claim). To describe nusinersen persistence, members were continuously enrolled from index claim to August 2018 and claims were compared to prescribing information. To forecast new gene therapy use, we identified members with at least one SMA Type 1 medical claim in the primary field. We assumed 50% of identified members would get gene therapy at $4 million.

RESULTS: From January 2017 to August 2018, 905 members had 1 or more SMA diagnosis codes and the most common was SMA unspecified (61%). 72 members had 214 nusinersen medical claims with $33M total paid and 7 members had 30 pharmacy claims with $4M total paid, for a total of $0.11 PMPM. The average age of nusinersen users

was 13. Average total paid per claim was $155,000 on the medical benefit and slightly lower at $136,000 for pharmacy claims. 68 (86%) members were continuously enrolled and 25 (37%) were persistent. If 50% of the 83 members identified with a primary field SMA Type 1 diagnosis receive gene therapy in 2019 at $4M, the potential net new spend is $0.93 PMPM.

CONCLUSIONS: Despite being used by less than 1 per 100,000 commercial members, nusinersen has contributed to PMPM trend. A new SMA gene therapy could have a large impact on trend for plans in 2019 and beyond, especially as the indication expands to all SMA types. Plans should consider nusinersen medical policies and utilize specialty drug forecasting to stay informed about pipeline products and potential impact.

SPONSORSHIP: Prime Therapeutics.

G2 Minimal Clinically Important Differences of the Expanded Hammersmith Functional Motor Scale in Later-Onset Spinal Muscular Atrophy: Results from the Phase 3 CHERISH Trial

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BACKGROUND: Minimal clinically important difference (MCID) is the change on a measure that may be interpreted as treatment benefit by caregivers and clinicians, and support coverage by payers. Currently there exists no definition of MCID or responder for patients with later-onset spinal muscular atrophy (SMA).

OBJECTIVE: To identify patients with later-onset SMA who responded to treatment and calculated a threshold of meaningful change in Expanded Hammersmith Functional Motor Scale (HFMSE) scores. Targeted analyses were conducted to estimate MCIDs and responder definitions for the HFMSE for later-onset SMA.

METHODS: Data from CHERISH, a phase 3 randomized, double-blind, multicenter, sham procedure-controlled clinical trial of later-onset SMA were analyzed. The HFMSE, the primary endpoint in CHERISH, was administered at screening and days 92, 169, 274, 365, and 456, in addition to 7-point global change ratings (CGICs) by the clinician and patient's caregiver at all follow-up days. Anchor-based methods using the CGICs were applied to determine MCIDs and responder definitions. Supportive, distribution-based methods, the half-standard deviation (SD) and standard error of measurement (SEM), were computed, as were receiver-operating characteristic (ROC) curve analyses and cumulative distribution functions.

RESULTS: Applying a conventional anchor-based definition for MCID yielded 3.82 based on the caregiver CGIC and 3.46 using the clinician CGIC at day 456; half-SD = 4.1 and SEM = 2.6. ROC curve analyses supported a smaller MCID of 2 HFMSE points of improvement as meaningful to caregivers and clinicians. A provisional MCID and responder definition for the HFMSE in later-onset SMA was approximately 3-4 points of improvement on the 0 to 66 HFMSE scale. Applying a 3-point change in HFMSE as the responder threshold to the CHERISH data, 60% (n = 21) of patients in the nusinersen group versus 21% (n = 4) patients in the sham group improved by ≥ 3 HFMSE points at day 456.

CONCLUSIONS: An MCID to help interpret HFMSE scores in later-onset, treated SMA patients was calculated using multiple methods. Provisional MCID and responder values converged on 3-4 points of improvement and were deemed meaningful and important to stakeholders such as caregivers and clinicians, to be confirmed in future studies. These values may also inform healthcare coverage decisions.

SPONSORSHIP: Biogen.

G3 Minimal Clinically Important Differences in Motor Function in Patients with Infantile-Onset Spinal Muscular Atrophy: Results from the Phase 3 ENDEAR Trial

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BACKGROUND: Minimal clinically important differences (MCIDs) and responder definitions are important to measure to support inferences regarding changes in spinal muscular atrophy (SMA), particularly the impact of therapies and evidence to support coverage decisions in the U.S. Currently there exists no definition for MCID or responder for patients with infantile-onset SMA.

OBJECTIVE: To calculate thresholds of meaningful change on the Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) and Hammersmith Infant Neurological Examination (HINE) motor milestones in patients treated for infantile-onset SMA.

METHODS: Data from ENDEAR, a phase 3 randomized, double-blind, multicenter, sham-procedure-controlled clinical trial were analyzed. Distribution- and anchor-based methods, latent growth modeling, cumulative distribution functions, and receiver operating characteristic curve analyses were applied to determine MCIDs and responder definitions.

RESULTS: Provisional MCIDs (group change) for the CHOP INTEND ranged from 3.4 to 4.0 points on the 0 to 64 CHOP INTEND scale and 0.4 to 0.7 points on the 0 to 23 HINE scale (without grasp). Responder definitions (individual change) were much larger than the MCIDs, reflecting actual change experienced by patients treated with nusinersen. For example, those in the nusinersen group showed a very large improvement in total HINE milestones score, (5.5 points, on average) versus no change (-0.4 points) for sham group. Thus, the calculated MCID values represent conservative levels of group (treatment arm) change in motor skills and motor milestones that are clinically meaningful, whereas the responder definitions reflect change at the individual patient level. The results of the responder analyses indicated that the majority of patients in the nusinersen group attained this higher threshold compared with those in the sham arm.

CONCLUSIONS: This is the first study to estimate MCIDs for the CHOP INTEND and HINE in patients treated for infantile-onset SMA. These values can help clinicians evaluate how well patients are responding to treatment and provide rationale for payer decisions about coverage for treatment. Future research evaluating MCID among subgroups (by age or disease duration) of infantile-onset SMA is warranted.

SPONSORSHIP: Biogen.

G8 Factors that Impact Health-Related Quality of Life in Patients with Tardive Dyskinesia: Regression Analyses of Data from the Real-World RE-KINECT Study

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BACKGROUND: RE-KINECT is an ongoing screening study of tardive dyskinesia (TD) in psychiatric outpatients treated with antipsychotic medications. It includes patients with visible uncontrollable movements that were confirmed by a clinician as possible TD (Cohort 2) and those with no visible movements or with non-TD movements (Cohort 1). Before cohort assignment, all patients were asked to complete the EuroQoL 5-Dimension 5-Level (EQ-5D-5L) questionnaire.

OBJECTIVE: To asses health-related quality of life (HRQoL) in patients with or without possible TD (Cohort 1vsCohort 2; adjusted for potentially confounding factors) and effects of the severity of possible TD on HRQoL (Cohort 2 only).

METHODS: To eliminate non-TD movement disorders as confounding factors, Cohort 1 was modified to exclude patients who presented with (or reported having) any uncontrollable movements not confirmed as TD. A linear regression model (adjusted for age, gender, overall health, psychiatric severity, functional status, and psychiatric diagnosis [mood disorder or schizophrenia/schizoaffective disorder]) at baseline was used to analyze the difference in EQ-5D-5L utility score (0 = health state equivalent to death; 1 = perfect health) between Cohort 2 (n = 204) and modified Cohort 1 (n = 450). Analyses were also conducted based on Cohort 2 patients who rated themselves as having "a lot" of overall TD severity (n = 53) or "a lot" of TD impact on daily activities (n = 41). In Cohort 2, the potential effects of TD severity (patient-rated, clinician-rated) and TD impact (patient-rated) on EQ-5D-5L utility were analyzed.

RESULTS: The adjusted difference (±standard error) between Cohort 2 and Cohort 1 was significant for EQ-5D-5L utility (-0.04 [±0.02], $P < 0.05$). Larger and statistically significant differences were found when the model only included Cohort 2 patients with "a lot" of TD severity (-0.09 [±0.03], $P < 0.001$) or "a lot" of TD impact on daily activities (-0.15 [±0.03], $P < 0.001$). Regression coefficients indicated that the EQ-5D-5L utility score was most strongly assocated with patient-rated TD impact (-0.021, $P < 0.001$), followed by patient-rated TD severity (-0.028, $P < 0.05$). No significant association was found with clinician ratings of TD severity (-0.007), which tended on average to be lower (less severe) than patient ratings of severity (mean [±standard deviation]: 2.3 [±1.4] vs. 2.7 [±1.6]).

CONCLUSIONS: TD is associated with worse HRQoL, especially from the perspective of patients vs. clinicians and particularly in patients who reported having relatively greater perceived TD severity/TD impact.

SPONSORSHIP: Neurocrine Biosciences.

G9 Hospital Utilization Rates Following Antipsychotic Dose Reductions Among Patients with Schizophrenia

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BACKGROUND: Tardive dyskinesia (TD), an often-irreversible movement disorder, develops in patients treated with antipsychotics. Although antipsychotic dose reduction has been utilized in the management of TD, the benefits and risks of lowering doses have not been well studied and could cause additional burden to patients.

OBJECTIVE: To analyze the healthcare burden of antipsychotic dose reduction in patients with schizophrenia.

METHODS: Medical claims from six U.S. states spanning 6 years are retrospectively analyzed for ≥ 10% or ≥ 30% antipsychotic dose reductions and compared with those from patients receiving stable doses. Outcomes measured include inpatient admissions and emergency room (ER) visits for schizophrenia and all psychiatric disorders.

RESULTS: Baseline analysis revealed 19,556 patients with ≥10% and 15,239 patients with ≥30% dose reduction. Patients with ≥10% dose reduction and matched controls were similar in age (mean 45.3 years), gender (51.5% male) and healthcare plan type. A ≥10% dose reduction led to an increased risk of admission or ER visit for schizophrenia (hazard ratio [HR]: 1.27; 95% confidence interval [CI]: 1.19-1.36; *P*<0.001) and all psychiatric disorders (HR: 1.16; 95% CI: 1.10-1.23; *P*<0.001) versus controls. Patients with ≥30% dose reduction were also at higher risk of admission or ER visit for schizophrenia (HR: 1.31- 95% CI: 1.21-1.41; *P*<0.001) and all psychiatric disorders (HR: 1.21; 95% CI: 1.14-1.29; *P*<0.001) compared with controls.

CONCLUSIONS: Patients with antipsychotic dose reductions may be at risk for significant increases in hospital utilization rates. This suggests that dose reductions may increase overall healthcare burden in some patients with schizophrenia and highlights the need for alternative strategies in the management of TD.

SPONSORSHIP: Teva Pharmaceuticals.

G10 Evaluation of Global Improvement and the Cost-Effectiveness of Treating Tardive Dyskinesia Shows Treatment with Valbenazine Is Dominant to Deutetrabenazine

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BACKGROUND: Tardive dyskinesia (TD) is associated with prolonged exposure to dopamine receptor blocking agents, including antipsychotics, and may have negative impacts on patients' quality of life, employment, social relationships, and activities of daily living. Valbenazine (VBZ) and deutetrabenazine (DTBZ) are vesicular monoamine transporter 2 inhibitors approved for treatment of TD in adults. An initial evaluation of these drugs used an economic model that defined response as ≥50% improvement in Abnormal Involuntary Movement Scale (AIMS) total score after 4 weeks of treatment.

OBJECTIVE: To evaluate the cost-effectiveness of TD treatment using a model that assessed global improvement after 1 year, as well as the effects of TD on managing underlying psychiatric diseases and overall survival.

METHODS: A discretely integrated condition event model was developed to assess cost-effectiveness of TD treatment in a synthetic patient population derived from population statistics in KINECT 3 (NCT02274558). Clinical inputs included response data from relevant studies (KINECT 3 extension, KINECT 4 [NCT02405091], AIM-TD [NCT02291861], ARM-TD [NCT02195700]). Other inputs were taken from published literature or other publicly available sources. Patients received VBZ or DTBZ for 48 wks and treatment response was assessed periodically using the Clinical Global Impression of Change–Tardive Dyskinesia (CGI-TD) scale, with response defined as a score ≤2 ("much improved" or "very much improved"). Responders at a given visit had an improved utility until their next assessment. At the completion of 1 year those not currently responding discontinued treatment. Responders at 1 year were assumed to maintain response indefinitely and remained on treatment until death. The model evaluated treatment response, life years, quality-adjusted life years (QALYs), psychiatric condition relapses, time employed, and costs.

RESULTS: In this model, patients treated with VBZ or DTBZ had better response to treatment, increased survival, improved quality of life, decreased disease management costs, and more time employed compared with no treatment. Treatment with VBZ had an incremental cost-effectiveness ratio of $198,243 per QALY compared with no treatment, and dominated DTBZ with higher response rates at 1 year (79% vs. 66%), more QALYs (10.2 vs. 9.7years), and lower lifetime costs ($748,053 vs. $828,298).

CONCLUSIONS: Treatment of TD with VBZ or DTBZ was associated with higher response rates. Over a lifetime horizon, VBZ was associated with better clinical and economic outcomes than DTBZ.

SPONSORSHIP: Neurocrine Biosciences.

G18 Relapses, Healthcare Resource Use, and Costs Among Patients with Multiple Sclerosis Taking Maintenance (Once- or Twice-Daily) Oral Disease-Modifying Drugs and Experiencing Lapses in Therapy

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BACKGROUND: Understanding lapses in therapy among patients receiving once- or twice-daily oral disease modifying drugs (DMDs; dimethyl fumarate, fingolimod, teriflunomide) is important in multiple sclerosis (MS).

OBJECTIVE: To describe lapses in therapy and clinical and economic outcomes of patients with/without a >60-day lapse in oral DMD treatment.

METHODS: This study used IQVIA RWD Adjudicated Claims-U.S. data from 1/1/2010-12/31/2017. Eligibility criteria were: ≥2 MS diagnoses and ≥1 claim for a once- or twice-daily oral DMD between 1/1/2011-6/30/2015, continuous commercial insurance 6 months pre- (baseline) and 18 months post- (follow-up) oral DMD initiation, and age 18-63 years. Lapses in therapy were defined as: number of days between lapsing of days' supply of the prior prescription and fulfillment of a new DMD prescription (ie, time period during which no DMD available based medical/pharmacy claims). Propensity score matching was used to match patients with and without a >60-day lapse in treatment 1:1. Covariates included a priori based on literature review were: age, sex, census region, Charlson score, depression diagnosis, diabetes diagnosis, 90-day pre-index neurologist visit, 90-day pre-index magnetic resonance imaging (MRI), 90-day pre-index relapse, and baseline non-medication costs.

RESULTS: A total of 8,779 patients met eligibility criteria; 1,326 (15.1%) had a lapse >60 days and 7,453 (84.9%) did not during the 18-month follow-up. Mean (standard deviation [SD]) lapse duration for patients with and without a >60-day lapse was 143.3 (94.2) and 17.6 (13.9) days, respectively. After matching (n=1,316), mean (SD) age was 44.4 (10.2) years and 75.2% were female for patients without a >60-day lapse, and 44.0 (10.2) years and 77.6% were female for patients with a >60-day lapse. Patients with a >60-day lapse had 27.6% more relapses (mean 1.16 vs. 0.84; *P*<0.0001), 40.0% more hospitalizations (0.20 vs. 0.12; *P*=0.0003), 24.6% more emergency room visits (0.61 vs. 0.46; *P*=0.0098), and 22.4% more outpatient visits (6.24 vs. 4.84; *P*<0.0001) vs. patients without a 60-day lapse during the 18-month follow-up. There was no difference in MRI use (1.16 vs. 1.14; *P*=0.6883). Non-medication costs over 18 months were 24.5% greater for patients with a >60-day lapse ($16,012 vs. $12,092; *P*=0.0006).

CONCLUSIONS: Among patients with MS receiving once- or twice-daily oral DMDs, those with a >60-day lapse in therapy had more relapses, healthcare resource use and higher costs over 18 months vs. patients without the lapse.

SPONSORSHIP: EMD Serono.

G19 Outcomes-Based Contracting in Multiple Sclerosis Disease-Modifying Therapies: Payer and Manufacturer Perspectives

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BACKGROUND: Outcomes-based contracts (OBCs) are becoming an increasingly popular area of interest as payers and pharmaceutical manufacturers seek to manage costs and promote access to innovative medications. Under OBCs, net payment is directly linked to achievement of mutually agreed upon patient outcomes. With the high cost of Multiple Sclerosis (MS) Disease Modifying Therapies (DMT) and the variability of responses across MS patients to DMTs, MS is a particularly opportunistic area to support an OBC structure.

OBJECTIVE: To identify the perspective of payers and pharmaceutical manufacturers on how medication therapy outcomes are selected for use as success measures in OBCs, current barriers and facilitators to OBCs, the potential role of clinical biomarkers as endpoints in an OBC and OBCs applicability to MS DMT.

METHODS: The author conducted a series of in-depth phone interviews with representatives from 7 payer/PBM organizations, 5 pharmaceutical manufacturers, and 5 industry consulting firms, all with some involvement in OBC development or evaluation.

RESULTS: Significant operational barriers have limited the success of OBCs; they are generally related to data issues (access to data, timeliness to obtaining, reconciliation of data) and challenges in identifying or defining meaningful, measurable and objective outcomes. Selection of OBC measurement endpoints is driven by clinical trials, availability of data to measure the outcome and negotiated between payers and manufacturers. Participants face significant data challenges when measuring an OBC endpoint which include availability of clinical data, data collection, and confidently attributing an outcome to the effect of the drug. MS is a therapeutic area where participants have faced challenges in selecting an objective, measurable endpoint. A majority of participants are open to using clinical biomarkers as a basis to measuring the success of an OBC as long as the biomarker is validated, accurately predicts clinical outcomes, is well-established in the therapeutic area, and is readily accessible in data available to the various stakeholders.

CONCLUSIONS: Clinical biomarkers that meet specific criteria may remove many of the barriers faced by payers and manufacturers in OBCs. Clinical biomarkers that are validated in a therapeutic area and accurately correlate to clinical outcomes may serve as an objective basis to measuring success of a medication under an OBC.

SPONSORSHIP: Octave Bioscience.

G20 Clinical and Economic Burden of Non-Adherence to Oral Disease-Modifying Drugs in Patients with Multiple Sclerosis: A Cost-Consequence Model

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BACKGROUND: The clinical and economic impact of non-adherence to once- or twice- daily oral disease modifying drugs (DMDs; dimethyl fumarate, fingolimod, and teriflunomide) in patients with multiple sclerosis (MS) has not yet been quantified. Cost-consequence analysis (CCA), a form of economic evaluation where multiple clinical outcomes are reported separately from costs, reports results in natural units of effect.

OBJECTIVE: To estimate the clinical and economic consequences associated with non-adherence to once- or twice- daily oral DMDs in patients with MS using CCA modeling techniques.

METHODS: Estimates of once- or twice-daily oral DMD non-adherence were obtained from a previous 2018 global meta-analysis of oral DMD adherence. A systematic literature review of published studies reporting the clinical and economic consequences associated with non-adherence to DMDs in patients with MS was conducted. The findings from the meta-analysis and literature review were used to construct a 1-year health economic CCA model that projected the clinical and economic burden of non-adherence in 1,000 patients with MS receiving oral DMDs. Outcomes assessed included relapses, hospitalizations, emergency room (ER) visits, outpatient visits, days of work loss, and direct and indirect costs. To present the various scenarios possible using plausible input values from the different data sources, ranges of clinical and economic consequences of non-adherence were calculated rather than point estimates.

RESULTS: Five studies comprising 3,786 patients were included in the meta-analysis. The pooled 1-year mean proportion of days covered (PDC; n = 4 studies) was 76.5% (95% confidence interval (CI): 72.0%-81.1%). Using a common threshold definition for non-adherence (PDC <0.8), pooled adherence from the meta-analysis was 71.8% (95% CI: 59.1%-81.9%). CIs were incorporated as plausible ranges of model input values. The CCA model estimated that among 1,000 patients receiving once- or twice-daily oral DMDs non-adherence accounted for (minimum and maximum values) 16-36 MS relapses, 10-36 hospitalizations, 13-70 ER visits, 127-286 outpatient visits, 2,835-4,200 days of work lost, $807,030-$2,378,744 in direct costs, and $302,400-$448,000 in indirect costs over one year.

CONCLUSIONS: Findings from this CCA model indicate that the clinical and economic burden of non-adherence among patients with MS taking once- or twice-daily oral DMDs can be considerable. Treatment options with improved adherence may result in reduced resource utilization and related costs.

SPONSORSHIP: EMD Serono.

G21 Multiple Sclerosis Relapse Rates and Healthcare Costs with Generic Glatiramer Acetate: A Retrospective Claims Analysis of U.S. Health Plan Commercial Insurance Data

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BACKGROUND: Glatopa (GLP; glatiramer acetate) 20 mg is the generic equivalent of Copaxone (CPX) 20 mg, approved for reducing relapse frequency in patients with relapsing forms of multiple sclerosis (MS). Little data exists on health outcomes and healthcare costs of MS patients treated with GLP in a real-world setting.

OBJECTIVE: To evaluate relapse rates and all-cause healthcare costs in patients treated with GLP and CPX in a large commercially insured patient population in the United States.

METHODS: A retrospective observational claims study was conducted among commercially insured patients identified from the HealthCore Integrated Research Database. Patients with ≥1 GLP or CPX fill between 04/01/2015 (GLP) or 01/01/2013 (CPX) and 04/30/2018 were included; the first fill was defined as the index date. Patients were excluded if they received prior treatment with CPX 40 mg or if they did not have health plan enrollment 6 months pre- and post-index date. Patients who switched from GLP to CPX were censored. GLP users were matched to CPX users through exact matching (age, gender,

follow-up length, baseline relapse rate, index year, baseline CPX 20 mg fills) and propensity score matching (including baseline comorbidities, medication use, healthcare utilization and cost). Relapse rates were calculated using a validated algorithm and compared using Chi-square tests. All-cause total costs (sum of prescription and medical costs) were compared using Wilcoxon tests.

RESULTS: Out of 633 GLP and 5,586 CPX total patients, 121 per cohort with commercial insurance were retained after matching. Key baseline characteristics were well balanced (mean age 47.1 years, 74% female, mean 3.5 CPX fills). At baseline, 10% of patients had ≥1 relapse with mean annualized relapse rates (ARR) of 0.23; at follow-up, the relapse rates were 8% vs. 17% (GLP vs. CPX; $P = 0.05$), and ARRs were 0.13 vs. 0.34 ($P = 0.04$). Mean time to first relapse or end of follow-up was 233 days vs. 216 days ($P = 0.34$). Mean (SD) all-cause total costs were \$49,137 (\$26,991) vs. \$54,422 (\$38,365; $P = 0.43$), of which all-cause prescription costs were \$44,520 (\$24,296) vs. \$46,319 (\$29,871; $P = 0.78$) and all-cause medical costs were \$4,617 (\$8,870) vs. \$8,103 (\$21,965; $P = 0.10$).

CONCLUSIONS: In this real-world study, MS patients treated with GLP experienced similar health outcomes and healthcare costs compared to those treated with CPX, with a potential trend towards cost savings (not significant in this sample).

SPONSORSHIP: Sandoz.

G22 Comparison of Healthcare Utilization Among Managed Medicaid Individuals Diagnosed with Multiple Sclerosis Treated with Emergent Versus Established Disease-Modifying Therapy

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BACKGROUND: Newer or emerging Disease-Modifying Therapies (DMTs) have evolved as an alternative treatment for patients with multiple sclerosis (MS). The efficacy and safety of established DMTs (interferons , glatiramer acetate, natalizumab, fingolimod, and mitoxantrone) have been well studied and clinical trials with small sample sizes have suggested that emerging DMTs (iteriflunomide, dimethyl fumarate/BG-12, alemtuzumab, and pegylated IFN) may have several distinct advantages relative to established DMTs including better outcomes and reduced healthcare utilization. However, there is limited real-world information regarding which DMTs (established vs. emerging) provide the best clinical response and outcomes in managed care populations of patients with MS.

OBJECTIVE: To compare MS related healthcare use within one year of initiating emergent and established DMTs among Managed Medicaid individuals diagnosed with MS in the U.S.

METHODS: A large national sample of patient-level administrative healthcare claims data were used for this analysis. MS patients aged 18 years and over with a new prescription fill for an established or emergent DMT between 2013 and 2016 were evaluated. Patients were eligible if they were continuously enrolled in a health plan with pharmacy and medical coverage for at least 6 months before and 1 year after initiation of therapy. Four types of healthcare use were examined: MS-related hospitalizations, emergency room (ER) visits, outpatient visits and relapse events (inpatient and outpatient). Multivariate negative binomial models with robust standard errors were used to estimate the association between MS related healthcare use and type of DMT. All models were adjusted for age, gender, Charlson index, and geographic region.

RESULTS: During the study period, 6,981 Managed Medicaid individuals with a MS diagnosis initiated a DMT. Of those, 79.8% were female, 50.4% were aged 40-64 years, and 21.5% were on emergent DMTs. Emergent DMT users were found to have fewer hospitalizations compared to established DMT users within one year of initiating therapy (adjusted risk ratio (ARR) = 0.64, 95% confidence interval (CI): 0.46-0.88) and fewer outpatient relapses (ARR = 0.86, CI: 0.79-0.95). Differences in inpatient relapses and ER visits were not observed by DMT type.

CONCLUSIONS: This study suggests that emergent DMTs are associated with reduced MS-related hospitalizations and outpatient relapses within one year of initiating therapy. Studies examining a longer treatment timeframe and additional healthcare outcomes are warranted to confirm these findings.

SPONSORSHIP: None.

G30 Prevalence of Probable Dravet Syndrome, Lennox-Gastaut Syndrome, and Other Refractory Epilepsies in Commercial and Medicaid Populations in the United States

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BACKGROUND: With the availability of new antiepileptic drugs (AEDs) to treat refractory epilepsies such as Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS), health plans have been interested in estimating the number of members with these conditions. Prevalence has been difficult to assess, and data are limited due to the absence of diagnosis codes for DS and recent introduction of diagnosis codes for LGS.

OBJECTIVE: To estimate the annual prevalence of DS, LGS, and other refractory epilepsies in U.S. Commercial and Medicaid plans

METHODS: Analyses were conducted in the IBM MarketScan Commercial and Medicaid databases with an identification period from 4/1/2016 to 3/31/2017 (Commercial) and from 1/1/2016 to 12/31/2016 (Medicaid). Continuously enrolled members were included if they had ≥1 AED claim and medical claims with ≥1 diagnosis code for LGS or refractory epilepsy or ≥1 claim for clobazam or rufinamide. Identified members were further stratified into 3 hierarchical cohorts: DS, LGS or other refractory epilepsies. The DS cohort required ≥1 diagnosis code for refractory epilepsy, ≥1 diagnosis code for intellectual disability/developmental delay, ≥2 AEDs or a diagnosis code for febrile seizures, <91 cumulative days' supply for AEDs that exacerbate DS, and no diagnosis codes for LGS or abnormal brain imaging. The LGS cohort required a diagnosis code for LGS or all of the following: ≥1 diagnosis code for refractory epilepsy, ≥1 diagnosis code for intellectual disability/developmental delay, and no diagnosis codes that preclude LGS. Patients remaining were classified as other refractory epilepsies.

RESULTS: Among 17,427,685 Commercial members <65 years, 210 were identified with DS, 2,273 with LGS, and 11,891 with other refractory epilepsies. For a 1-million member Commercial plan, the estimated annual prevalence is 12 patients with DS, 130 patients with LGS, and 682 patients with other refractory epilepsies. Among 7,865,949 Medicaid members, 514 were identified with DS, 4,786 with LGS, and 8,307 with other refractory epilepsies. For a 1-million member Medicaid plan, the estimated annual prevalence is 65 patients with DS, 608 patients with LGS, and 1,056 patients with other refractory epilepsies.

CONCLUSIONS: These results may help Commercial and Medicaid plans estimate the number of members with probable DS, LGS, or other refractory epilepsies potentially eligible for treatment with new AEDs. Further research is needed to validate the accuracy of the claims-based algorithm in identifying patients with these conditions.

SPONSORSHIP: Greenwich Biosciences.

G31 Healthcare Resource Utilization and Costs Associated with Triptan Discontinuation, Switching, and Add-On Use

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BACKGROUND: Triptans are recommended for first-line acute treatment of moderate to severe migraine attacks. Persistence to triptan therapy is low. Discontinuation or switching of the initial triptan may be a proxy for efficacy and tolerability issues; and may result in increased healthcare resource utilization (HCRU).

OBJECTIVE: To compare HCRU and cost differences among subgroups who continued their initial triptan, discontinued, added on or switched to a different triptan in a 12-month period.

METHODS: This retrospective observational cohort study used the U.S. IBM MarketScan Research databases to identify migraine patients (≥ 18 years old) initiating a triptan from 2013 to 2016 (index=first triptan claim). Inclusion criteria required 12 months of pre- and post-index continuous medical and prescription enrollment. Patients were divided into 4 mutually exclusive groups based on their triptan use pattern 12-months post-index: continuers, discontinuers, switchers or add-on users. Descriptive statistical analyses were performed and unadjusted HCRU and cost were reported.

RESULTS: A total of 171,988 patients (80.4% female) with mean age of 39 years were included: continuers (67,136 [39%]), discontinuers (90,851 [53%]), switchers (12,124 [7%]) and add-on users (1,877 [1%]). Discontinuers generally had comparable HCRU and medical costs to continuers. Switchers and add-on users had significantly more triptan claims, compared with continuers, with an average of 4.2, 7.1 and 3.8/patient, respectively ($P<0.001$). Compared with continuers, switchers and add-on users had greater HCRU, with 16% (+$444) and 47% (+$1,308) higher medication costs and 27% (+$1,671) and 45% (+$2,804) higher medical costs, respectively, as well as migraine-specific HCRU, including ≥ 2.1-fold higher outpatient costs and >25% more neurologist visits.

CONCLUSIONS: Although a small group (8% of triptan users), patients who switched or added on to their triptan usage demonstrated a greater increase in HCRU and costs. Discontinuers had similar HCRU compared to continuers, suggesting they were either misdiagnosed, had low frequency of migraine attacks or stopped seeking medical care. An unmet need of these patients needs to be studied further. Future analyses will also explore additional patient characteristics that may influence costs and HCRU. Patients with migraine who lack tolerability or response to a triptan may have limited benefit from switching to or adding on a different triptan. A new pharmacological approach may optimize acute treatment of migraine.

SPONSORSHIP: Eli Lilly.

G32 The Impact of Formulary Restrictions on Likelihood of Successful Fill of Antiepileptic Drug Treatment

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BACKGROUND: Antiepileptic drug (AED) therapy is the primary treatment option for patients with epilepsy. Delayed or no initiation of prescribed AEDs may lead to insufficient seizure control. Formulary restrictions may have unintended consequences of delaying or reducing likelihood of therapy initiation. This has not been studied for patients with focal seizure (FS) who were prescribed AED therapy.

OBJECTIVE: To study the association between formulary restriction and time to fill of prescribed AED treatment and likelihood of a successful fill.

METHODS: Symphony Health Solutions open-source claims data for 04/01/15-06/30/18 were analyzed. Patients were included if they had a diagnosis for FS and ≥ 1 new AED pharmacy claim. Index date was defined as the earliest AED pharmacy claim date that was approved or rejected for a formulary-related reason. Patients with no medical claim in 6 months prior to index date, evidence of pregnancy, and <6 months of pharmacy data before or after index date were excluded from the analysis. Patient cohorts were constructed based on whether the index AED claim was approved or rejected due to a formulary restriction. Demographic and clinical characteristics were measured during the 6-month baseline period. Proportion of patients filling the index AED and time to its fill were analyzed during the 6-month follow-up period. A multivariable Cox proportional hazards model was used to study the impact of formulary restriction on likelihood of prescribed AED's successful fill.

RESULTS: 54,097 patients were included: 44,964 in the approved claim cohort and 9,133 in rejected claim cohort. Proportion of patients with an index claim for a generic AED was higher in the approved cohort compared to the rejected cohort (93.0% v. 78.9%). Mean (SD) time to first fill was 1.8 (11.1) days for the approved cohort and 8.7 (23.5) days for the rejected cohort. A greater proportion of patients in the approved cohort had a successful fill of their index AED at 6 months from initial prescription relative to patients in the rejected cohort (91.7% vs. 70.1%). Adjusted for baseline characteristics, formulary-related rejections of a prescribed AED were associated with a lower likelihood of successful fill of index (35%) and any AED (30%; Index AED-HR: 0.65; $P<0.001$; Any AED-HR: 0.70; $P<0.001$).

CONCLUSIONS: Study results suggests formulary restrictions may lead to an average delay of 6.9 days and reduced likelihood for successful fill of AED treatment for patients diagnosed with FS. The impact of this delay on clinical and economic outcomes should be examined in future studies.

SPONSORSHIP: Sunovion Pharmaceuticals.

G33 Comorbidity, Treatment Patterns, and Economic Burden of Primary Headache Disorders: An Administrative Claims Data Analysis

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BACKGROUND: Tension-type headache (TTH), migraine, and cluster headache (CH) account for majority of headache disorders; understanding the treatment patterns and burden of which may assist in evidence-based treatment decisions.

OBJECTIVE: To describe comorbidity burden, real-world healthcare resource utilization (HCRU) and costs, and treatments among adults diagnosed with primary headache disorders, using integrated health insurance claims data.

METHODS: The study employed a retrospective cohort design using data from January 2012 through December 2017. Adults diagnosed with TTH, migraine, or CH, identified by ICD-9/10-CM codes, were included. The index date was the earliest primary headache disorder date between January 2013 and December 2016. Patients not continuously enrolled during the 12-month pre- and post-index periods were excluded. Comorbidities were assessed during the pre-index period. Treatments, annual all-cause and headache-related HCRU and costs (USD 2017) were assessed post-index per patient.

RESULTS: The following patient cohorts were identified: TTH (n=34,147), migraine (n=363,976), CH (n=4,326), and >1 primary headache type (n=16,330). The mean age across the cohorts ranged from 44-48 years. Majority of the CH patients were male (63%), whereas the TTH, migraine, and >1 headache type patients were predominantly female (76-84%). Most prevalent comorbidities across all 4 cohorts were sinusitis (20-31%), hypertension (21-28%), and anxiety disorders (16-23%). Majority of the patients had evidence of analgesic (54-73%), and psychotropic (57-81%) drug use: primarily opioids (36-53%), NSAIDs (31-41%), and antidepressants (33-59%). Adherence to prophylactic treatments was low (mean proportion of days covered range: 0.2-0.4). Triptans (10-50%) were the predominant acute headache treatment after opioids (36-53%) for all cohorts, except TTH patients. One-tenth (8-10%) of the patients were hospitalized over the year, one-third had emergency department visits (26-36%), and 21-54% had neurologist visits. Patients diagnosed with >1 headache type incurred the highest mean (SD) annual all-cause costs ($17,853 [$32,073]), followed by migraine ($15,320 [$31,802]), CH ($15,037 [$40,018]), and TTH ($12,825 [$27,829]). Headache-related costs accounted for approximately one-fifth of all-cause costs.

CONCLUSIONS: Patients diagnosed with primary headache disorders have significant comorbidity and economic burden; especially patients diagnosed with >1 headache type. Opioids are predominantly used for acute treatment.

SPONSORSHIP: The Dr. Reddy's Laboratories group of companies.

G34 Comparing Patient-Reported Outcomes in Patients Using CGRP Antagonists or OnabotulinumtoxinA for Chronic Migraine

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BACKGROUND: Calcitonin gene-related peptide (CGRP) antagonists are a new drug class indicated for chronic migraine prevention. With the release and availability of CGRPs, there is little real-world evidence that compares patient reported outcomes (PROs) of CGRP antagonists and onabotulinumtoxinA in patients with chronic migraine.

OBJECTIVE: To compare PROs between patients on CGRP antagonists vs. onabotulinumtoxinA for chronic migraine.

METHODS: A customized electronic questionnaire for migraine related outcomes was created and implemented into the specialty pharmacy workflow. Patients were identified if they were on a CGRP antagonist (CGRP; including erenumab-aooe, galcanezumab-gnlm, and fremanezumab-vfrm) or on onabotulinumtoxinA (ONA) for the indication of chronic migraine prophylaxis from 1/1/2018 through 12/1/18. Pharmacists telephonically reached out to patients to assess number of migraine headache days (MHD), average pain severity of migraines on a scale of 1 to 10, average duration of migraines in hours; a HIT-6 questionnaire was also conducted. Responders were identified if they had at least a 50% reduction in baseline MHD during the study period, and proportions were compared using chi-square. Patients were also identified if they had at least a one severity class improvement per the HIT-6, and proportions were compared between the groups using chi-square. Student's t-test was used to determine differences between MHD, average pain score, and average HA duration.

RESULTS: A total of 42 patients were identified, with 21 in the ONA and CGRP groups. At baseline, the ONA group was 90% female with average age of 47, 20 MHD, pain severity 9, and 45 hours duration per migraine. The CGRP group was 71% female with an average age of 47, 16 MHD, pain severity of 7, and 23 hours duration. There was no

difference in proportion of patients (P>0.05) who experienced at least a 50% reduction from baseline in MHD between the groups, (CGRP 62%, ONA 52%) or in patients who experienced at least a one class decrease in severity per the HIT-6 (CGRP 44%, ONA 35%). Both the ONA and CGRP groups experienced significant decreases from baseline in MHD (12 and 8, P<0.05) and pain severity (7 and 5, P<0.05). Only the ONA group experienced significant decrease in duration of migraine (23, P<0.05).

CONCLUSIONS: There was no difference between CGRP and ONA groups using PROs with at least a 50% reduction from baseline in MHD or HIT-6 class severity improvement. Patients in both groups experienced significant improvement in MHD and pain, but only the ONA group experienced decrease in migraine duration.

SPONSORSHIP: None.

G35 Opioid Use at the Emergency Department of a Large Tertiary Care Integrated Delivery Network in Texas

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BACKGROUND: Migraine is a debilitating neurological disease that affects 9.7% of U.S. males and 20.7% of U.S. females. Evidence suggests that the use of opioids is associated with increased risk of chronification, leading to increased morbidity and higher costs. Opioid use in the emergency department (ED) continues to remain high despite guidelines recommending otherwise. There is limited evidence on the use of acute abortive medications and opioids for migraine patients in the emergency setting.

OBJECTIVE: To describe and compare opioid and non-opioid medication use in migraine-related emergency department (ED) visits.

METHODS: This was a retrospective analysis using electronic medical records (EMRs) from Baylor Scott & White Health Plan, obtained via ReachNet, from 2010 to 2017. Records were extracted for patients aged ≥18 with ≥1 ED visit coded for migraine [ICD-9 346.xx or ICD-10 G43.xx]. Descriptive statistics of patient demographics, opioid and non-opioid medication use were summarized and analyzed using SAS 9.4.

RESULTS: The database included 10,677 ED visits for 7,840 migraine patients, with average age of 43.4 (±14.2) years, 86.2% female, 75.6% Whites, and 17.0% African-Americans. Among 10,677 migraine-related ED visits, 4,803 (45.0%) had ≥1 medication administered during the ED visit. The top 5 medication classes were opioids (n=2,571 [24.1%]), anti-emetics (n=2,414 [22.6%]), non-opioid analgesics (n=1,940 [18.2%]), anti-histamines (n=1,346 [12.8%]), and corticosteroids (n=610 [5.7%]). Of the 2,571 ED visits with opioids administered, the top 5 opioids used were morphine (n=805 [31.3%]), hydromorphone (n=612 [23.8%]), fentanyl (n=507 [19.7%]), hydrocodone (n=351 [13.7%]), and butorphanol (n=72 [2.8%]). About one-fourth (n=2,753/10,677 [25.8%]) of all migraine-related ED visits resulted in ≥1 prescription to be filled at a pharmacy after the ED visit; 9.0% (n=963/10,677) for opioids and 13.9% (n=1,488/10,677) for abortive medications.

CONCLUSIONS: Despite guidelines discouraging the use of opioids for migraine, they were the class of medications most often administered during migraine ED visits, given during about one-fourth of ED visits. Also, for about one-tenth of the ED visits, take-home prescriptions for opioids were written. Future research should focus on exploring factors related to opioid use and barriers to migraine prophylaxis.

SPONSORSHIP: None.

G36 Shift from Chronic Migraine to Episodic Migraine Status in a Long-Term Phase 3 Study of Galcanezumab

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BACKGROUND: Relative to episodic migraine, chronic migraine is associated with substantially greater disease-state burden due to higher rates of disability, comorbid conditions, acute medication use and healthcare resource utilization. Galcanezumab is approved for prevention of chronic and episodic migraine. Results from a long-term Phase 3 study in patients with chronic migraine are reported.

OBJECTIVE: To assess proportions of patients with chronic migraine who shift to episodic migraine status during treatment with galcanezumab or placebo.

METHODS: REGAIN included patients aged 18-65 years with an ICHD-3β diagnosis of chronic migraine who met chronic criteria during a 1-month prospective baseline period (i.e., ≥15 headache days/month, of which at least 8 are migraine headache days [MHDs]). Patients were randomized 2:1:1 to receive subcutaneous monthly injections of placebo, galcanezumab 120mg (with a loading dose of 240 mg) or galcanezumab 240 mg for up to 3 months of double-blind treatment. Patients who completed the double-blind period could enter a 9-month open-label extension (120 or 240 mg/mo galcanezumab). Results from patients who received galcanezumab during the double-blind and/or open-label periods are reported. Achieving episodic migraine status was defined as <8 MHDs or <15 headache days/month for ≥3 consecutive months. In addition, we evaluated the proportions of patients who shifted to <8 MHDs/month (low frequency) and <4 MHDs/month (very low frequency).

RESULTS: In REGAIN, at baseline, mean (SD) number of MHDs/month was 19.4 (4.5) and mean (SD) number of headache days/month was 21.4 (4.1). At the end of double-blind treatment period (Month 3), a greater proportion of galcanezumab-treated patients shifted to episodic status (30.9%) than did placebo-treated patients (19.7%). Among galcanezumab-treated patients across the entire 12-month trial, 65.1% shifted from chronic migraine to episodic status, 44.2% shifted to low frequency and 21.5% shifted to very low frequency for ≥3 consecutive months. Proportions of patients shifting from chronic migraine to episodic status for ≥3 consecutive months and until last patient visit were: shift to episodic status: 55.0%; shift to low frequency: 33.4%; shift to very low frequency: 13.9%.

CONCLUSIONS: Treatment with galcanezumab led to a majority of patients with chronic migraine shifting to episodic migraine status. These results suggest that long-term treatment with galcanezumab may lead to substantial reductions in the disability and economic burden associated with chronic migraine.

SPONSORSHIP: Eli Lilly.

G37 OnabotulinumToxinA and Migraine: Persistence, Utilization and Expenditure Within the Botulinum Toxin Drug Class

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BACKGROUND: Botulinum Toxins (BT) are FDA approved for a variety of conditions including muscle dystonia, gland secretion, and migraine prevention. OnabotutinumtoxinA (ObA) is the only BT of the 4 commercially available indicated for migraine prevention. The recent approval of calcitonin gene-related peptide (CGRP) products for migraine prevention emphasizes the importance of understanding migraine-related ObA use, cost and persistency for payers and stakeholders.

OBJECTIVE: To (a) determine the ObA proportion of BT utilization and expenditure across the pharmacy and medical benefit and (b) detail ObA migraine cost and treatment persistence.

METHODS: Integrated medical and pharmacy claims for 15 million commercially insured members were queried for BT claims from October 2017 to September 2018. All BT claims, units, and allowed costs were summed for the 12-month period, and proportion of ObA used for migraine was determined along with average dose and cost per treatment. An ObA claim was considered migraine-related when a member had a migraine diagnosis claim within 180 days prior to or 90 days after their ObA claim. ObA migraine treatment persistence, defined as a second ObA claim within 104 days after the index ObA claim, was assessed for new starts identified between October 2015 to September 2016 who were continuously enrolled 365 days prior to and 104 days after index claim.

RESULTS: ObA migraine use accounted for 66% (40,694/61,944) of all BT claims and 65% ($52.3 mil/$80.3 mil) of all BT expenditure. ObA migraine use was $0.29 PMPM out of the entire BT drug category $0.45 PMPM, in the 12 month peroid. Among ObA for migraine the average dose was 194 units (which is close to an available vial size of 200 U) with an average allowed cost per claim of $1,287. 56% (1,400/2,496) of the members new to ObA therapy for migraine were persistent.

CONCLUSIONS: In this large commercially insured population, ObA for migraine accounted for two-thirds of all BT claims and expenditures. Using the ObA migraine dose found in this study of 194U at an average cost of $1,284 and applying it to the labeled every 84 day dosing, the estimated annual cost for 4 treatments is $5,148. However, nearly half of new starts do not receive a second dose. These findings highlight opportunities for clinical program development and value based contracting.

SPONSORSHIP: Prime Therapeutics.

G38 Getting Employers Engaged in Addressing Migraine: A New Approach to Demonstrating the Economic Impact

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BACKGROUND: Employers may not recognize migraine as a significant population health issue because it is under-diagnosed and has relatively low direct treatment costs (including pharmacotherapy) and because of failure to measure indirect costs.

OBJECTIVE: To evaluate healthcare resource utilization (HCRU) and costs among migraineurs (confirmed and suspected) relative to non-migraineurs, from an employer perspective.

METHODS: This retrospective, observational cohort study used claims data from a multi-employer database. Subjects 18-64 years old with continuous enrollment from 7/1/15-6/30/17 were included in the study. HCRU endpoints and attributed costs for number of outpatient (OP) visits, emergency department (ED) visits, and imaging tests were analyzed for one year (7/1/16-6/30/17). Descriptive statistics were used to describe the population prevalence of migraine and the demographic profile. Analyses of variance were used to compare the

effect of migraine status on HCRU and cost in confirmed, suspected, and non-migraineurs. Amgen's Migraine Impact Model was used to estimate absenteeism and presenteeism.

RESULTS: The study included 27,746 employees and dependents. Of these, 8.9% had confirmed or suspected migraine. Approximately 84% of the migraine population were female and 55% were ages 35-54. Mean annual total health expenditure per member was similar between confirmed and suspected migraineurs, but greater than non-migraineurs ($11,902 [a] and 12,564 [b] vs. 7,778, respectively; $P < 0.05$ for both a and b). Mean HCRU were similar between confirmed and suspected migraineurs, but greater than non-migraineurs for OP visits (7.67 [a] and 7.43 [b] vs. 4.67, respectively; $P < 0.05$ for both a and b), ED visits (0.9 [a] and 0.91 [b] vs. 0.39, respectively; $P < 0.05$ for both a and b), and MRI scans (0.15 [a] and 0.12 [b] vs. 0.02; $P < 0.05$ for both a and b). Mean CT scans per member showed increased utilization among the suspected migraineurs compared to confirmed and non-migraineurs (0.25 vs. 0.16 [a] and 0.03 [b], respectively; $P < 0.05$ for both a and b). Indirect costs per employee per year attributed to absenteeism and presenteeism were estimated at $270 and $597, respectively.

CONCLUSIONS: Both confirmed and suspected migraine incur greater HCRU and healthcare costs than individuals without migraine in this population. Employers should be cognizant of these disparities and implement strategies such as care management protocols or examine appropriate benefit design to support employees with migraine.

SPONSORSHIP: Amgen.

G39 Treatment Outcomes for Oral, Subcutaneous, and Intranasal Forms of Sumatriptan: Survey Results from Migraine in America Symptoms and Treatment Study

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BACKGROUND: Triptans are indicated for acute treatment of migraine and are available in oral, injectable, and nasal formulations. Patients may try various forms of triptans in the course of treatment.

OBJECTIVE: To evaluate the response to triptans by route of administration.

METHODS: Using cross-sectional survey data from the 2017 Migraine in America Symptoms and Treatment (MAST) Study, 15,133 participants met modified ICHD-3 criteria for migraine. 2,401 (15.9%) reported triptan medications as their primary treatment for attacks, with route of delivery preferences as follows: oral n = 1,935 (80.6%), subcutaneous n = 1,37 (5.7%) and intranasal n = 3,29 (13.7%) routes. Frequency data and chi-square analysis ($P < 0.05$) were used to compare the proportion receiving complete and meaninful relief of pain, photophobia, phonophobia, nausea "after one dose" and the percent reporting "average time to relief" < 1-hour.

RESULTS: Rates of complete and meaningful relief with one dose were 86.9% subcutaneous, 60.2% intranasal and 80.9% for oral triptan users (Chi: 77.651, $P < 0.001$). Rates of relief of photophobia were 83.7% subcutaneous, 50% intranasal and 76.5% for oral users (Chi: 101.192, $P < 0.001$). Rates of relief of phonophobia were 81.1% subcutaneous, 48.7% intranasal and 76.8% for oral users (Chi: 111.195, $P < 0.001$). Rates of relief for nausea were 78.1% subcutaneous, 49.2% intranasal and 64.2% for oral users (Chi: 34.816, $P < 0.001$). Among responders, the proportion achieving a response in < 1-hour was consistently greatest for intranasal, followed by subcutaneous and followed by oral triptan users.

CONCLUSIONS: The proportion of participants achieving complete and meaningful relief of pain and associated symptoms was highest for subcutaneous, intermediate for intranasal and lowest for oral triptan users. Among responders, a higher proportion of participants achieved relief within one hour with intranasal vs. subcutaneous triptans followed by oral triptans. Non-oral triptans are faster and more effective in real world settings than oral triptans, despite the influence of confounding by indication.

SPONSORSHIP: Dr. Reddy's Laboratories group of companies.

G40 Identifying Sociodemographics and Symptoms Associated with Emergency Department and Urgent Care Use in People with Migraine: Survey Results from Migraine in America Symptoms and Treatment Study

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BACKGROUND: Unplanned medical treatment at a hospital emergency department or urgent care center (ED/UC) for a chronic condition such as migraine increases the economic burden and is considered by some clinicians as a treatment failure.

OBJECTIVE: To identify sociodemographic and symptom characteristics associated with ED/UC utilization within the prior 6 months in a population sample of persons with migraine.

METHODS: Respondents to the Migraine in America Symptoms and Treatment (MAST) Study were recruited from a nationwide online research panel. A stratified sample of U.S. adults age 18 and older were invited to participate and migraine cases were identified using a validated symptom screener based on modified ICHD-3b criteria. Inclusion in the study required an average of at least one headache day per month over the last 3 months. In addition to headache symptoms, the assessment included sociodemographics (age, gender, race, income, smoking, BMI), monthly headache day (MHD) frequency, ictal cutaneous allodynia (ASC12), psychological symptoms (anxiety and depression; PHQ4). Logistic modeling was used to identify variables associated with ED/UC use after controlling for sociodemographics and MHD frequency.

RESULTS: 15,133 of 95,821 respondents met study inclusion criteria. There were 1,284 (8.5%) with > 1 ED/UC visit (men 9.7%, women 8.0%; $P < 0.001$); mean number of visits was 2.4 (men 3.1, women 2.1; $P < 0.001$). ED/UC use occurred more often in younger respondents (39.3 vs. 43.4 years; $P < 0.001$), non-Caucasians (25.4% vs. 18.4%; $P < 0.001$), current smokers (24.8% vs. 10.1%; $P < 0.001$) and those with below normal BMI (9.6% vs. 2.6%, $P < 0.001$). Episodic migraine cases comprised 81.3% of ED/UC users and 18.7% met headache frequency criteria (> 15 MHDs) for chronic migraine. Those with allodynia were 2.3 times more likely to be seen in ED/UC (95% CI: 2.06-2.65), as were those with frequent vomiting OR 3.2 (95% CI: 2.79-3.76), frequent nausea OR 2.0 (95% CI: 1.77-2.26), PHQ anxiety OR 1.5 (95% CI: 1.27-1.74) and PHQ depression OR 1.7 (95% CI: 1.45-2.00).

CONCLUSIONS: Men and younger respondents were more likely to report ED/UC use, as were current smokers, non-Caucasians and those with below normal BMI. After considering sociodemographics and MHD frequency, allodynia was associated with increased odds of ED/UC utilization, as were frequent nausea and vomiting, perhaps due to dehydration risk. The presence of clinical anxiety and depression were also risk factors.

SPONSORSHIP: Dr. Reddy's Laboratories group of companies.

G41 Efficacy and Safety of Fremanezumab in Patients with Chronic or Episodic Migraine

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BACKGROUND: Fremanezumab, a fully humanized monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) ligand, is approved for the preventive treatment of migraine.

OBJECTIVE: To evaluate the efficacy and safety of two doses of fremanezumab in the preventive treatment of chronic (CM) and episodic (EM) migraine.

METHODS: The HALO CM and HALO EM trials were concurrent, multicenter, randomized, double-blind, placebo-controlled, parallel-group studies evaluating the efficacy and safety of fremanezumab in the preventive treatment of CM or EM. Adults with CM or EM, confirmed during a 28-day pre-treatment (baseline) period, were randomized to receive either subcutaneous fremanezumab quarterly (675 mg at baseline and placebo at Weeks 4 and 8), fremanezumab monthly (HALO CM: 675 mg at baseline, and 225 mg at Weeks 4 and 8; HALO EM: 225 mg at baseline and Weeks 4 and 8), or matching placebo, over a 12-week period. The primary efficacy endpoints were the mean change from baseline in the monthly average number of headache days of at least moderate severity for HALO CM, and the mean change from baseline in the monthly average number of migraine days for HALO EM, during the 12-week treatment period.

RESULTS: Patients with CM treated with fremanezumab had a significant reduction in the number of monthly headache days of at least moderate severity for both fremanezumab quarterly (-4.3 days, $P<0.0001$) and monthly (-4.6 days, $P<0.0001$) compared with placebo (-2.5 days). Similar reductions were observed in the secondary endpoint of number of monthly migraine days (fremanezumab quarterly: -4.9 days; fremanezumab monthly: -5.0 days; both $P<0.0001$ compared with placebo: -3.2 days). Patients with EM treated with fremanezumab had a significant reduction in the number of monthly migraine days for both fremanezumab quarterly (-3.4 days; $P<0.0001$) and monthly (-3.7 days; $P<0.0001$) compared with placebo (-2.2 days). Similar reductions were observed in the exploratory endpoint of number of monthly headache days of at least moderate severity (fremanezumab quarterly: -3.0 days; fremanezumab monthly: -2.9 days; both $P<0.0001$ compared with placebo: -1.5 days). Treatment effects in both trials were seen during the first 4 weeks of treatment. The most commonly reported adverse event in both studies was injection-site pain, with similar rates in the placebo and active groups.

CONCLUSIONS: These results confirm the efficacy and safety profile of fremanezumab for the preventive treatment of CM or EM.

SPONSORSHIP: Teva Pharmaceuticals.

G42 Triptan Discontinuation and Treatment Patterns Among Migraine Patients Initiating Triptan Treatment in a U.S. Commercially Insured Population

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BACKGROUND: Migraine is a chronic disease with episodic attacks defined by often incapacitating neurological symptoms. Triptans are commonly prescribed for the acute treatment of migraine attacks.

OBJECTIVE: To examine real-world patterns of acute treatment of migraine among new triptan users in a commercially insured U.S. population.

METHODS: Adult patients were selected if they had ≥1 triptan claim between January 1, 2013 and December 31, 2013 (first claim assigned as index date) and at least 12 months of pre- and 24 months of post-index continuous enrollment in the Optum Clinformatics claims database. Patients were required to have ≥1 migraine diagnosis but no prior triptan claims in the pre-index period. Treatment patterns among these patients initiating a new triptan were examined over a 12- and 24-month period.

RESULTS: In our sample of 10,509 new triptan users, 50.8% did not refill their index triptan over the 12-month post-index period and 43.6% did not refill it over the 24-month period. The majority of the new triptan users (56.4%) had a quantity of ≤4 pills on their first fill; refill rates were similarly low in these patients. Only 8.4% of the new triptan users received 2 different triptan agents and 1% received 3 different triptan agents over 24 months. Approximately 35% of patients filled ≥1, whereas another 10% filled ≥2, guideline-listed agents from a non-triptan acute medication class over 24 months, most commonly for an NSAID followed by butalbital combination. However, over half of all new triptan users (54.3%) and the subgroup with no refills for their initial triptan (52.6%) had filled a guideline- or non–guideline-listed opioid medication over the 24-month follow-up.

CONCLUSIONS: These results demonstrate poor refill patterns and minimal use of >2 different triptan agents over a 2-year period in a large, commercially insured population of new triptan users in the U.S.

SPONSORSHIP: Allergan plc.

G43 Opioid Use, Rebound Headache, and Resource Utilization Among Migraine Patients with Insufficient Response to Triptans Based on Real-World Data

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BACKGROUND: Real-world observational studies have demonstrated low persistence with triptans. Data related to outcomes among patients inadequately managed on triptans are limited.

OBJECTIVE: To assess the proportion of triptan insufficient responders and evaluate outcomes associated with triptan insufficient response in migraine patients.

METHODS: This analysis utilized U.S. data from the Adelphi Disease-Specific Programme, a multi-country, cross-sectional study using data from electronic medical records (EMR), and patient and physician surveys collected from August to December 2017. Triptan insufficient responders were defined as patients currently prescribed triptans/had received triptans in the past 6 months and failed to achieve pain freedom at 2 hours post dose, or responded to triptans but discontinued due to lack of efficacy or side effects. Outcomes included opioid use, hospital admissions (inpatient/emergency room), and healthcare professional (HCP) visits extracted from EMR, and self-reported rebound headache. Logistic and Poisson regression models were used to compare each outcome between triptan insufficient responders and responders, adjusting for demographics, migraine type, frequency, and severity.

RESULTS: Triptan insufficient responders (n=331) had a mean±SD age of 43.3±13.2 years, whereas triptan responders (n=535) were younger (40.9±13.6 years). Triptan insufficient responders were 13 times more likely to receive an opioid (adjusted odds ratio [aOR] [95% CI]: 12.8 [2.4-68.4], $P=0.003$) and 3 times more likely to suffer from

rebound headaches (aOR: 3.1 [1.6-6.0], $P=0.001$) and to be admitted to a hospital for headache in the past year (aOR: 2.5 [0.9-6.9], $P=0.081$) than triptan responders. Triptan insufficient responders had 37% more visits to an HCP in the past year (adjusted incident rate ratio: 1.4 [1.0-1.8], $P=0.021$).

CONCLUSIONS: Triptan insufficient response was associated with increased opioid utilization, more frequent rebound headaches, and greater healthcare resource utilization, including hospital admissions and HCP visits, suggesting a need for improved acute treatment of migraine and a role for novel therapeutic options in this population.

SPONSORSHIP: Allergan plc.

G44 Ubrogepant Is Effective for the Acute Treatment of Migraine in Patients for Whom Triptans Are Ineffective

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BACKGROUND: Use of triptans for the acute treatment of migraine is often limited by suboptimal efficacy, side effects, or contraindications (i.e., triptan ineffective). It is therefore clinically relevant to determine if ubrogepant, a small molecule CGRP receptor antagonist, is effective in patients for whom triptans are ineffective.

OBJECTIVE: To examine the efficacy of ubrogepant in patients based on historical experience with triptans.

METHODS: Multicenter, double-blind, single-attack, Phase III trials (ACHIEVE-I/NCT02828020; ACHIEVE-II/NCT02867709). Adults with a history of migraine, with/without aura, were randomized 1:1:1 to placebo or ubrogepant (50 mg or 100 mg, ACHIEVE-I; 25 mg or 50 mg, ACHIEVE-II). At baseline, patients were categorized as triptan-effective, triptan-ineffective, or triptan-naïve, based on historical experience. Co-primary efficacy endpoints in both trials were pain freedom and absence of most bothersome migraine-associated symptom (MBS), 2 hours post initial dose. Data from both trials were pooled (placebo and ubrogepant-50 mg) for this analysis. Ubrogepant vs. placebo treatment effect was estimated using logistic regression model including treatment by subgroup interaction (between group variation in efficacy).

RESULTS: At baseline, patients (mITT population: N=912 placebo, N=887 ubrogepant-50 mg) were categorized as triptan-effective (38% placebo, 37% ubrogepant-50 mg), triptan-ineffective (24% placebo, 26% ubrogepant-50 mg), and triptan-naïve (37% placebo, 37% ubrogepant-50 mg). In the triptan-ineffective subgroup, response rates were higher for ubrogepant-50 mg vs. placebo for 2-hour pain freedom (8% placebo, 16% ubrogepant-50 mg; OR: 2.16 [95% CI: 1.19-3.95]) and absence of MBS (23% placebo, 36% ubrogepant-50 mg; OR: 1.76 [95% CI: 1.16-2.68]). Higher response rates were also observed for ubrogepant-50 mg vs. placebo in triptan-effective and triptan-naïve subgroups. Magnitude of effect (ubrogepant vs. placebo) was not significantly different among the 3 subgroups for pain freedom ($P=0.2898$) or absence of MBS ($P=0.7045$), indicating comparable treatment effect regardless of historical triptan experience. Placebo response rates were lowest in triptan-ineffective and highest in triptan-naïve. Proportion of patients reporting adverse events was comparable across subgroups; no safety concerns were identified.

CONCLUSIONS: Ubrogepant was effective for the acute treatment of migraine in patients categorized as triptan-ineffective. No differences were observed in the magnitude of treatment effect between the defined triptan subgroups.

SPONSORSHIP: Allergan plc.

G45 Economic Burden of Adverse Drug Events Associated with Epileptic Therapy in Emergency Departments and Acute Care Hospitals in the United States

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BACKGROUND: Adverse drug events (ADE) associated with antiepileptic drugs (AED) therapy could have significant impact on patients' quality-of-life and treatment failures, with economic and clinical consequences.

OBJECTIVE: To estimate the economic burden of ADEs in emergency departments (ED) using 2011-2014 Healthcare Cost and Utilization Project's (HCUP) Nationwide Emergency Departments Sample (NEDS), and in hospital inpatient (IP) settings using 2011-2015 HCUP Nationwide Inpatient Sample (NIS).

METHODS: We identified patients aged ≥18 years with a diagnosis of epilepsy using appropriate ICD 9 or ICD 10 codes (345.X, 780.X, G40.X, R56.X). We identified patients with an ADE using two different definitions: 1) unintentional injury codes due to AEDs using ECODES (e.g., E936.X) in any diagnosis position and 2) ADEs specified in drug inserts/literature (e.g., Steven Johnson Syndrome, ICD 10 L299) as a primary diagnosis (PADE). Charges for ED visits and costs for IP visits (using HCUP cost-charge ratios-not available for NEDS) were estimated using log-linked gamma regression controlling for demographics and Charleston Comorbidity Index, accounting for sampling weights to obtain national estimates.

RESULTS: There were 3.7% of patients aged ≥18 years with epilepsy claims for an ED visit and 1.6% discharge claims from an acute care hospital. Of these claims, the proportion coded as ECODES were 3% and those coded as PADE were 22% in the ED setting. Similarly, there were 5% and 10%, respectively, in the IP setting. For ED visits, the mean charges (±SD) in 2017 US\$ accounting for medical inflation, for ECODES and PADE were \$3,252 (± \$4,634) and \$4,502 (± \$5,302), respectively. For IP admissions, the mean cost for ECODES and PADE, were \$15,455 (± \$24,816) and \$9,283 (± \$15,049), respectively. For IP cost, the difference was higher (+ \$816, PPPP < 0.0001) in PADE vs. no PADE. While these differences in ED charges were not considerable based on the definition of the ADE, the difference in the inpatient setting was considerable.

CONCLUSIONS: ADEs pose an added burden to the healthcare system whether considered as principal diagnosis in the ED or IP settings or if considered as unintentional injury secondary to AED use. The use of ECODES is a conservative approach limited by accurate coding by coders. Use of PADE is likely overestimated since it is not immediately preceded by drug use, limiting the use of only HCUP for such estimates.

SPONSORSHIP: UCB Pharma.

G46 Comparing Fall Risk Among Antiepileptic Drugs in the Elderly: A Nested, Case-Control Study of a Medicare Database

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BACKGROUND: Falls are the most common cause of fatal and non-fatal injuries and hospital admissions for trauma in the elderly. Numerous studies demonstrated an increased fall risk related to antiepileptic drug treatment.

OBJECTIVE: To compare the association between antiepileptics and fall risk requiring hospitalization in the elderly.

METHODS: This nested, case-control study used claims data from a Medicare database and included all patients ≥65 years of age with an epilepsy diagnosis and inpatient admission in 2014. Patients with an inpatient admission for fall (ICD-9: E880-E888) were matched to controls, those admitted for a diagnosis aside from fall, fracture, or trauma, in a 1:3 ratio based on age, sex, and osteoporosis diagnosis. Initially, the increased fall risk with antiepileptics was reestablished by comparing the odds of filling a prescription for an antiepileptic prior to admission, based on Part D claims data, to the controls. To compare fall risk among antiepileptics, a second cohort, limited only to patients receiving antiepileptics, was subsequently re-matched in a 1:1 ratio based on the same characteristics. Multivariate logistic regression analysis was used to control for concomitant medications and comorbidities that may increase fall risk.

RESULTS: The first cohort consisted of 15,345 cases and 46,035 controls. The mean age was 77.9 ± 8.6 years, 63.3% were female, and 27.1% had osteoporosis. Fifty-four percent of cases were diagnosed with a fracture or trauma, with the most common being a femur fracture or traumatic brain injury. Antiepileptics were associated with a higher fall risk with odds ratio (OR) of 3.24 (95% confidence interval [CI]: 2.76-3.80, $P < 0.001$). The second cohort consisted of 197 cases and 197 controls. A combination of two or more antiepileptic drugs accounted for 27.2% of all antiepileptic use, followed by gabapentin monotherapy (23.9%), and levetiracetam monotherapy (15.7%). Phenytoin, levetiracetam, and gabapentin were the most common medications used in combination treatment. As compared to gabapentin, fall risk was higher for those receiving carbamazepine (OR 7.86, 95% CI: 2.01-30.73, $P < 0.001$), levetiracetam (OR 6.77, 95% CI: 3.30-13.93, $P < 0.001$), phenytoin (OR 5.76, 95% CI: 2.36-14.07, $P < 0.001$), and combination treatment (OR 2.69, 95% CI: 1.5-4.81, $P < 0.001$).

CONCLUSIONS: Antiepileptic use in the elderly with epilepsy was associated with an increased fall risk. Carbamazepine, levetiracetam, phenytoin, and combination antiepileptic treatment was found to increase fall risk relative to gabapentin.

SPONSORSHIP: None.

G47 Demographics, Headache Characteristics, and Other Factors Associated with Opioid Use in People with Migraine: Results from the Chronic Migraine Epidemiology and Outcomes Study

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BACKGROUND: Opioid use for acute treatment of migraine is not recommended by scientific organizations and is of concern because it may be associated with dependence, suboptimal outcomes, and increased risk of new-onset chronic migraine (CM).

OBJECTIVE: To identify variables associated with opioid use among those using acute prescription medications for migraine.

METHODS: The Chronic Migraine Epidemiology and Outcomes (CaMEO) study identified persons with ICHD-3 migraine from a Web panel demographically matched to the U.S. population. We compared the features of self-reported opioid users (currently using opioids or having them on hand for migraine) with those of nonusers. Nested, multivariable binary logistic regression models evaluated opioid use/nonuse as the outcome. Covariates were entered in blocks (sociodemographics, headache and respondent characteristics, psychiatric comorbidities, emergency facility use for headache in the preceding 6 months, and ≥1 cardiovascular [CV] comorbidity). Nonsignificant sociodemographic variables were trimmed from the model.

RESULTS: Of 2,388 people with migraine currently using acute prescription medications for migraine, 867 (36.3%) were opioid users. Factors significantly associated (odds ratio [95% CI]) with opioid use included male sex (1.74 [1.38, 2.20]), increasing BMI (1.02 [1.00, 1.03]), allodynia (1.39 [1.14, 1.70]), increasing monthly headache day frequency (0-4 days [reference] vs. 10-14 days: 1.37 [1.02, 1.82]; ≥15 days: 1.62 [1.24, 2.13]), increasing Total Pain Index (TPI; excluding head, face, neck; 1.32 [1.15, 1.52]), anxiety (1.37 [1.08, 1.73]), depression (1.50 [1.18, 1.89]), ≥1 CV comorbidity (1.56 [1.28, 1.90]), and emergency facility use for headache (1.73 [1.30, 2.31]). Physician-diagnosed migraine or CM was associated with a significantly decreased likelihood of opioid use (0.38 [0.30, 0.48]).

CONCLUSIONS: Despite recommendations to the contrary, opioid use is common among migraine patients using prescription medication and is generally associated with markers of worse health, including elevated BMI, CV and psychiatric comorbidities, elevated TPI, and emergency facility use. Modifiable variables associated with opioid use include presence/absence of physician diagnosis and greater monthly headache days.

SPONSORSHIP: Allergan plc.

G48 Budget Impact Analysis of FDA-Approved Cannabidiol Oral Solution for Treatment of Seizures Associated with Lennox-Gastaut Syndrome or Dravet Syndrome

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BACKGROUND: Lennox-Gastaut syndrome (LGS) and Dravet syndrome (DS) are severe, treatment-resistant epilepsy syndromes that begin in childhood and persist with lifelong seizures. Epidiolex (cannabidiol oral solution) is a recently FDA-approved treatment for seizures associated with LGS or DS in patients 2 years of age and older.

OBJECTIVE: To estimate the total healthcare budget impact of including FDA-approved cannabidiol for treatment of seizures associated with LGS or DS in a U.S. commercial plan

METHODS: An Excel-based model was developed to assess the 3-year budget impact of introducing FDA-approved cannabidiol in a 1-million member hypothetical U.S. commercial plan evaluating 2 scenarios: (a) without FDA-approved cannabidiol utilization; and (b) with FDA-approved cannabidiol on formulary. The number of eligible members was based on U.S. prevalence estimates for LGS and DS with adjustments for the commercial business line and the percent of members uncontrolled with other antiepileptic drugs (AEDs). FDA-approved cannabidiol uptake of 20% per year was applied, mirroring uptake in the most recent AED launches. The base model assumed no changes in concomitant AEDs. Percent reduction in seizures and discontinuation of FDA-approved cannabidiol were based on Phase 3 trial results. FDA-approved cannabidiol wholesale acquisition costs were used. Other cost inputs were from a claims analysis of members with probable LGS or DS. FDA-approved cannabidiol adherence inputs were from published data for AEDs in children with epilepsy. Outputs were per member per month (PMPM) cost differences with FDA-approved cannabidiol in Years 1-3. Sensitivity analyses studied varying model parameters ±20%.

RESULTS: The model estimated 92 treatment-eligible members. After introducing FDA-approved cannabidiol, estimated pharmacy costs PMPM increased by $0.020 in Year 1, $0.044 in Year 2, and $0.069 in Year 3. Estimated medical costs PMPM decreased by -$0.016 in Year 1, -$0.042 in Year 2, -$0.069 in Year 3. While estimated total healthcare costs PMPM increased by $0.004 in Year 1 and $0.003 in Year 2, there was no impact ($0.00) in Year 3. Additional savings could be achieved

with reduced utilization of other AEDs. Limitations include use of assumptions from broader populations for inputs without available data.

CONCLUSIONS: For commercial plans, introducing FDA-approved cannabidiol for treatment of seizures associated with LGS or DS is estimated to have a modest impact on total healthcare costs in Years 1 and 2 and a negligible impact by Year 3, driven by decreases in medical costs due to seizure reduction.

SPONSORSHIP: Greenwich Biosciences.

G54 National Estimates of Under-Treatment and Drug-Drug Interaction of Migraine Pharmacotherapy in U.S. Ambulatory Care Settings

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BACKGROUND: Migraine is the sixth most disabling disease in the world causing substantial economic and personal burden to public health systems. In spite of various sophisticated medications available for migraine treatment, it continues to be under diagnosed and under-treated. In addition, there are concerns regarding potential drug-drug interactions (DDI). However, very little research is available to identify these issues.

OBJECTIVE: To investigate the prevalence of under-treatment and drug-drug interactions of migraine pharmacotherapy.

METHODS: A retrospective population-based study was conducted by analyzing a national database from the 2015 National Ambulatory Medical Care Survey. All patient visits with a diagnosis of migraine were included. A series of weighted descriptive analyses were used to estimate the prevalence of migraine medications recommended in the American Neurology Association practice guidelines. Drug-drug interaction was defined according to the Drug Interaction Facts. All analyses utilized SAS PROC SURVEY applications and incorporated sample weights to adjust for the complex sampling design.

RESULTS: Among 6.9 million outpatient visits that took place in 2015 with a diagnosis of migraine, females accounted for nearly five-times more than males (83.0% vs. 17.0%). More individuals between the ages of 45 to 64 years had migraine (48%) as compared to other age groups. Whites (80.2%) were overwhelmingly affected by migraine more than Hispanics (11.0%), Blacks (6.4%) and others (2.4%). Only 72.3% of them received at least one prescribed medication for migraine. 23.7% of these treatments had potential major or moderate DDI such as combination of triptans and SSRIs/SNRIs.

CONCLUSIONS: The study revealed that under-treatment and DDI in migraine are significant problems in the U.S. Although the nature of serotonin syndrome cases reported from DDI in the literature is still questionable, it may lead to potential morbidity or even mortality if appropriate clinical actions are not taken. Unfortunately, drug-drug interactions can be difficult to identify and are commonly missed. Future research is recommended to explore intervention and educational strategies to ensure that physicians are well-informed and employ evidence-based practice guidelines as well as provided timely and appropriate treatment for people with migraine.

SPONSORSHIP: None.

G55 Pain Medication Utilization Patterns in Cancer Survivors with Chronic Pain

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BACKGROUND: Pain is commonly experienced among cancer survivors and can have a significant physiological and psychological effect on their life. However, pain medication usage in cancer survivors has not been extensively investigated.

OBJECTIVE: To (a) compare the pain medication utilization patterns in cancer survivors and individuals without cancer history who experience chronic pain, and (b) to investigate factors associated with opioid use in cancer survivors.

METHODS: A cross-sectional study using the Medical Expenditure Panel Survey 2008-2012 longitudinal files was conducted. The study included adult patients with cancer diagnosis ≥ 3 years before and not undergoing active cancer treatment at the survey year. Age, sex, ethnicity, geographical region, and survey year-matched controls without history of cancer were identified in a ratio of 1:1 and served as a comparison group. Both cancer survivors and controls who reported chronic pain for two years were included in the study. The pain medication utilization patterns (opioid analgesics and combination analgesics containing opioids, non-opioid combination analgesic, and other analgesics) over a period of 1 year in cancer survivors and controls were compared using Rao-Scott chi-square tests. Patient sociodemographic and clinical factors associated with opioid prescription utilization among cancer survivors were investigated using a multivariable logistic regression.

RESULTS: A total of 2,460 cancer survivors and matched controls were identified. Mean (SE) age was 64.8 (0.4) years, and 61.9% were female. A higher percentage of cancer survivors used pain medications compared to matched controls [opioid analgesics: 10.7% in cancer survivors vs. 5.1% in controls, $P < 0.001$, opioid analgesic combinations: 24.9% vs. 20.6%, $P = 0.04$, SSNRI: 8.0% vs. 5.0%, $P = 0.013$, and gabapentin/pregabalin: 12.1% vs. 8.3%, $P = 0.008$]. In cancer survivors, 31.2% had an opioid as one of their pain prescriptions compared to 23.2% of controls ($P < 0.001$). Younger age, having insurance, lower physical and mental component of health-related quality of life measures were associated with higher odds of utilizing opioids in cancer survivors.

CONCLUSIONS: Cancer survivors with chronic pain had higher utilization of opioid containing pain prescriptions and agents used for peripheral neuropathy than the matched controls without cancer history. Future studies may be necessary to further address the appropriateness of opioid utilization in cancer survivors.

SPONSORSHIP: None.

G56 Evaluating Pharmacotherapies for Postpartum Depression: A Match-Adjusted, Indirect Comparison of SSRIs to Brexanolone Injection, A Novel Investigational Compound

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BACKGROUND: In randomized controlled trials (RCTs) in women with postpartum depression (PPD), 60 hours of continuous brexanolone injection infusion (90 mg/kg) was associated with significant reductions in Hamilton Depression Rating Scale (HAM-D), which was sustained throughout the study period (30 days).

OBJECTIVE: To understand how brexanolone injection, an investigational compound, compares to selective serotonin reuptake inhibitors (SSRIs), the class of medicines most commonly used to treat PPD, using clinician-reported (HAM-D) and patient-reported instruments (specifically the Edinburgh Postnatal Depression Scale [EPDS]).

METHODS: A systematic literature review identified RCTs assessing SSRI efficacy data in PPD. Matched-adjusted indirect comparison (MAIC) methods were used for analyses at day 3, week 4 and last observation (LO) following treatment initiation; linear interpolation and last observation carried forward were employed to account for differences in timepoints measured between studies. Differences in change from baseline (CFB) between treatments with 95% confidence intervals for HAM-D and EPDS were calculated.

RESULTS: Following MAIC, brexanolone injection demonstrated greater reductions than SSRIs for both scales at all time points, as measured by the difference in CFB. Differences in CFB between brexanolone injection and SSRIs ranged from 13.5 (day 3) to 2.0 (LO) for HAM-D. For EPDS, differences in CFB ranged from 8.0 (day 3) to 3.3 (LO).

CONCLUSIONS: Applying MAICs showed that brexanolone injection had larger treatment differences in CFB than SSRIs for both patient- and clinician-reported scales at all investigated time points.

SPONSORSHIP: Sage Therapeutics.

G57 Lemborexant Versus Zolpidem Extended Release on Morning Postural Stability in Older Adults

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BACKGROUND: Non-benzodiazepine hypnotics (e.g., zolpidem tartrate extended release [ZOL]) used to treat insomnia are associated with impaired postural stability (PS) and increased risk of falls. In the Phase 3 SUNRISE-1 study (NCT02783729), lemborexant (LEM), a dual-orexin-receptor antagonist for insomnia treatment, significantly improved both objective sleep onset and maintenance parameters vs. placebo (PBO) and ZOL in subjects with insomnia. To address safety concerns of commonly used insomnia treatments, the LEM clinical program included extensive safety assessments, including PS.

OBJECTIVE: To examine effects of LEM vs. ZOL on PS at morning waketime following dosing at bedtime.

METHODS: Two studies enrolled male and female subjects (age ≥ 55 y). Study E2006-A001-108 (n = 63) was a 4-period, randomized, double-blind, double-dummy, crossover study consisting of four 1-day treatment periods with a 14-day washout between periods in healthy subjects without insomnia. SUNRISE-1 (E2006-G000-304; n = 1,006) was a 1-mo, double-blind, randomized, parallel group, PBO- and active-controlled study. In both studies, patients were randomized to PBO, ZOL (6.25 mg), LEM 5 mg (LEM5) or 10 mg (LEM 10). PS was evaluated within 5 min of morning waketime at ~8h postdose with an ataxiameter to assess body sway after each single dose treatment (Study 108) and after the 1st 2 and last 2 doses in SUNRISE-1. Subjects stood on a firm surface with feet comfortably apart, and were instructed to stand still with eyes closed for 1 min. Outcome was amount of body sway in 1 min in 1/3° angle of arc (units [U]; higher values = greater body sway, i.e., less PS).

RESULTS: Least square mean change from baseline in body sway ~8h postdose for PBO, ZOL, LEM5, and LEM10 was -1.1, 5.9, 1.3, and 0.7U after single dose in Study 108 study completers (n = 56), and -6.5, 7.0, -2.7, and -3.8U after 1st 2 doses; -3.5, 4.6, -2.9, -4.4 U after last 2 doses, in SUNRISE-1 full analysis set. In both studies, comparisons of PBO vs. LEM5 and LEM10 were not statistically significant (all P > 0.05). In contrast, for ZOL, body sway was statistically significantly higher vs. PBO (Study 108: P = 0.01 after single dose; SUNRISE-1: P < 0.01 after 1st 2 doses), vs. both LEM 5 and LEM 10 after 1st 2 doses (SUNRISE-1: both P < 0.02), and vs. LEM 10 after last 2 doses (SUNRISE-1: P = 0.03).

CONCLUSIONS: LEM does not impair PS upon typical morning waketime vs. PBO when administered ~8h prior, while ZOL continued to produce larger changes in body sway than PBO, both after single doses and at the end of a month of continuous treatment.

SPONSORSHIP: Eisai and Purdue.

H00-H95 Diseases of the Eye and Adnexa
(e.g., Macular Degeneration)

H1 Real-World Adherence and Persistence of Cyclosporine Ophthalmic Emulsion and Lifitegrast Ophthalmic Solution in Patients with Dry Eye Disease

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BACKGROUND: Dry eye disease (DED) is one of the most common ophthalmic disorders, with a prevalence of 5%-34% globally. Its pathogenetic mechanisms include inflammation of the ocular surface and lacrimal gland, and anti-inflammatory treatment is often required. Two anti-inflammatory treatments are currently FDA approved and commercially available for the treatment of DED: cyclosporine ophthalmic emulsion 0.05% (CYC) and lifitegrast 5% ophthalmic solution (LIF).

OBJECTIVE: To examine the real-world treatment patterns of topical CYC and LIF use in patients with DED using the MarketScan claims database.

METHODS: Patients aged ≥ 18 years with a diagnosis of DED and ≥ 1 prescription of CYC or LIF between July 2016 and February 2018 were identified. The date of the first prescription filled was considered the index date. All patients included had ≥ 12 months medical and pharmacy benefit in both the pre- and post-index periods, and no prior use of the index medication. Over the 12-month post-index period, the proportion of days covered (PDC) by CYC or LIF was calculated. Rates of adherence (PDC ≥ 0.8), non-persistence (no refill within 120 days for CYC or 90 days for LIF), discontinuation (treatment gap ≥ 150 days for CYC or ≥ 120 days for LIF), and switching were examined. Time to discontinuation was analyzed using Kaplan-Meier (KM) curves.

RESULTS: Overall, 6,537 CYC patients (82.7% female; mean age 60.1 years) and 3,235 LIF patients (81.9% female; mean age 56.8 years) were included. In both cohorts, the adherence rate was low (CYC 5.9%; LIF 9.7%) with a mean PDC of 0.3 (standard deviation: CYC 0.2; LIF 0.3). The 12-month discontinuation rate was 70.8% for CYC and 64.4% for LIF. The KM median time from initiation to discontinuation was 89 days for CYC and 29 days for LIF. Non-persistence was identified in 7.1% of CYC and 6.8% of LIF patients, with a median of 89 and 105 days from initiation to non-persistence, respectively. Overall, 9.6% of patients switched from LIF to CYC and 5.0% switched from CYC to LIF and the median time to switching was 124 for CYC and 76 days for LIF.

CONCLUSIONS: The adherence of CYC and LIF was low among DED patients, and majority of the patients discontinued treatment within 12 months of treatment initiation. The median time to discontinuation was 3 months for CYC and 1 month for LIF.

SPONSORSHIP: Sun Pharmaceutical Industries.

I00-I99 Diseases of the Circulatory System
(e.g., Atrial Fibrillation, ACS, Pulmonary Hypertension)

I1 A Retrospective Database Analysis Evaluating the Relationship Between Pharmacy Quality Alliance-Defined Adherence and Healthcare Costs and Utilization for Commercially Insured Patients on Renin-Angiotensin System Antagonists

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BACKGROUND: Poor medication adherence is linked to increased morbidity, mortality and healthcare costs. The Pharmacy Quality Alliance (PQA) measures are used by the Centers for Medicare and Medicaid Services (CMS) to assess quality. Yet, the impact of these measures on healthcare use and costs in other populations has not been assessed.

OBJECTIVE: To determine the relationship between renin-angiotensin system (RAS) antagonists PQA-defined adherence and healthcare expenditure and utilization for commercially insured patients.

METHODS: This one-year retrospective study used a cohort of eligible individuals from Truven Health MarketScan Research Databases (2009-2015). Generalized linear models (GLM) with log link and gamma distribution (costs) or negative binomial distribution (use) assessed relationships between adherence (≥80% proportion of days covered) and healthcare use and costs (adjusted to 2015 U.S. dollars) while adjusting for covariates (e.g., age, gender, Charlson Comorbidity Index). Beta coefficients were used to compute cost ratios (CR) and rate ratios (RR). Cohort characteristics were assessed via t-tests, Wilcoxon rank sum tests, or chi square tests. An alpha level of 0.001 was set a priori. Analyses were conducted using SAS Version 9.4.

RESULTS: A total of 4,842,058 individuals were eligible; of those, 3,310,360 (68.4%) were adherent. All subject characteristics were different ($P < 0.001$) between adherent and non-adherent groups. In multivariable analyses adherent patients were associated with: fewer inpatient (RR = 0.612, 95% CI = 0.607-0.617) and outpatient visits (RR = 0.995, 95% CI = 0.994, 0.997); and lower inpatient (CR = 0.614, 95% CI = 0.613-0.615) and total (CR = 0.876, 95% CI = 0.874-0.878) costs. Adherence was associated with lower incremental costs per member per month for inpatient costs ($93.84) and total costs ($97.98) compared to nonadherence.

CONCLUSIONS: RAS antagonist adherence was associated with fewer outpatient and inpatient visits, and lower total costs compared to nonadherence.

SPONSORSHIP: Pharmacy Quality Alliance, Merck, and SinfoniaRx.

I4 Patient Characteristics Affects Adherence to Statins Among Patients with Existing ASCVD: A MEPS Analysis

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BACKGROUND: On the basis of NHANES 2011 to 2014 data, an estimated 92.1 million American adults have at least one type of cardiovascular disease (CVD). One in every three deaths in the United States (U.S.) is due to CVD. Even though the AHA/ACC guidelines recommend statin use among patients with existing atherosclerotic cardiovascular disease (ASCVD), data show that only 60% of ASCVD patients are on statin with a wide adherence range.

OBJECTIVE: To describe how adherence to statin varies by patient's characteristics and comorbidities within the population with MI, angina pectoris, or stroke.

METHODS: We conducted a retrospective analysis using 2015 and 2016 Medical Expenditure Panel Survey (MEPS), which are surveys of families and individuals, their medical providers, and employers across the U.S. Adults with a history of MI, angina pectoris, or stroke were included if they had sufficient pharmacy data to calculate the proportion of days covered (PDC) on statin during the entire year of survey. Patients were categorized as (a) high adherence (PDC ≥ 0.80), (b) intermediate/low adherence, (c) non-statin users (PDC = 0). To determine the degree of influence of various risk factors and comorbidities on high adherence, a logistic regression model examined predictors of high adherence.

RESULTS: 3,795 samples representing 19.4 million patients with history of MI, angina pectoris, and stroke were included: 4.87 million with PDC ≥ 0.8, 5.49 million with PDC < 0.8, and 9.08 million with PDC = 0. Statin high adherence occurred more frequently in males, older patients, and those with better self-assessed health condition or higher family income. Of those prescribed statin, patients with diabetes (OR = 1.20) and history of myocardial infarction (OR = 1.43) were more likely to be adherent. Poly-medication users were more likely to be adherent. Each additional class of medication use other than statin increased adherence by 13.9%.

CONCLUSIONS: Adherence to statins among patients with high risk of CVD was low overall, and differed by patient characteristics and specific comorbid conditions. Variation in adherence rates reveals subgroups of patients who are particularly at risk due to non-adherence. Statins are a proven, inexpensive therapy that improve cardiovascular outcomes. Efforts to improve adherence may be tailored based on the patient profile.

SPONSORSHIP: The Medicines Company.

I5 National Trends in ASCVD Prevalence, Lipid-Lowering Therapy Use, and Expenditures in the U.S. from 2002 to 2016: A MEPS Analysis

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BACKGROUND: Cardiovascular disease (CVD) is the leading cause of death in the United States (U.S.) and one of the costliest chronic diseases. As the population ages, the number of CVD patients and their medical costs are expected to increase substantially. To improve cardiovascular health and control costs, we must understand the national trends of prevalence and costs of CVD.

OBJECTIVE: To understand the prevalence, statin use and adherence, and medical costs of patients with myocardial infarction (MI), angina pectoris (AP), and stroke from 2002 to 2016 in the U.S.

METHODS: We conducted a 15-year retrospective analysis using Medical Expenditure Panel Survey (MEPS), which is a survey of families and individuals, their medical providers, and employers across the U.S. To be included in the study, individuals must be ≥ 21 years of age at the time of survey with history of MI, AP, and/or stroke. Individual's annual expenditures from various points of service were summarized and adjusted to 2016 dollars. The statin adherence was measured by the proportion of days covered (PDC).

RESULTS: From 2002 to 2016 the U.S. adult population increased from 200.9 to 233.4 million, and the number of individuals with MI, AP, and stroke increased from 13.3 (6.6%) to 19.7 million (8.5%). The total annual medical expenditures of those individuals increased 44.5% over 15 years, from $231 billion in 2002 to $333 billion in 2016.

In contrast, the annual out-of-pocket (OOP) costs decreased from $34 to $24 billion in 2016.The percentage of individuals filling their statin prescriptions was <50% in 2002 and 2003, and then 53% and 58% between 2004 and 2016. Among these taking statins, the percentage of patients with PDC≥0.8 was never >53% between 2002 and 2016. The utilization of statin and medical costs varied depending on the category of insurance and CV event.

CONCLUSIONS: The prevalence of MI, AP and Stroke and overall medical costs steadily increased in the past 15 years. Despite the availability of generic statins and the reduction in OOP for more than 10 years, the use of statins in this high risk cohort remained suboptimal. Half of individuals on statins didn't achieve the threshold of 80% adherence to achieve optimal benefit. These findings suggest significant under treatment may be contributing to rising cardiovascular medical costs. Further strategies are needed to improve statin use and reduce the recurrence of heart attack and stroke and their economic consequences.

SPONSORSHIP: The Medicines Company.

I6 Examining the Real-World Management of Non-Valvular Atrial Fibrillation Based on Clinical Guidelines

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BACKGROUND: The 2014 American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society (HRS) Guidelines recommend oral anticoagulants (OAC) for patients with atrial fibrillation (AF) and intermediate-high risk of stroke.

OBJECTIVE: To assess real-world guideline adherence among patients newly diagnosed with non-valvular AF (NVAF).

METHODS: Patients aged 18-89 with AF diagnosis from 10/1/2014 to 9/30/2015 were identified from Humana claims data and followed for 12 months. Those with evidence of prior AF diagnosis, valvular heart disease, or transient AF were excluded. Exposure to OACs was identified by prescription claims for dabigatran, apixaban, rivaroxaban or warfarin. Provider guideline adherence included OAC initiation, renal testing for dosing and prescribing OACs to patients with end-stage renal disease. Patient guideline adherence included medication adherence, i.e., proportion of days covered (PDC) ≥ 0.8, and INR monitoring for warfarin. Provider/patient scores were calculated as the proportion of components in compliance with guideline recommendations. Demographic and clinical factors associated with guideline adherence were examined via logistic regression.

RESULTS: The study population (N=24,923) included 2,743 patients with CHA2DS2-VASc<2 (lower stroke risk) and 22,180 with a CHA2DS2-VASc≥2 (higher stroke risk). Among patients with higher stroke risk, 52% (n=11,428) were not treated with OACs, of which 37% (n=4,172) were not contraindicated based on claims. The untreated group had more comorbidities and higher bleeding risk than the treated group at baseline. Mean provider adherence score was 31%, primarily due to low renal testing rates among patients prescribed OAC. Patient medication adherence was high, with 73% reporting PDC≥0.8. The factors that predicted guideline adherence included geographic region, select comorbidities, use of non-OAC medications, and one or more baseline office visits.

CONCLUSIONS: Results suggest overall adherence to guidelines was suboptimal. Higher comorbidity complications and bleeding risk may confound clinical decision-making associated with recommended OAC use in NVAF patients.

SPONSORSHIP: Bristol-Myers Squibb and Pfizer.

I7 Budget Impact Analysis of One-Time Screening for Atrial Fibrillation

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BACKGROUND: Anticoagulant therapy (OAC) is effective at reducing the risk of stroke in patients with atrial fibrillation (AF), but the potentially asymptomatic nature of AF means that many cases remain undetected and untreated. Screening for AF and subsequent anticoagulation can lead to fewer strokes and better quality of life.

OBJECTIVE: To estimate the budget impact of an AF screening program in the United States (U.S.) compared to the status quo (no systematic screening).

METHODS: A Markov cohort model was used to compare outcomes of patients screened for AF versus no systematic screening, in terms of thromboembolic and major bleeding events and consequent medical costs (in 2016 USD). We assumed that patients would be screened once at age 75 with a handheld electrocardiogram (ECG) device that records a single lead ECG twice daily and upon symptoms over 14 days. The prevalence of undiagnosed AF detected by screening was assumed to be 3% as observed in the STROKESTOP trial (NCT01593553); risks of clinical events in AF patients were obtained from the ARISTOTLE trial (NCT00412984) and published meta-analyses. The model assumed that patients with AF received apixaban. Budget impact over five years was evaluated from the perspective of a hypothetical U.S. payer with one million members with the U.S. general population age distribution. We assumed that 0.67% of plan members would turn 75 and become eligible for screening each year, and that plan membership would grow by 0.68% per year, based on U.S. Census Bureau monthly residential population estimates for 2016 and 2017.

RESULTS: On average 6,761 plan members became eligible for screening every year. Screening detected 1,040 additional AF cases (out of 33,805 screened persons) and avoided 71 ischemic strokes; assuming all cases receive OAC, treatment led to 16 additional major bleeds over 5 years. Over 5 years, screening was projected to cost $5.2 million; additional OAC usage and major bleed events led to an increase in costs by $10 million and $204,000 respectively; and a decrease in systemic embolism and ischemic stroke events reduced costs by $72,000 and $1.4 million respectively, resulting in an overall budget impact of $13.6 million. The average budget impact per member per year was $2.69 ($0.22 per member per month).

CONCLUSIONS: This analysis suggests that a potential AF screening program (once per lifetime at age 75) has a modest budget impact relative to its clinical benefits.

SPONSORSHIP: Pfizer and Bristol-Myers Squibb.

I16 Comparison of Costs Among VTE Patients Initiating Apixaban or Warfarin in the U.S. Medicare Population

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BACKGROUND: The economic burden of venous thromboembolism (VTE) ranges between $13.5 and $27.2 billion per year in the United States. Direct oral anticoagulants have emerged to treat VTE and have comparable efficacy to warfarin, with limited need for routine

monitoring. The AMPLIFY randomized clinical trial demonstrated that apixaban was associated with significantly lower major bleeding (MB) compared to warfarin for VTE.

OBJECTIVE: To compare all-cause, MB-related, and recurrent VTE-related healthcare costs of patients treated with warfarin vs. apixaban from a payer perspective.

METHODS: Using 100% CMS Medicare data, elderly patients prescribed apixaban or warfarin within 30 days following a VTE event (inpatient or ambulatory setting) were selected from September 1, 2014-December 31, 2016. The first apixaban or warfarin prescription claim was defined as the index date. Patients were required to have had continuous health plan enrollment for 6 months and no parenteral or oral anticoagulant use before the index VTE event. All-cause healthcare costs were calculated by combining inpatient and outpatient medical and pharmacy costs. These included costs associated with the hospitalization for the initial MB event or recurrent VTE, as well as subsequent MB or recurrent VTE-related costs in all settings. Propensity score matching (PSM) was used to balance the demographics and clinical characteristics. Generalized linear and two-part models were used to estimate all-cause, MB-, and recurrent VTE-related costs (per patient per month [PPPM]) and costs were adjusted to 2016 U.S. dollars.

RESULTS: In the pre-matched cohort, 25,284 patients initiated warfarin (66.9%) and 12,515 patients initiated apixaban (33.1%). After 1:1 PSM, 11,363 matched pairs of warfarin-apixaban patients were assessed for a mean follow-up time of 4.4 and 4.0. In the matched cohorts, mean age was 78 years, and the mean Charlson comorbidity index score was 2.9. Patients initiating warfarin had significantly higher all-cause ($3,267 vs. $3,033; $P<0.001$) and MB-related costs ($147 vs. $75; $P=0.003$). The recurrent VTE-related medical costs were similar among warfarin and apixaban patients ($30 vs. $36; $P=0.516$).

CONCLUSIONS: In the elderly Medicare population, anticoagulant-naïve VTE patients prescribed warfarin incurred significantly higher all-cause and MB-related medical costs compared to those prescribed apixaban.

SPONSORSHIP: Pfizer and Bristol-Myers Squibb.

I17 A Retrospective Database Analysis Evaluating the Relationship Between Pharmacy Quality Alliance Cholesterol Medication Adherence Measure Performance and Economic Outcomes for Commercially Insured Patients

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BACKGROUND: Poor medication adherence is linked to increased morbidity, mortality and healthcare costs. The Pharmacy Quality Alliance (PQA) created measures to evaluate medication adherence for chronic drug therapies. The impact of these measures on healthcare use and costs has not been assessed.

OBJECTIVE: To determine the relationship between PQA adherence measure performance and economic outcomes (use and costs) for commercially insured patients using statin medications.

METHODS: This one-year retrospective study used a cohort of eligible individuals from the Truven Health MarketScan Research Databases (2009-2015). Generalized linear models with log link and gamma distribution (costs) or negative binomial distribution (use) assessed relationships between adherence (≥80% proportion of days covered) and

healthcare use and costs (adjusted to 2015 U.S. dollars) while adjusting for covariates (e.g., age, gender, Charlson Comorbidity Index). Beta coefficients were used to compute cost ratios (CR) and rate ratios (RR). Cohort characteristics were assessed via t-tests, Wilcoxon rank sum tests, or chi square tests. An alpha level of 0.001 was set a priori. All analyses were conducted using SAS Version 9.4.

RESULTS: A total of 4,450,308 individuals were eligible; of those, 2,757,288 (61.9%) were adherent. All demographic characteristics were different ($P<0.001$) between adherent and non-adherent groups. Multivariable analyses showed adherent patients were associated with: fewer inpatient (RR=0.746, 95% CI=0.739-0.753) but more outpatient visits (RR=1.009, 95% CI=1.007-1.010); and lower inpatient (CR=0.780, 95% CI=0.779-0.782) and total (CR=0.975, 95% CI=0.973-0.977) costs. Adherence was associated with and lower per member per month inpatient costs ($44.90) and total healthcare costs ($18.91) compared to nonadherence.

CONCLUSIONS: Statin adherence was associated with fewer inpatient visits, more outpatient visits, and lower total costs compared to non-adherence.

SPONSORSHIP: Pharmacy Quality Alliance, Merck, and SinfoniaRx.

I18 Real-World Droxidopa and Midodrine Treatment Persistence in Patients with Orthostatic Hypotension

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BACKGROUND: Orthostatic hypotension (OH) is a sustained drop in blood pressure upon standing that can lead to falls, impaired function, and poor quality of life. Neurogenic OH (nOH) is OH due to a neuropathy. Droxidopa and midodrine are approved in the United States to treat symptomatic nOH and symptomatic OH in adults, respectively.

OBJECTIVE: To determine the real world treatment persistence of droxidopa and midodrine in patients with nOH or OH.

METHODS: Retrospective analyses of patients prescribed either droxidopa or midodrine were performed using the Symphony Health Solutions Database (Symphony Health; Conshohocken, PA, USA). Inclusion criteria were: (1) a pharmacy insurance claim in at least 16 consecutive quarters from mid-2014 to 2018 and (2) an active prescription for droxidopa or midodrine of ≥30 days' duration during that period. The primary diagnosis for which these agents were prescribed could not be ascertained from the database. Persistence was defined as the time to the first break in drug coverage of greater than 45 days. Persistence was capped at 365 days to provide an unbiased comparison between midodrine (introduced in 1996) and droxidopa (introduced in 2014) and modeled using Kaplan-Meier survival curves with a log-rank test for significance. Multi-variable hazard ratios were calculated using a Cox proportional hazards model.

RESULTS: Data from 2,305 patients who received droxidopa (54.2% ≥65 years of age; 52.9% women) and 117,243 patients who received midodrine (46.7% ≥65 years of age; 57.6% women) were included. Patient diagnoses in the droxidopa and midodrine groups included Parkinson disease (30.1% and 6.0%, respectively) and cardiovascular disease (58.6% and 61.6%, respectively). Of the patients with Parkinson disease, 19.2% and 4.3% in the droxidopa and midodrine groups (respectively) had comorbid cardiovascular disease. Median (95% CI) persistence was significantly longer in the droxidopa cohort vs. the midodrine cohort (303 [274-325] vs. 172 [169-176] days; $P<0.0001$). After adjustment for confounding factors, patients on droxidopa were 24.7% more likely to be persistent (remain on their medication) than patients on midodrine ($P<0.0001$).

CONCLUSIONS: In this real-world data analysis, patients using droxidopa were more likely to remain on treatment than patients on midodrine.

SPONSORSHIP: Lundbeck.

J00-J99 Diseases of the Respiratory System
(e.g., Asthma, COPD, Rhinitis, RSV)

J1 Medicare Savings Resulting from Reductions in Prevalence of Respiratory Tract Infections Among the Elderly

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BACKGROUND: Respiratory tract infections (RTIs, including upper RTI, lower RTI, influenza-like illness and community-acquired pneumonia) pose substantial morbidity and mortality risks among people aged ≥65 years; particularly people with asthma and aged ≥85. However, little is known about the burden of RTIs among these patients.

OBJECTIVE: To estimate the prevalence of RTIs, describe the excess economic burden of RTIs (from Medicare perspective), and estimate the value of a reduction in RTI prevalence among Medicare enrollees aged (a) 65-84 years with asthma and (b) ≥85 years.

METHODS: We used claims data for a 5% random sample of Medicare enrollees. For each cohort (i.e., aged 65-84 with asthma and ≥85), the prevalence rate was defined as the proportion of enrollees with ≥1 month of Medicare eligibility who also had ≥1 RTI diagnosis during influenza season (10/2014-4/2015). Excess economic burden was estimated among subsets of RTI patients enrolled in Medicare for 12 months before (baseline) and 12 months after the first RTI claim (index date). Propensity score models were used to match patients in these cohorts to control patients with similar demographics, comorbidities, and healthcare resource use (HRU), but no RTI between 10/2014-4/2015. Patients with an RTI during baseline were excluded from the analysis. All-cause HRU and costs (2018 USD) during the 12 months post-index were compared separately across 32,133 matched pairs for 65-84 years old with asthma and 23,096 matched pairs for those aged 85+.

RESULTS: The prevalence of RTIs in the 2014-2015 flu season was 23.4% among patients 65-84 years old with asthma and 32.6% among those aged 85+. Relative to matched control patients, RTI patients had significantly ($P < 0.01$) higher rates of hospitalizations (65-84 with asthma: 29.9% vs. 16.4%; 85+: 39.5% vs. 20.3%), emergency department use (65-84 with asthma: 47.8% vs. 33.6%; 85+: 58.4% vs. 42.4%), and total medical costs (65-84 with asthma: $18,461 vs. $11,375; 85+: $22,097 vs. $12,557) during the 12-month follow-up period.

CONCLUSIONS: Approximately 1 in 4 Medicare enrollees aged 65-84 years with asthma and 1 in 3 enrollees aged ≥85 years are predicted to have an RTI during influenza season.The annual HRU and total medical costs for elderly patients with RTIs are nearly twice as high as matched controls with no RTIs. These findings suggest that reductions in RTI prevalence among the elderly could result in substantial savings to Medicare (e.g., a 25%-65% decrease in RTI prevalence could reduce medical costs by $558-$1,502 per Medicare enrollee per year).

SPONSORSHIP: resTORbio.

J6 Impact of Omalizumab on Work Absenteeism and Productivity in Asthma: Results from PROSPERO

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BACKGROUND: Asthma, a chronic and heterogeneous condition, negatively affects work-related productivity and daily activities. From 2008-2013, asthma-related absenteeism in the U.S. was reported to be >8.7 million workdays; the estimated economic burden was $1.9 billion. Disease burden and absenteeism/productivity loss are greater in patients with more severe uncontrolled asthma.

OBJECTIVE: To understand changes in work absenteeism/productivity in patients treated with omalizumab in a real-world setting.

METHODS: PROSPERO was a U.S.-based, 48-week, single-arm, open-label, observational study in patients (≥ 12 years) with allergic asthma. Employment data was collected at baseline. The Work Productivity and Activity Impairment Questionnaire (WPAI-Asthma) was administered at baseline, 6 and 12 months. The WPAI-Asthma captures data in 4 domains, including absenteeism (% of work missed), presenteeism (% of time with reduced productivity while working), overall work impairment (absenteeism and presenteeism) and activity impairment (not limited to work).

RESULTS: A total of 806 patients with moderate-severe asthma were enrolled in PROSPERO. At baseline, 48% of adults (N = 737) reported being employed full-time. Improvements in productivity were seen for all 4 domains. Absenteeism decreased from 7.7% at baseline to 3.6% by study end (3.1 hours and 1.5 hours missed/week [assuming a 40-hour work week], respectively). Presenteeism improved from 31.2% at baseline to 15.3% at study end. Overall work impairment decreased from 33.5% at baseline to 17.3% at study end. Activity impairment decreased from 47.7% at baseline to 25.7% at study end. Overall safety results for this study are available in Chipps et al. JACI 2017;139(2):AB8.

CONCLUSIONS: In a real-world setting of patients with allergic asthma, treatment with omalizumab was associated with improvements in work absenteeism, presenteeism, overall work impairment, and activity impairment. These findings highlight the significant impact of asthma on work productivity, and the potential role of omalizumab in improving these work-related outcomes.

SPONSORSHIP: Novartis Pharma AG and Genentech.

J7 Economic Burden of Asthma for Patients with and Without Exacerbations Who Received GINA Step 4/5 Therapy: U.S. Administrative Claims Database Analyses

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BACKGROUND: The economic burden of asthma is considerable.

OBJECTIVE: To provide updated health care costs of patients with asthma receiving medium-to-high-dosage ICS/LABA (GINA Step 4/5 therapy [G4/5]), with and without exacerbations and/or high rescue medication use (Ex/R).

METHODS: U.S. administrative claims from the IBM MarketScan Research Databases were evaluated for patients with asthma aged ≥ 12 years with records between 1/1/2012-12/31/2015. Patients were indexed on their earliest medical claims for asthma and were required

to have had evidence of ≥2 years of continuous eligibility. G4/5 classification required ≥1 medium-or high-dosage ICS/LABA claim, ≥1 omalizumab claim, or systemic corticosteroid supply covering ≥50% of the 12-month baseline period. G4/5 with Ex/R classification followed ERS/ATS criteria for severe uncontrolled asthma, modified for claims data. Health care costs were measured during the 12-month post-index period and are reported in 2017 USD.

RESULTS: The study identified 605,614 total patients with asthma; 92,027 (15.2%) receiving G4/5 therapy, and 37,220 (6.1%) with G4/5 and Ex/R. Compared with non-G4/5 patients, G4/5 patients incurred greater total ($15,244 vs. $10,860) and asthma-related ($3,853 vs. $1,670) health care costs during the 12-month follow-up period. G4/5 patients with Ex/R incurred greater total health care costs than G4/5 patients without Ex/R ($18,233 vs. $13,215), and greater asthma-related pharmacy expenditures ($2,160 vs. $327).

CONCLUSIONS: Cost differences between G4/5 and non-G4/5 patients were primarily driven by the sub-group of G4/5 patients with Ex/R, partly because of asthma-related pharmacy expenditures. Future research exploring approaches to minimize and better control exacerbations, which may reduce the economic burden of asthma, is warranted.

SPONSORSHIP: AstraZeneca.

J8 Analysis of Clinical and Financial Outcomes of a Pharmacy Benefit Manager's Respiratory Health Program Intervention in a Commercial Client Population

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BACKGROUND: Respiratory exacerbations can take a toll on patients and the healthcare system. Contributing factors include suboptimal treatment, cost of medications, and exacerbations. Navitus has a respiratory health program that looks at claims data targeting high-risk members who are likely to have an exacerbation in the near future. This is determined using asthma medication ratio (AMR) and COPD treatment ratio (CTR), whose calculations are as follows: # of controller medications divided by the sum of the # of controller medications plus the # of short-acting beta agonist (SABA) rescue inhalers. Research has shown that AMR<0.5 and CTR<0.3, the patient is at risk for future exacerbations.

OBJECTIVE: To determine the clinical and financial impact of mailed interventions to members and prescribers regarding high risk asthma and COPD patients six months after the intervention.

METHODS: A retrospective cohort study was conducted with subjects through a PBM's Respiratory Health Program which identifies members with uncontrolled asthma and COPD at risk for exacerbations through pharmacy claims data and diagnosis codes. Inclusion criteria were AMR<0.5 or CTR<0.3 and at least six fills for rescue medications in the past 12 months. Once identified, intervention letters included a full patient profile listing all rescue and controller medication fills, were sent to members and their prescribers about regimen optimization. A total of 25 members were included in this study, 18 asthma and 7 COPD. Intervention letters were sent on 4/29/18 and data were collected 6 months pre and post intervention from 11/1/17 to 10/31/18.

RESULTS: Repeated analysis of variance with post hoc analysis of significant main effects indicated a significant ($P<0.5$) decrease of 52% (8.05+2.139 to 3.05+2.621) in rescue inhaler use between pre and post intervention. The number of controller medications increased by 46% (1.2 to 1.75). There were no other significant changes clinically. Financially, baseline AMR/CTR are positively correlated with baseline plan cost (0.410) but not with member cost ($r=0.139$). Post

AMR/CTR showed strong correlation with post plan cost ($r=0.885$) and post member costs ($r=0.479$).

CONCLUSIONS: After the intervention, there was a statistically significant decrease in rescue inhaler fills and an increase in controller medication fills. There were no significant changes in plan or member cost though AMR/CTR seemed to be positively correlated with plan cost. Research shows clinical and financial benefits can take up to 5 years to be apparent. Additional follow up is warranted to determine if positive cost correlations continue.

SPONSORSHIP: Navitus Health Solutions.

J9 Association Between Transient Opioid Use and Short-Term Respiratory Outcomes Among Adults with Chronic Obstructive Pulmonary Disease

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BACKGROUND: Patients with chronic obstructive pulmonary disease (COPD) are prone to repeated exacerbations, which are defined as an acute worsening of respiratory symptoms that affect lung functioning, leading to increased mortality, healthcare utilization and costs, and reduced quality of life. Narcotic analgesics are used frequently among adults with COPD. Pharmacological evidence suggests that the adverse effects due to opioid use often manifest in the short-term, often after acute or transient use. However, previous research has only tested the association of opioid use on mortality and healthcare utilization among COPD patients using cohort study designs with lookback periods from 30 to 180 days. Evidence regarding the short-term risk of COPD exacerbation from acute or transient opioid exposure is lacking.

OBJECTIVE: To examine the association of transient opioid use and short-term respiratory exacerbations among adults with COPD.

METHODS: A case-crossover design was used to evaluate the impact of transient risk factors on abrupt outcomes. The study population included enrollees in the Mississippi Medicaid program who were diagnosed with COPD and had a COPD-related exacerbation event during the identification period from July 1, 2013 to December 31, 2017. The frequency and dose of opioid exposure in the seven days prior to the exacerbation were compared to opioid exposure in ten control windows prior to the exacerbation. Adjusted odds ratios (OR) were estimated using conditional logistic regression models to estimate the risk of opioid use on exacerbations after controlling for the use of bronchodilators, corticosteroids, benzodiazepines, and β-blockers.

RESULTS: A total of 1,972 qualifying exacerbation events occurred among 1,354 beneficiaries enrolled between 2013-2017. Overall, opioid exposure in seven days before an exacerbation was significantly associated with acute respiratory exacerbation (OR: 1.81 [95% CI: 1.60-2.05]). Each 25 mg increase in morphine equivalent daily dose (MEDD) was found to be associated with an 11.2% increase in the odds of an acute respiratory exacerbation (OR: 1.11 [95% CI: 1.04-1.20]).

CONCLUSIONS: Transient use of opioids was significantly associated with short-term acute respiratory exacerbation of COPD. Risk of exacerbation increased with MEDD. These findings demonstrate the need to consider more stringent restrictions on opioid use and MEDD levels for beneficiaries with COPD. Readmission prevention programs for patients with COPD also need to include management of opioid use.

SPONSORSHIP: None.

J10 Association of the Healthcare Effectiveness Data and Information Set-Recommended Pharmacotherapy of Chronic Obstructive Pulmonary Disease Exacerbation and Risk of Subsequent Exacerbation

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BACKGROUND: Patients with chronic obstructive pulmonary disease (COPD) often suffer from exacerbations, which are significantly associated with health care utilization. The Healthcare Effectiveness Data and Information Set (HEDIS) recommended two classes of the drugs to manage COPD exacerbation. However, the HEDIS measure is not quite consistent with what was recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD).

OBJECTIVE: To test the association between receiving HEDIS-recommended medication for COPD exacerbation and 30-day re-exacerbation and to compare the therapeutic effects of HEDIS-recommended medications and GOLD-recommended medications.

METHODS: This was a retrospective study using 2014-2016 5% national Medicare claims data. HEDIS specifications were used to identify beneficiaries age >40 years with COPD exacerbation. The first acute COPD exacerbation discharge during Jan 2015 to Nov 2016 was identified as index event. Exacerbations with a previous exacerbation within 30 days were excluded. Beneficiaries receiving HEDIS-listed systemic corticosteroids within 14 days and/or bronchodilators within 30 days post-index were identified. Beneficiaries receiving GOLD-recommended medications including short-acting bronchodilators, long-acting bronchodilators, oral corticosteroids, and inhaled corticosteroids, were also identified in the same period. Logistic regressions were used to examine the associations between HEDIS-recommended medications and 30-day re-exacerbation, as well as GOLD-recommended medications and 30-day re-exacerbation respectively while adjusting for beneficiary demographics, index exacerbation admission type, COPD severity, Elixhauser index, and acute respiratory events.

RESULTS: 8,971 beneficiaries met the inclusion criteria. Among them, 51.48% received HEDIS-listed systemic corticosteroid, and 50.34% received HEDIS-listed bronchodilators following discharge. 6.97% of subjects had a subsequent exacerbation within 30 days after the index. HEDIS-listed systemic corticosteroids were associated with an increased risk of 30-day re-exacerbation (OR: 1.263; 95% CI: 1.052-1.515). HEDIS-recommended bronchodilators were not significantly associated with re-exacerbation (OR: 0.870; 95% CI: 0.714-1.061). Results of GOLD-recommended medications showed that taking long-acting bronchodilators (OR: 0.754; 95% CI: 0.604-0.942) was associated with a significant reduction in subsequent COPD exacerbation.

CONCLUSIONS: The results indicate that current HEDIS measure specifications for managing COPD exacerbation may not be effective in preventing short-term re-exacerbations. There might be a need to incorporate GOLD-recommended medications in the HEDIS measure.

SPONSORSHIP: None.

J11 Effects of Psychological Distress on Medication Utilization in Asthma

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BACKGROUND: Asthma affects more than 300 million people worldwide. In the United States, where it affects more than 26 million people, the incidence of mental health comorbidities, specifically anxiety and depression, is on the rise, but little is known about how such comorbidities affect medication use of specific kind.

OBJECTIVE: To examine the effect of psychological distress (PD) in asthmatics on the utilization of a specific class of drugs, namely reliever medications, and to identify the predictors of overuse of relievers in such individuals.

METHODS: A retrospective, cross-sectional research data, obtained from the Medical Expenditure Panel Survey (MEPS), was utilized to address the study objectives. We analyzed data (2013-2015) on 5307 community dwelling adults diagnosed with asthma, and PD was identified by using Kessler-6 Distress Scale (a score of $\geq$ 13). Use of more than 3 canisters of acute prescription inhalers was defined as overuse of relievers for the purpose of the study. A series of Chi-Square analyses was performed to assess differences in reliever medication use with respect to key demographics and other patient characteristics and to evaluate association between PD and reliever overuse. A Logistic regression (LR) analysis was also performed to identify predictors of overuse of relievers in asthmatics with PD.

RESULTS: Out of 5,307 asthma cases identified, around 12% were found to have symptoms of PD based on the K-6 cut-off score of 13. Compared to those without PD, a higher proportion of asthmatics with PD reported reliever overuse (23.3% vs. 12.2%, $P<0.0001$). In addition, reliever medication use varied in the PD population with respect to key demographic characteristics (age, gender, socioeconomic status, education, race, smoking status, marital status). The LR analysis also showed that females were more likely to overuse asthma reliever medications than males (OR= 2.263, CI= 2.255-2.2343, $P<0.0001$), and smokers were more likely to overuse relievers compared to non-smokers (OR= 2.615, CI= 2.609-2.621, $P<0.0001$).

CONCLUSIONS: Comorbidity of PD in asthma results in over-utilization of reliever medications. Inappropriate medication use can affect asthma treatment plans, compromise patient's quality of life, further contributing to the rising clinical, social and economic burden of asthma. Timely intervention and active monitoring of pharmacotherapy are necessary in PD to prevent wasteful utilization and medication non-adherence in Asthma.

SPONSORSHIP: None.

J12 Assessing Economic Burden and Hospitalization Among Asthma Patients in the U.S. Veterans Health Administration Population

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BACKGROUND: Asthma is a chronic condition that affects quality of life, work productivity, and health care resource use, and may result in death. Measuring the current economic burden of asthma provides important information on the impact of asthma on society.

OBJECTIVE: To assess the health care costs and predictors of hospitalization among patients with asthma in the U.S. Veterans Health Administration (VHA) population (April 1, 2013-MArch 31, 2018).

METHODS: Adult patients with $\geq$1 inpatient diagnosis (first diagnosis=index date) for asthma (*International Classification of Disease, Ninth Revision, Clinical Modification* code 493; ICD-10-CM: J45) during the identification period (April 1, 2014-March 31, 2017) were included from the VHA population. Patients without asthma diagnosis, but with the same age, sex, race, and index year as an asthmatic patient were identified as controls. The index date for controls was randomly selected to minimize bias. Health care costs and hospitalization

during the 1-year follow-up period were compared among 1:1 matched patients with and without asthma. Predictors of hospitalization were examined using logistic regression. Odds ratio (OR) and 95% confidence interval (CI) were reported.

RESULTS: After matching, 264,853 patients were included in each group. The mean age (standard deviation) was 60.3 (18.0) years; 84.0% were men and 67.8% were white. Compared to control patients, those with asthma had a higher mean Charlson comorbidity index (CCI) score (1.4 vs. 0.9; $P < 0.0001$), higher proportion of patients with ≥1 hospitalization (9.8% vs. 3.0%; $P < 0.0001$), and incurred higher inpatient ($3,412 vs. $1,082), outpatient ($5,384 vs. $2,590), pharmacy ($1,166 vs. $602), and total costs ($9,962 vs. $4,274; all $P < 0.0001$). The logistic regression results showed that the likelihood of hospitalization was significantly higher among those with higher CCI scores (OR: 1.3, 95% CI: 1.33-1.34). Patients aged 55-64 years had higher odds of hospitalization (OR: 1.4, 95% CI: 1.34-1.4) compared to the other age groups. Higher odds of hospitalization were found among black patients versus other races (OR: 1.4, 95% CI: 1.3-1.5), and among men compared to women (OR: 1.1, 95% CI: 1.0-1.1).

CONCLUSIONS: Patients diagnosed with asthma had significantly higher hospitalization and economic burden than those without asthma. Higher CCI score, age 55-64 years, male sex, and black race were significant positive predictors of hospitalization.

SPONSORSHIP: None.

J15 Real-World Incidence and Cost Assessment of Pneumonitis During Chemoradiotherapy for Unresectable Locally Advanced, Non-Small Cell Lung Cancer Patients

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BACKGROUND: Chemoradiation (CRT) is the standard of care for patients (pts) with unresectable, stage III locally-advanced non-small cell lung cancer (LA-NSCLC). Pneumonitis (PN) is one potential complication of CRT which at high severity grades is associated with significant morbidity and mortality. Real-world data on PN incidence or associated costs is lacking.

OBJECTIVE: To estimate the incidence of PN post-CRT initiation for NSCLC pts and to compare treatment costs between PN and non-PN pts.

METHODS: LA-NSCLC pts who received CRT between 01/01/2013-06/30/2017 were selected from the Symphony Integrated Dataverse claims database. LA-NSCLC pts were required to have coverage during the 12-month pre and post treatment periods. Pts were also required to not have any history of surgical resection and no secondary malignancies at any time during the study period. CRT definition: ≥5 radiation claims within 45 days pre- or post-chemo start. PN events were identified based on the presence of non-diagnostic medical codes.

RESULTS: 5,979 LA-NSCLC pts treated with CRT were identified; the cumulative incidence of PN was 12.4% (n = 742). The PN incidence rate was 126.4 cases/1,000 months post CRT (95% CI: 117.4-135.8). No significant differences were observed in the demographic characteristics between PN and non-PN pts. Mean follow-up from CRT was longer (26.4 mo vs. 23.7 mo) among PN pts. PN pts had a higher baseline Charlson comorbidity score at CRT initiation (5.85 vs. 5.13).

CONCLUSIONS: PN was observed to occur in 12.4% of LA-NSCLC pts within 12 months of receiving CRT. Resource utilization was more frequent among PN-treated pts and represented a 7.1% PPPM total cost increase compared to non-PN pts.

SPONSORSHIP: AstraZeneca.

K00-K93 Diseases of the Digestive System
(e.g., Crohn's Disease, IBD, IBS)

K1 Health-Related Quality of Life, Work Productivity, and Indirect Costs Among Patients with Diabetic Gastroparesis

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BACKGROUND: Diabetic gastroparesis (DG) is a complication of long-standing diabetes mellitus (DM) estimated to affect 5% and 1% of type 1 and type 2 DM patients, respectively. Symptoms include abdominal pain, nausea, vomiting, postprandial fullness, early satiety, and bloating, which can impact health-related quality of life (HRQoL) and work productivity. Data on the humanistic impact of DG are limited.

OBJECTIVE: To assess the impact of DG on HRQoL, work productivity, activity impairment, and indirect costs among a sample of the U.S. population.

METHODS: Adult respondents were identified from the 2017 National Health and Wellness Survey, a self-administered, internet-based survey. DG patients self-reported a diagnosis of DM (type 1 or 2) and gastroparesis. Controls were those with no reported diagnosis of DM or gastroparesis. EQ-5D-5L index, SF-36v2 mental and physical component summary (MCS, PCS; range: 0-100), and SF-6D (health utility; range 0-1) assessed HRQoL. Work Productivity and Activity Impairment Questionnaire: General Health (WPAI:GH) evaluated absenteeism, presenteeism, and daily activity impairment (higher percentages = greater impairment). Mean annualized indirect costs were estimated based on overall work productivity loss (absenteeism + presenteeism). A propensity scoring approach was used to create a 1:1 match between DG patients and controls. Generalized linear models compared DG patients to matched controls, adjusting for variables that remained unbalanced between groups post-match (i.e. age, ethnicity, exercise, alcohol consumption, income, body mass index, geographic region).

RESULTS: 236 respondents were included (118 DG patients and matched controls). After regression adjustment, DG patients had significantly lower HRQoL vs. matched controls based on EQ-5D-5L index (0.65 vs. 0.71; $P = 0.010$), MCS (40.75 vs. 43.66; $P = 0.045$), PCS (37.58 vs. 43.64; $P < 0.001$), and SF-6D (0.59 vs. 0.65; $P = 0.001$) mean scores. DG patients reported 2.02 times greater presenteeism (mean: 31.02% vs. 15.37%; $P = 0.029$), 2.14 times greater overall work impairment (mean: 38.29% vs. 17.92%; $P = 0.023$), and 1.29 times greater activity impairment (mean: 50.34% vs. 39.04%; $P = 0.006$) vs. matched controls. Estimated total indirect costs were nearly 6 times higher for DG patients vs. matched controls (mean: $15,330.09 vs. $2,573.97; $P = 0.002$).

CONCLUSIONS: Compared with matched controls, DG patients have significantly lower HRQoL, greater impairments in work and daily activities, and higher indirect costs, imposing a considerable burden on patients and employers.

SPONSORSHIP: Allergan plc.

K2 Healthcare Resource Utilization and Total Costs of Care Among Patients with Esophageal Cancer: An Administrative Claims Analysis

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BACKGROUND: There is a paucity of data on the economic burden of advanced and metastatic (adv/met) esophageal cancer (EC) in the U.S. Furthermore, with rapidly evolving treatment landscape of EC, little is known on the appropriate timing and most effective sequence of agents in the care of patients.

OBJECTIVE: To assess real-world treatment patterns, healthcare resource utilization (HCRU), and costs by line of therapy (LOT) to understand the treatment landscape in EC patients.

METHODS: Patients aged ≥ 18 years with adv/met EC from January 1, 2012-June 30, 2017 in the HealthCore Integrated Research Database (HIRD) were selected. The index date was the first systemic treatment. Patients with other cancers in the study period, with pregnancy, gastrectomy or esophagostomy three months before the index date, and < 1-month follow-up were excluded. Costs were calculated as per patient per month (PPPM) basis.

RESULTS: Of 436 patients treated with first line (1L), 25.5% received second line (2L) and 6.9% received third line (3L). Median age was 64 years, and 77.1% were males. The median treatment durations of L1 and L2 were 71 and 76 days, respectively. In 1L, most frequent regimens were Carboplatin (CAR)+paclitaxel (PAC; 29.6%), CAR (20.4%), and 5-fluorouracil (FLU)+oxaliplatin (OXA; 11.5%). Of the 40 uniquely observed regimens in 2L, the most commonly used were FLU+OXA (12.6%), CAR+PAC (9.0%) and bevacizumab (BEV; 6.3%). No clear standard therapy emerged in 3L. The mean total all-cause healthcare cost at follow-up was $11,433 PPPM allocated as follows: systemic therapy and related services, 22.6%; hospitalizations/ED, 35.6%; outpatient services, 39.1%; and pharmacy, 2.7%. All cause-healthcare costs were the highest in 1L. The frequency of hospitalization was high across all LOTs (30% to 40%). Hospice HCRU increased over time from 3% in 1L to 10% in 3L.

CONCLUSIONS: Fewer than 26% of patients received subsequent therapy after 1L, and the median durations were less than 80 days for both 1L and 2L treated patients. These results highlight the unmet need and considerable economic burden in managing metastatic EC, suggesting more effective treatments are needed.

SPONSORSHIP: Bristol-Myers Squibb.

K4 Prevalence of Crohn's Disease (CD) and Ulcerative Colitis (UC), Biologic Therapy Use, and Total Medical and Pharmacy Claims Expense Associated with CD and UC in a Population of 15 Million Commercially Insured Members

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BACKGROUND: 5 biologic treatments (BT) have FDA approval for Crohn's disease (CD) and 4 for ulcerative colitis (UC) . There is interest in current, real-world total prevalence of CD and UC, BT rates and health care costs.

OBJECTIVE: To determine CD and UC prevalence, percentage treated with BT, and total pharmacy (Rx) and medical claims expense per member incurred between July 2017 and June 2018 (12 months) compared with matched members without CD or UC.

METHODS: From 15 million commercially insured members, we identified individuals continuously eligible July 2014 to June 2018 (4 years) and age < 65 years. Based on validated criteria, CD and UC were defined as all who had ≥ 5 medical claims and majority of 10 most recent coded claims with a diagnosis code for CD or UC. We selected two random samples of members, not-CD and not-UC, from all members with no claims for CD or UC, matched 5:1 with CD and UC by sex, age, and plan. All Rx claims were categorized by NDC,

medical outpatient by HCPCS, inpatient by primary diagnosis codes. Claims cost is the sum of allowed amounts without adjustment for rebates or coupons.

RESULTS: Of 4.12 million continuously eligible members, 8,652 (0.21%, mean age 44 yrs) were classified as CD and 7,977 (0.19%, mean age 46 yrs) as UC. 4,258 (49.2%) of CD and 2,021 (25.3%) of UC members had a claim for a biologic. For UC and CD members with any BT, mean total cost of care, BT cost, and all other cost was: CD $80,236, $59,048 (73.6%) and $21,187 (26.4%); UC $75,157, $53,698 (71.4%) and $21,459 (28.6%). We selected 43,260 matched not-CD and 39,885 not-UC members. Mean total cost of care for all study members was $50,514 CD, $33,691 UC, $7,916 not-CD and $8,186 not-UC, for an excess cost of $42,598 for CD and $25,505 for UC. Of the excess cost: 68.2% of CD and 53.3% of UC was for BT, 6.7% of CD and 18.4% of UC was for non-BT Rx, 14.9% of CD and 16.1% of UC was for medical outpatient, 10.2% of CD and 12.2% of UC was for inpatient. During the 12 months, 448 (5.2%) of CD and 237 (3.0%) of UC members had a CD or UC hospitalization, respectively; these members had a mean non-BT cost of $75,239 CD and $90,845 UC and accounted for 18.2% of the total non-BT cost of CD and 13.4% of UC.

CONCLUSIONS: In this large commercial population, CD and UC each have a prevalence of 2 per 1000 members. BT was twice as common among members with CD (49%) as among UC (25%). BT accounts for the vast majority of either CD or UC total cost. Members hospitalized for CD or UC account for a disproportionate share of non-BT cost. BT value needs to be assessed from a societal perspective and with a long time horizon.

SPONSORSHIP: Prime Therapeutics.

K5 Association Between Hospitalization for Crohn's Disease or Ulcerative Colitis and Biologic Drug Therapy Adherence

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BACKGROUND: Clinical trials have shown hospitalization risk reduction in moderate to severe Crohn's disease (CD) or ulcerative colitis (UC) with biologic therapy (BT). Little is known of the real-world CD or UC hospitalization rate or difference in rate among BT adherent and non-adherent members.

OBJECTIVE: To assess the association between BT adherence and hospitalization for UC and CD members, in a 15 million commercially insured population.

METHODS: CD and UC members were defined as continuously eligible July 2014 to June 2018 (4 years) with ≥ 5 medical claims and majority of 10 most recent coded claims with a CD or UC diagnosis, respectively. Members were divided into any (Hosp group) or no (NoHosp group) inpatient claim with CD or UC as primary diagnosis. Hosp were assigned earliest such claim date as the member's index date and limited to those with index date > August 2015. NoHosp members were each randomly assigned one of the Hosp index dates. For all Hosp and NoHosp who had any BT in the 12 months preceding index date, BT proportion of days covered (PDC) during these 12 months was determined from claim dates and days supply on Rx or assumed as the lesser of the number of days to next claim or recommended dosing interval for medical BT claims; adherent was defined as PDC > 80%. Odds ratio (OR) was calculated as Hosp divided by NoHosp odds of adherent. Number need to treat (NNT) to avoid 1 hospitalization was estimated from absolute risk reduction (ARR) associated with BT adherence.

RESULTS: In 4 years, 1,386 of 8,652 (16.0%) CD members and 856 of 7,977 (10.7%) UC members had one or more hospitalization for CD or UC (Hosp group); the remaining 7,266 CD and 7,121 UC had no

hospitalizations (NoHosp group). Of Hosp, 917 CD and 555 UC members had index date > August 2015; 431 of these 917 (47.0%) CD and 124 of 555 (22.3%) UC had a biologic in the 12 months before index date of whom 209 (48.6%) and 56 (45.2%) were adherent. Of NoHosp, 2,929 of 7,266 (40.3%) CD and 1,314 of 7,121 (18.5%) UC had a biologic in the 12 months before index date; 1,969 (67.2%) and 858 (65.3%) were adherent. OR was 0.46 (95% confidence limits [CL] 0.37, 0.56, P < 0.001) CD and 0.44 (95% CL 0.30, 0.64, P < 0.001) UC. ARR associated with adherence was 9.2% for CD and 6.9% for UC, for an NNT of 10.9 and 14.6, respectively.

CONCLUSIONS: Among CD or UC members treated with BT, those who were adherent to therapy for 12 months had approximately 2-fold associated lower odds of hospitalization. These findings can be used for managed care clinical program justification and value based contracting.

SPONSORSHIP: Prime Theraputics.

K6 Greater than Expected Dosing Assessment Among Targeted Immunomodulators in Management of Inflammatory Bowel Disease

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BACKGROUND: As targeted immunomodulators (TIMs) have flexible dosing options, understanding real-world dose escalation provides insight into the true cost of treating inflammatory bowel disease (IBD) patients to U.S. payers.

OBJECTIVE: To assess the prevalence and magnitude of greater than expected dosing (GTED) for IBD therapies including adalimumab (ADA), infliximab (IFX), vedolizumab (VDZ), ustekinumab (UST), certolizumab pegol (CTZ), and golimumab (GOL).

METHODS: Using the Source Healthcare Analytics database, a national commercial claims database with over 1 billion pharmacy and medical claims, IBD patients newly treated with ADA, IFX, VDZ, UST, CTZ, and GOL between July 2015 and June 2017 were identified. Patient utilization of these biologics was tracked for 12 months following initiation. All included patients had at least 2 diagnoses for ulcerative colitis or Crohn's disease with at least 1 occurring in the last 12 months and had at least 5 claims for a biologic of interest. GTED was defined as an increase of at least 30% in the average daily dose (ADD) relative to the expected daily dose (EDD) on two consecutive maintenance claims. GTED magnitude was determined by calculating GTED patient's ADD across all non-induction dose claims and comparing it to EDD. GTED prevalence and magnitude were used to quantify the equivalent patient treatment rate representing the number of patients per 100 that could be treated with EDD given observed GTED.

RESULTS: A total of 1,966 ADA; 2,406 IFX; 1,745 VDZ; 472 UST; 285 CTZ; and 154 GOL patients met eligibility criteria and are included in the study. GTED was observed in 27.5%, 39.4%, 22.7%, 21.6%, 20.0%, and 14.3% of IBD patients on ADA, IFX, VDZ, UST, CTZ, and GOL respectively. At 39.4%, IFX patients dose escalated more often than any other therapy (P < 0.001 for all therapies). The average observed dose escalation for GTED patients was 58.7% (ADA), 70.2% (IFX), 62.0% (VDZ), 131.4% (UST), 50.2% (CTZ), and 45.4% (GOL). At 131.4% of EDD, UST GTED patients dose escalated by a greater magnitude than all other therapies (P < 0.001 for all therapies). At 128, the calculated patient equivalence was highest for IFX and UST as compared to 116, 114, 110, and 106 for ADA, VDZ, CTZ, and GOL, respectively.

CONCLUSIONS: GTED occurs among IBD patients treated with all examined TIMs with varying degrees of prevalence and magnitude. Payers need to understand the impact of real-world utilization on patient treatment and cost.

SPONSORSHIP: AbbVie.

K7 Infliximab Costs and Reasons for Treatment Discontinuation Among Patients with Crohn's Disease Receiving Treatment in U.S. Hospitals: 2012-2015

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BACKGROUND: Crohn's Disease (CD) is a chronic autoimmune disease associated with substantial health and economic burden. Infliximab (IFX) is proven to be safe and efficacious for CD patients. However, it is underutilized potentially due to high cost. Understanding current cost of IFX treatment and causes of treatment discontinuation may help clinicians and pharmacists better serve CD patients in need of IFX treatment.

OBJECTIVE: To assess IFX treatment costs and reasons for treatment discontinuation among CD patients from 483 U.S. hospitals during 2012-2015 using Premier Healthcare Database, a census of patients treated in hospital inpatient and outpatient settings.

METHODS: A retrospective cohort study was conducted in eligible patients: aged ≥ 18 years; had principal/secondary diagnosis of CD and ≥ 1 IFX charge at index hospital encounter (IE); had ≥ 1 outpatient visit during 12-month look-back and ≥ 2 outpatient visits during 12-month follow-up. IFX use at IE was classified as New start (no IFX during look-back) and Continued (had IFX during look-back). All costs were adjusted to 2016 U.S. dollars. Cox proportional hazard modeling was used to assess predictors of IFX discontinuation without switching to other IV biologics adjusting for confounders. Linear regression was used to examine time trend of IFX cost.

RESULTS: Overall, 6,934 CD patients (4,278 New start, 2,656 Continued) were analyzed. IFX New start and Continued patients were comparable in most characteristics at IE except that a higher percent of New starters had private insurance (40.2% vs. 36.5%) and were treated as inpatient (16.7% vs. 3.4%). Average annual IFX cost during follow-up was estimated to be $19,033 and was higher among Continued and patients in Midwest, Northeast and West regions. From 2012 to 2015, average annual IFX cost per patient increased $755 per year. New starters were more likely to discontinue IFX treatment than Continued (48.2% vs. 27.1%). Multivariable analysis showed that risk of IFX discontinuation was associated with younger age, New start, public or no insurance at IE, losing insurance coverage, and having severe infections during follow-up. All reported results had P values < 0.05.

CONCLUSIONS: Annual IFX treatment cost was high and it increased 4% yearly. IFX New start, loss of insurance coverage and severe infections are strong predictors of IFX discontinuation. Clinicians and pharmacists may need to monitor patients under IFX treatment more closely especially new starters to ensure that they benefit most from IFX and avoid unnecessary discontinuation.

SPONSORSHIP: Merck.

K11 Treatment Persistence and Costs in New Initiators of Linaclotide and Lubiprostone

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BACKGROUND: Linaclotide (LIN) and lubiprostone (LUBI) are two FDA-approved therapies for the adult treatment of IBS-C and CIC. Little is known about treatment persistence and economic outcomes associated with LIN and LUBI in a real-world setting.

OBJECTIVE: To compare real-world persistence and costs associated with LIN or LUBI treatment.

METHODS: Commercially insured (Comm) and Medicare Part D (MAPD) patients (≥ 18 years) with ≥ 1 claim for LIN or LUBI between June 1, 2013 and September 30, 2017 were identified in Truven Health MarketScan database. Index date was the first LIN or LUBI claim in the presence of ≥ 6 months of continuous enrollment pre-index. The first treatment episode was defined as consecutive prescriptions of the index medication with ≤ 60-day gap between fills. Treatment data were considered censored if the patient unenrolled from the health plan or the end of the study period was reached during the episode. Persistence was evaluated using the Kaplan-Meier estimator and Cox proportional hazards to estimate relative rates of discontinuation for LIN vs. LUBI controlling for age, sex, region, and comorbidities. Costs were adjusted to 2017 USD and compared using generalized linear models controlling for age, sex, region, comorbidity score, and 6-month pre-index costs. Robustness of cost analyses were evaluated by applying alternative methods of estimating heavily censored cost data.

RESULTS: A total of 110,523 LIN (84% Comm) and 46,642 LUBI (76% Comm) patients were identified for analysis. Mean age was 46.1 years and 75.7 years for Comm and MAPD patients, respectively. Majority of patients, 84.9% (Comm) and 63.6% (MAPD), were female. After one year of follow-up, 18% of patients (Comm & MAPD) who initiated LIN remained on treatment compared with 12% of Comm and 15% of MAPD patients who initiated LUBI. Over a 4-year follow-up, LUBI patients were significantly more likely to discontinue treatment compared to LIN patients (Comm: HR = 1.27, $P < 0.0001$; MAPD: HR = 1.15, $P < 0.0001$). After adjusting for baseline characteristics, monthly insurance costs during treatment were an estimated 5% ($P < 0.001$) and 2% ($P = 0.42$) lower for LIN vs. LUBI among Comm and MAPD patients, respectively. Alternative statistical analysis of costs revealed small but statistically non-significant differences between LIN and LUBI cohorts.

CONCLUSIONS: LIN was associated with significantly lower rates of discontinuation across Comm and MAPD cohorts versus LUBI in this population. Higher LIN persistence was not associated with an increase in medical, pharmacy or total costs of care in comparison to LUBI.

SPONSORSHIP: Allergan plc and Ironwood Pharmaceuticals.

K13 Medication Regimen After Hospitalization for Hepatic Encephalopathy and Its Impact on Hospital Readmissions in Medicare Beneficiaries

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BACKGROUND: Chronic liver disease affects 5.5 million U.S. patients and most cirrhotic patients develop hepatic encephalopathy (HE) manifesting in neuropsychiatric and motor abnormalities. HE is associated with frequent recurrence requiring hospitalization, poor prognosis, and increased medical costs. Studies investigating optimizing transition of care, in this case, drug regimens after HE hospitalization in a real-world setting are scarce.

OBJECTIVE: To evaluate drug regimens and hospital readmissions for Medicare Advantage Plan (MAP) patients after HE hospitalization.

METHODS: A retrospective cohort study was conducted using claims data from a Texas MAP from 2011 to May 2018. Of patients who had an HE hospitalization, three separate cohorts were constructed for those continuously enrolled for 1, 3 and 6 months post the index hospital discharge. Medication exposure was evaluated as a refill within 30 days of the index discharge and the association between medication use and hospital readmission at 30 and 90 days were evaluated in each study cohort using multivariable logistic regression after adjusting for age, sex, low-income subsidy status, and CMS risk score.

RESULTS: There were 347 patients hospitalized for HE and more than half of them were not prescribed a guideline recommended medication post-discharge (54.5%). Among 184 patients with 30-day follow up enrollment and a refill or post-discharge outpatient visit, no medications were prescribed in 67 (36.4%) patients. Of the 184 patients, 43.5% received lactulose, 6.5% patients were on rifaximin or neomycin and 13.6% patients had a combination. At 30 days, similar admission rates (~9%) were observed among those with and without medications. At 90 days, 14.4% patients with medication and 20% patients with no medication were readmitted. There was various attrition at 180 days between the medication and no medication groups with more patients lost to follow up in the no medication group. Results of the logistic regression for readmission at 30 days (OR: 0.96 [95% CI: 0.33-2.80]), 90 days (OR: 0.61 [95% CI: 0.25-1.47]) and 180 days (OR: 1.74 [95% CI: 0.67-4.54]) were not significant.

CONCLUSIONS: Medication utilization among patients hospitalized for HE was low despite guideline recommendations, which may lead to more readmissions and increased costs. Our results show a trend of lower readmission rates during the 3 months following an HE admission among patients using medication that did not reach statistical significance, possibly due to the low power given the small sample size.

SPONSORSHIP: Valeant Pharmaceuticals International.

K20 Adherence to Subcutaneous Biologic Therapy Among Patients with Inflammatory Bowel Disease and Rheumatoid Arthritis: Impact of Therapy Management

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BACKGROUND: Adherence for biologic therapy is critical for patients with immunological conditions to ensure positive outcomes. Therapy management programs (TMPs) may be associated with improvements in adherence.

OBJECTIVE: To examine the impact of participation in a TMP on adherence in patients with rheumatoid arthritis (RA) or inflammatory bowel disease (IBD) treated with subcutaneous injectable (sub-Q) biologic medications.

METHODS: The sample included Fairview Specialty Pharmacy (FSP) patients on sub-Q biologics for RA or IBD from 1/1/16-10/31/17. All patients were invited to participate in a TMP. Participation was defined as completion of ≥ 1 telephonic visit with an FSP nurse or pharmacist. Adherence was measured as proportion of days covered (PDC). Differences between patients with IBD and RA were assessed using Student's t-test and chi-square analysis. Factors associated with adherence were assessed using logistic regression and included age, sex, biologic experience, and TMP participation.

RESULTS: The sample included 3,248 patients: 2,116 with RA and 1,132 with IBD. The majority (79%) of patients were adherent (PDC > 0.8). Compared to RA, patients with IBD were younger (51.3 vs. 40.7, $P < 0.01$), male (49.6% vs. 26.8%, $P < 0.01$), and more likely to be bio-experienced (66.3% vs. 58%, $P < 0.01$). While TMP participation was similar (IBD: 51.4% vs. RA: 54.6%, $P = 0.08$), optimal adherence was achieved by more patients with IBD than RA (87.4% vs. 74.3%, $P < 0.01$). After adjustment, factors associated with adherence included IBD diagnosis (OR: 2.8, $P < 0.01$), age (50-64 y, OR 2.0, $P < 0.01$ vs. 18-29 y; 65+ years, OR: 3.2, $P < 0.01$ 18-29 y), and no prior biologic therapy (OR: 2.3; $P < 0.01$). The interaction term between

bio-experience and TMP participation (OR: 2.6; *P*<0.01) suggests that TMP is associated with increased adherence in bio-naïve vs. bio-experienced patients.

CONCLUSIONS: Overall, this patient population was highly adherent to biologic therapy regardless of TMP participation. Disease state, age, prior biologic use, and TMP participation were predictors of adherence. The significant interaction term suggested that TM was associated with improved adherence for bio-naïve patients. The effect of TMP among bio-experienced patients requires additional examination to determine the factors associated with nonadherence in this group. These results contribute to the current understanding of drivers of adherence and participation in TMP.

SPONSORSHIP: Janssen Scientific Affairs.

L00-L99 Diseases of the Skin and Subcutaneous Tissue *(e.g., Psoriasis, Pressure Ulcers)*

L1 Psoriasis Patients Switching Biologics Within the First Year of Biologic Treatment Initiation Have More Comedications, Higher Healthcare Resource Utilization, and Are Costlier than Persistent Patients

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BACKGROUND: Real-world data on biologic persistence in psoriasis (PSO) patients is available, but little is known about patients who switch biologics and associated costs.

OBJECTIVE: Describe the frequency of switching biologics in the 1st year of treatment, and differences in healthcare resource utilization (HCRU), costs, and characteristics of patients who switch vs. patients who are persistent.

METHODS: This retrospective study analyzed U.S. commercial claims data from 2012-2016. Eligible PSO patients were biologic naïve, ≥18 years old, with continuous enrollment in both the 12-month baseline (BL) and follow-up (FU) periods. Index date was the 1st claim for a biologic (all anti-TNFs, secukinumab, ustekinumab) or apremilast (small molecule). Diagnoses were based on ICD-9/10 codes. Patients were considered persistent at 12 months if they had a ≤90-day gap in the index treatment. Those initiating a 2nd biologic/apremilast within 90 days of stopping the 1st were classified as having switched. If a patient first experienced a dose escalation or PSO treatment add-on or discontinued biologics for >90 days, they were excluded from this analysis.

RESULTS: We identified 4,499 persistent patients and 1,507 patients who switched biologics. Compared to persistent patients, switch patients were more likely to be female (56% vs. 47%), have systemic PSO treatment at BL (62% vs. 53%), and have topical corticosteroid (66% vs. 51%) and opioid (40% vs. 31%) use in FU. At BL, psoriatic arthritis and depression were more prevalent in switch vs. persistent patients (36% vs. 30% and 16% vs. 11%, respectively). Mean all-cause HCRU rate/1,000 PY was higher in switch vs. persistent patients at both BL (ER: 325 vs. 241; outpatient: 18,981 vs. 16,996) and FU (ER: 329 vs. 227; outpatient: 19,213 vs. 15,234), with increasing rates from BL to FU for switch patients vs. decreasing rates for persistent patients. Compared to persistent patients, median all-cause medical/pharmacy costs (per member per year) were higher at BL ($6,726 vs. $5,371) and FU ($47,649 vs. $39,778) for switch patients, and the increase in all-cause pharmacy costs from BL to FU was $6,168 greater. There was an $11,603 increase in median all-cause pharmacy costs in FU from pre- to post-switch.

CONCLUSIONS: Compared to persistent users, patients switching biologics in the 1st year of treatment have higher rates of comorbidities and comedications, with higher pre-existing and subsequent HCRU and costs. Understanding reasons for switching may highlight ways to cost-effectively improve persistence, e.g. more durable treatments.

SPONSORSHIP: UCB Pharma.

L2 Healthcare Costs Among Psoriasis Patients Treated with Ixekizumab or Adalimumab

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BACKGROUND: As newer biologics with substantially greater efficacy become available, there is a lack of direct comparison of healthcare costs between psoriasis (PsO) patients (pts) who are treated with older versus newer biologics, such as adalimumab (ADA) and ixekizumab (IXE).

OBJECTIVE: To assess the differences in healthcare costs among PsO pts treated with IXE or ADA.

METHODS: Pts diagnosed with PsO between 7/1/2015 and 5/31/2018 and who received IXE or ADA between 3/1/2016 and 5/31/2018 were identified from the IBM MarketScan Databases. The first claim of IXE or ADA set the index date. Pts had 12 months of continuous eligibility before and after the index date. Pts with other indications for the index drug in the pre-period or with use of the index drug within 90 days before the index date were excluded. Inverse probability of treatment weighting was employed to balance cohorts. All-cause and PsO-related healthcare costs per member per month (PMPM) incurred during the 12-month follow-up period were compared between IXE and ADA. Costs were adjusted by medication possession ratio (MPR) and discount rates (0.44/IXE and 0.31/ADA) published by the Institute for Clinical and Economic Review (ICER).

RESULTS: A total of 388 IXE and 2,578 ADA users were selected. Compared to ADA, IXE users were older (49 years vs. 47), had higher rates of baseline hypertension (39% vs. 33%), hyperlipidemia (34% vs. 29%), obesity (24% vs. 19%), and prior biologic use (69% vs. 42%). Cohorts were balanced post-weighting. After weighting, mean all-cause healthcare costs were $6,535/IXE and $5,557/ADA (*P*=0.026). Mean PsO-related costs were $5,792/IXE and $4,754/ADA (*P*=0.017). Index drug costs made up 82% and 92% of all-cause and PsO-related costs for IXE, and 65% and 75% for ADA, respectively. Weighted mean MPR were 0.68/IXE and 0.66/ADA (*P*=0.362). Weighted MPR-adjusted index drug mean costs were $8,407/IXE and $5,534/ADA. After applying ICER discounts, adjusted index drug mean costs were $4,708/IXE and $3,818/ADA. ICER-MPR-adjusted mean PsO-related costs were comparable between IXE and ADA ($5,172 vs. $4,985, *P*=0.656).

CONCLUSIONS: This real-world study estimated that mean first year PMPM PsO-related costs were similar between pts treated with IXE or ADA after adjusting for treatment adherence and ICER discounts. Costs of psoriasis management are predominately driven by pharmacy costs. Further examination of drug survival and patient quality of life will benefit comprehensive cost-effectiveness analyses between IXE and ADA.

SPONSORSHIP: Eli Lilly.

L3 Clinical Implications of Early PASI Responses to Tildrakizumab in Patients with Moderate to Severe Plaque Psoriasis

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BACKGROUND: Tildrakizumab, a humanized, IgG1/κ monoclonal antibody selectively inhibiting the p19 subunit of IL-23, is approved for the treatment of adult patients with moderate-to-severe plaque psoriasis. Psoriasis Area Severity Index (PASI) improvements from baseline differed between tildrakizumab non-responders (PASI < 50), responders (PASI ≥ 75), and super responders (PASI ≥ 90) as early as week 4.

OBJECTIVE: To evaluate whether early improvements in PASI scores potentially identify week 28 PASI responders and non-responders.

METHODS: This analysis included patients from the pooled phase-3 trials of tildrakizumab in plague psoriasis (reSURFACE 1 [NCT01722331] and reSURFACE 2 [NCT01729754]) who were randomized to receive tildrakizumab 100 mg at weeks 0, 4, 16 and 28. Four mutually exclusive groups were created based on each patient's week-28 PASI response: PASI < 50, 50-74, 75-89, and 90-100 (observed data). Percent of PASI improvements from baseline at weeks 4, 8, 12, and 16 were analyzed for each of the week-28 PASI response groups. Additionally, improvements in PASI scores from baseline at weeks 4, 8, and 16 were examined to identify week-28 PASI response groups.

RESULTS: Overall, 575 patients (mean age: 45.6 years, male: 69.5%) treated with tildrakizumab 100 mg from baseline to 28 weeks were included. The proportions of patients achieving PASI < 50, 50-74, 75-89 and 90-100 at week 28 were 8.3%, 14.3%, 23.8% and 53.5%, respectively. 85% of patients with PASI < 50 at week 16 did not achieve week-28 PASI responder status, while 58% of the week-28 non-responders did not achieve at least a PASI 50 response at week 16. 41% of patients achieved PASI ≥ 50 at week 4: two-thirds became super responders and over 85% were responders at week 28. Among the week-28 super responders and responders, 50% and 45% achieved PASI ≥ 50 at week 4, respectively.

CONCLUSIONS: The majority of patients with moderate-to-severe psoriasis treated with tildrakizumab 100 mg achieved PASI 75 responder status at week 28. PASI improvements as early as week 4 can be used to potentially identify patients' week-28 PASI improvement status. By week 16, few patients were non-responders and did not become responders by week 28. In comparison, patients achieving PASI ≥ 50 at week 4 were more likely to become responders and even super responders by week 28.

SPONSORSHIP: Sun Pharmaceutical Industries.

L4 Tildrakizumab Efficacy over Time Stratified by Week-28 Response Levels and by Prior Biologic Use

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BACKGROUND: Tildrakizumab is a humanized, IgG1/κ monoclonal antibody selectively targeting IL-23p19. Its efficacy in patients with moderate-to-severe plaque psoriasis has been demonstrated in 2 phase-3, double-blinded, randomized and controlled trials.

OBJECTIVE: To examine tildrakizumab efficacy from baseline to week 52, stratified by week-28 response levels and prior biologic use.

METHODS: Both reSURFACE 1 and reSURFACE 2 trials used a three-part study design. Part 1 (weeks 0-12) randomized patients to placebo, tildrakizumab 100 mg, and tildrakizumab 200 mg; Part 2 (weeks 12-28) re-randomized placebo patients to tildrakizumab; Part 3 (weeks 28-64, reSURFACE 1; weeks 28-52, reSURFACE 2) re-randomized patients with Psoriasis Area and Severity Index (PASI) response ≥ 50 at week 28 to continue, increase or decrease tildrakizumab dose, or to placebo (ReSURFACE 1 only). This post-hoc pooled analysis included patients on the same dose of tildrakizumab 100 or 200 mg during the first 28 weeks from both trials. Bio-naïve and bio-experienced sub-cohorts were created based on prior exposure to biologic therapy for psoriasis. Each sub-cohort was further divided into 5 mutually exclusive groups based on week-28 PASI response: PASI 100, 90-99, 75-89, 50-74, and < 50. The percent of PASI improvement from baseline was examined.

RESULTS: The analysis included 475 bio-naïve and 100 bio-experienced patients on tildrakizumab 100 mg and 482 bio-naïve and 99 bio-experienced patients on tildrakizumab 200 mg. Among bio-naïve patients, 24.4%, 29.9%, 24.2%, 14.5%, and 6.9% tildrakizumab 100 mg patients, and 29.3%, 29.9%, 19.3%, 18.0%, and 3.5% tildrakizumab 200 mg patients achieved PASI 100, 90-99, 75-89, 50-74, and < 50 at week 28, respectively. Among bio-experienced patients, the percentages were 17%, 33%, 22%, 13%, and 15% for tildrakizumab 100 mg and 29.3%, 25.3%, 21.2%, 18.2% and 6.1% for tildrakizumab 200 mg. Patients achieving week-28 PASI 90-100 had ≥ 44% PASI improvement at week 4. Among patients achieving week-28 PASI ≥ 50 and continuing on the same dose in the first 52 weeks, the PASI improvements were maintained or improved from week 28 to week 52.

CONCLUSIONS: Tildrakizumab efficacy was similar regardless of patients' prior biologic exposure. Majority of patients achieved a PASI ≥ 50 response at week 28, which was maintained or improved from week 28 to 52. Patients with PASI 90-100 at week 28 showed rapid PASI improvement by week 4, suggesting that super responders to tildrakizumab might be identified early during the therapy.

SPONSORSHIP: Sun Pharmaceutical Industries.

L5 Biologic and Apremilast Treatment Patterns in Moderate to Severe Plaque Psoriasis

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BACKGROUND: Psoriasis (PsO) is a chronic immune-mediated disease requiring long term therapies. Long-term real-world treatment patterns are not well characterized.

OBJECTIVE: To examine treatment patterns of PsO patients newly initiating secukinumab (SEC), ixekizumab (IXE), adalimumab (ADA), ustekinumab (UST), etanercept (ETA), or apremilast (APR) using the MarketScan Commercial and Medicare databases.

METHODS: Adults with PsO newly initiating APR or a biologic from 01/01/2015 to 07/31/2018, with no prior use of the index medication, and continuous medical and pharmacy benefit over the 12-month

pre-index and 24-month post-index periods (IXE: 12-month post-index period only due to limited data) were selected. Adherence (proportion of days covered [PDC] ≥ 0.8), non-persistence (no refill within the pre-defined gaps [weeks]: ETA and APR, 4; ADA, 8; SEC and IXE, 10; and UST, 18), discontinuation (no claim for any study medication after a treatment gap), re-initiation (subsequent claim of the index medication after a treatment gap), and switching (initiation of a biologic, APR, or other systemic medications that is different from the index medication after a treatment gap) were examined for the 12-, 18-, and 24-month post-index periods, respectively.

RESULTS: Overall, 7,773 patients with the 24-month post-index period were included: SEC, 275; ADA, 2,684; UST, 910; ETA, 1,063; and APR, 2,841. Adherence rates were low (SEC, 33.5%; ADA, 27.1%; UST, 22.5%; ETA, 21.3%; and APR, 22.8%); the median PDC was 0.37-0.58. Non-persistence rates were high (SEC, 66.9%; ADA, 73.2%; UST, 58.4%; ETA, 86.5%; and APR, 85.3%) with median days to non-persistence ranging from 117 to 208 days. Discontinuation rates were high (SEC, 47.6%; ADA, 51.3%; UST, 38.4%; ETA, 42.1%; and APR, 44.5%), and the median days to discontinuation were 113-254 days. Some patients reinitiated the same therapy (SEC, 19.3%; ADA, 21.9%; UST, 20%; ETA, 44.5%; and APR, 40.8%) after they discontinued, and the median days to reinitiation were 50-195 days. In addition, many patients switched therapies. Similar trends were observed for the 12- and 18-month post-index periods, with worse outcomes for longer follow-up duration.

CONCLUSIONS: Among patients with moderate-to-severe psoriasis, adherence rates for biologics and APR were low over 24-month post-index period. Many patients were non-persistent with treatment; and discontinuation, re-initiation, and switching were also very common. Therefore, staying on long term therapy is still a challenge for many patients.

SPONSORSHIP: Sun Pharmaceutical Industries.

L13 Cost per Responder Analysis of Guselkumab Versus Secukinumab Using Efficacy Results from a Head-to-Head Clinical Trial in Patients with Moderate to Severe Plaque Psoriasis

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BACKGROUND: Insurers are seeking comparative effectiveness data to inform formulary and benefit design decisions.

OBJECTIVE: To estimate the cost per responder in the United States (U.S.) for guselkumab relative to secukinumab in the first 48 weeks of treatment based on efficacy results from a head-to-head clinical trial (ECLIPSE).

METHODS: In the Eclipse study patients were randomized to receive GUS 100mg at Weeks 0/4/12, then every 8 weeks (n = 534), or SEC 300 mg at Weeks 0/1/2/3/4, then every 4 weeks (n = 514), both through Week 44. Because psoriasis is a chronic disease requiring long-term treatment, the primary endpoint was the proportion of patients achieving a PASI 90 response at Week 48. The calculation used to estimate the cost per responder was: (per unit drug cost in U.S.) × (number of doses for 48 weeks of treatment) ÷ (percentage of patients with a response at 48 weeks from the ECLIPSE trial). Response was based on the percentage of patients achieving at least 90% improvement in their Psoriasis Area and Severity Index score (PASI 90 response) at 48 weeks (guselkumab 84.5%, and secukinumab 70.0%). Dosing was based on the FDA label in the first year of treatment, and number of doses was based on treatment through 48 weeks for both therapies

(7 doses of guselkumab, 15 doses of secukinumab). It was assumed that patients take every dose as prescribed in a calendar year, and cost for guselkumab and secukinumab were based on wholesale acquisition cost (WAC) as of September 2018. A sensitivity analysis was also conducted to estimate cost per responder for the first full year (52 weeks) of treatment by extrapolating 48-week efficacy to 52 weeks.

RESULTS: The cost per PASI 90 responder through the first 48 weeks of treatment was $84,153.42 for guselkumab ($84,153.42 = $71,109.64/84.5%) versus $100,979.57 for secukinumab ($100,979.57 = $70,685.70/70.0%). Results of the sensitivity analysis for cost per PASI 90 responder through the first year of treatment was $96,175.34 for guselkumab ($96,175.34 = $81,268.16/84.5%) versus $114,443.51 for secukinumab ($114,443.51 = $80,110.46/70.0%).

CONCLUSIONS: This cost per responder analysis from the ECLIPSE trial demonstrates that guselkumab is a more cost-effective treatment (lower cost per responder) than secukinumab for achieving a PASI 90 response through the first 48 weeks of treatment among patients with moderate to severe plaque psoriasis.

SPONSORSHIP: Janssen Scientific Affairs.

L14 Cost per Responder Analysis of Guselkumab Versus Tildrakizumab Using Efficacy Results from Two Pivotal Clinical Trials in Patients with Moderate to Severe Plaque Psoriasis

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BACKGROUND: Several new treatments for moderate to severe plaque psoriasis have recently been approved. Information on their relative value is important for payers.

OBJECTIVE: To estimate the cost per responder in the United States (U.S.) for guselkumab relative to tildrakizumab through 28 weeks of treatment using an indirect comparison of efficacy from two pivotal trials.

METHODS: Response rates, defined as the percentage of patients achieving at least 75%, 90% or 100% improvement in Psoriasis Area and Severity Index (PASI) score compared to baseline (PASI 75, 90, or 100 responses, respectively), were estimated for the first year of treatment using data from two pivotal clinical trials (VOYAGE 1 for guselkumab and RESURFACE 1 for tildrakizumab). Analyses were based on non-responder imputation methodology. Response rates at 28 weeks were used for both biologics. No baseline patient characteristics or placebo adjustment were made due to the low placebo response rates in both trials (< 3.0% PASI 90 response). Dosing was based on recommendations from the FDA labels for each therapy in the first year through week 28 (4 doses of guselkumab 100 mg and 3 doses of tildrakizumab 100 mg), and it was assumed that patients took every dose as prescribed. Costs for guselkumab and tildrakizumab were based on respective U.S. wholesale acquisition costs (WACs) as of September 2018. The cost per responder for each biologic was calculated as the drug cost through 28 weeks divided by the PASI 75, 90, or 100 response rates for each treatment at 28 weeks. A sensitivity analysis was conducted to estimate cost per responder for the first full year of treatment.

RESULTS: The PASI 75, 90, and 100 response rates at 28 weeks were 90.6%, 78.7%, and 42.2%, respectively for guselkumab, and 77.0%, 49.0%, and 22.0%, respectively for tildrakizumab. Drug costs for treatment through 28 weeks were $40,634.08 for guselkumab and $39,768.00 for tildrakizumab. Cost per responder through 28 weeks for patients achieving PASI 75, 90, and 100 responses were $44,850,

$51,632, and $96,289, respectively, for guselkumab versus $51,647, $81,159, and $180,764 respectively, for tildrakizumab.

CONCLUSIONS: This cost per responder analysis, based on indirect comparisons of efficacy from the VOYAGE 1 and RESURFACE 1 trials, demonstrated that guselkumab is more cost effective given lower costs per PASI 75, 90, and 100 responder compared to tildrakizumab through the first 28 weeks of treatment.

SPONSORSHIP: Janssen Scientific Affairs.

L18 Examining the Real-World Healthcare Costs of Treating Chronic Wounds

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BACKGROUND: Approximately 1% to 2% of the general population in the United States suffer from chronic wounds. Recent research by Nussbaum and colleagues (2018) suggests that the Medicare spending on chronic wounds is significant ranging from $28.1 to $96.8 billion. Chronic wounds are commonly treated with various skin replacement products such as Theraskin (TS), Apligraf (AG), or Dermagraft (DG).

OBJECTIVE: To examine differences in the real-world healthcare costs of chronic wound patients treated with either TS, AS, or DG.

METHODS: The Humana claims database was used to identify chronic wound patients aged 18 years or older based on the first application of either TS, AG, DG (index date) between 01/01/2007 and 12/31/2017. Patients were required to have a wound size of at least 20 cm2 and at have at least 90 days of continuous coverage following the index date. All-cause healthcare costs and healthcare utilization were examined from the index date to 60, 90, and 180 days as well as 1- and 2-year windows.

RESULTS: A total of 414 patients were identified (TS n=69; AG n=283; DG n=62). Cohorts did not differ in their distribution of age or gender as well as comorbidities. All-cause medical costs at 60, 90, and 180 days as well as 1 year ranged from $17,470 to $62,035 for the TS cohort, $16,826 to $60,695 for the AG cohort, and $30,175 to $101,889 for the DG cohort representing a significant ($P<0.05$) cost savings for patients treated with TS relative to DG. Across all time windows, relative to the AG and DG cohorts a smaller proportion of TS patients in experienced an emergency room (ER) visit, were admitted to the hospital, and received an opioid or antibiotic prescription. TS patients also generally received fewer applications of the skin substitute than the AG or DG patients.

CONCLUSIONS: The results of this real-world study suggest that costs of treating chronic wounds is significantly lower in patients treated with TS compared to DG. In fact, the total medical costs for TS patients were, on average, 40% lower than the costs incurred by DG patients. The total cost of care for TS and AG were comparable. Across most of the study period, TS patients had the lowest medical resource utilization (i.e., ER visit and hospital admission) and the lower proportion of patients prescribed opioid or antibiotics in the relative to patients treated with AG or DG.

SPONSORSHIP: Solsys Medical.

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

M1 Treatment Patterns in New User Cohorts of Non-Specialty First-Line Therapy for Immune-Mediated Inflammatory Diseases

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BACKGROUND: Immune-mediated inflammatory diseases (IMIDs) share similar disease development pathways and pharmacological treatment modalities. First line therapy recommendations for patients newly diagnosed with IMIDs are non-biologic (traditional) medications, such as methotrexate or corticosteroids. Non-adherence to treatment has been associated with recurrence and progression of disease. Adding or switching to a biologic specialty medication is indicated for patients with increased severity. Understanding early first line treatment patterns and the progression to specialty medication use could inform patient management strategies.

OBJECTIVE: To identify and describe a cohort of new users with IMID initiating first line treatment, and to describe one year post-initiation treatment patterns, including adherence to first line therapy.

METHODS: We conducted a retrospective observational cohort study using administrative claims data. The study cohorts consisted of patients aged 18-89 years indexed on the first line prescription claim (1/01/2014-12/31/2015), 12 months pre- and post-index continuous enrollment, evidence of select joint, skin, gastrointestinal (GI) conditions within 90 days of index, and naïve to first line and specialty medications in the pre-index period. Post-index treatment patterns were described.

RESULTS: New user cohorts for selected joint (n=3,163), skin (n=3,732), and GI (n=1,530) conditions were identified. For all conditions, patients were majority female with an average age greater than 65 years. Co-occurrence of conditions was most common for selected joint conditions (8.0%), and least common for selected GI (3.8%) conditions. The majority (95.8%) of first line new users started on monotherapy. Adherence to first line therapy based on proportion of days covered (>0.8) in the post-index period was low for joint (19.9%), skin (43.7%), and GI (5.3%) conditions. Few patients switched or added a specialty therapy within one year within the cohorts (joint [<1%], skin [<1%], and GI [1.5%] conditions).

CONCLUSIONS: Adherence to first line therapy and escalation to specialty treatment were found to be low among cohorts of new users of non-specialty medications with IMIDs within a year of initiating a non-specialty first line therapy. Given the risk of increased disease severity and escalation to specialty treatment for patients with IMIDS beyond one year, healthcare clinicians should focus on scalable interventions that help patients with early adherence to first line therapy. Time to escalation to specialty medication beyond one year may warrant additional study.

SPONSORSHIP: Humana.

M2 Real-World Treatment Patterns of Rheumatoid Arthritis Patients Who Switched from Infliximab to Iinfliximab-dyyb

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BACKGROUND: The first infliximab biosimilar, infliximab-dyyb, was FDA-approved in April 2016 and commercialized in the U.S. in November 2016. While physicochemical and pharmacokinetics studies have been performed on infliximab-dyyb, there are few real-world (RW) data on patients who switch from infliximab to a biosimilar in the U.S.

OBJECTIVE: To describe patient characteristics and treatment patterns of rheumatoid arthritis (RA) patients treated with infliximab or infliximab-dyyb including switchers from infliximab to infliximab-dyyb.

METHODS: A retrospective cohort analysis of RA patients who initiated infliximab or infliximab-dyyb (index date) between 12/1/2016 and 10/31/2017 was conducted using an electronic medical records and point-of-care claims database. Patients were ≥18 years old at index date and had ≥6 months pre-index and ≥3 months post-index observation. Patient characteristics and treatment patterns were summarized using descriptive statistics.

RESULTS: A total of 663 infliximab and 120 infliximab-dyyb RA patients were identified. In the ≥12-month period prior to infliximab-dyyb initiation, a switch from infliximab to infliximab-dyyb was observed among 47 (39%) infliximab-dyyb patients. Patients who switched were mostly female (68%) with a median age of 70 years at diagnosis, and the majority (70%) were covered by Medicare. Median treatment duration was 95.3 weeks for infliximab and 24.3 weeks for infliximab-dyyb (median follow-up: 30.8 weeks from infliximab-dyyb start). Among switchers, median time between last infliximab infusion to first infliximab-dyyb start was 8.2 weeks. Mean dose of infliximab at last infusion was 4.9 mg/kg with 7.2 weeks between last two infusions. Upon switching, mean dose of infliximab-dyyb was 6.6 mg/kg with 6.3 weeks between first two infusions. Additionally, after switching from infliximab to infliximab-dyyb, 15 (32%) patients switched back to infliximab, and 1 (2.1%) switched to another biologic (rituximab) during the follow-up period.

CONCLUSIONS: Most patients who switched from infliximab in this RW setting started infliximab-dyyb within 2 months of discontinuing infliximab and at a higher and more frequent dose compared to infliximab. In addition, nearly one third switched back to the innovator product (32%) or another biologic (2%) over the follow-up period. Further studies are needed to understand the reasons for switching between an innovator drug to a biosimilar and to assess subsequent long-term outcomes.

M3 Treatment and Switching Patterns in Patients with Immune-Mediated Inflammatory Diseases Treated with Originator Infliximab or Its Biosimilars

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BACKGROUND: Infliximab (IFX) biosimilars have been available in the U.S. since 2016. However, data describing treatment patterns of patients initiated on an IFX biosimilar versus originator IFX and describing switching patterns of patients initiated on an IFX biosimilar remains scarce.

OBJECTIVE: To describe treatment patterns among new users of originator IFX or IFX biosimilars and to describe switching patterns among patients treated with an IFX biosimilar in the U.S.

METHODS: Symphony Health Solutions' Patient Transactional Datasets were used (10/2012-02/2018) to identify adults with ≥2 claims with either ulcerative colitis (UC), Crohn's disease (CD), plaque psoriasis (PsO), psoriatic arthritis (PsA), rheumatoid arthritis (RA), or

ankylosing spondylitis (AS), ≥1 claim for originator IFX or an IFX biosimilar on or after 04/2016 (first claim is the index date), and no IFX claim in the 6 months pre-index (baseline). Time to treatment discontinuation was compared between originator IFX and IFX biosimilars using Kaplan Meier curves and a Cox proportional hazards regression adjusting for baseline characteristics. In a separate analysis assessing the proportion of IFX biosimilar users switching to another biologic, all patients with ≥1 IFX biosimilar claim, ≥2 claims with either UC, CD, PsO, PsA, RA, or AS, and ≥6 months of pre- and post-index clinical activity were included.

RESULTS: A total of 28,662 and 664 new users of IFX and its biosimilars were identified, respectively. Among patients with ≥6 months post-index, 61.2% of originator IFX patients remained on the index treatment after 6 months versus 54.2% IFX biosimilar patients (log rank $P=0.006$). Among all patients, new users of originator IFX were 18% less likely to discontinue their treatment versus new users of an IFX biosimilar (hazard ratio=0.82, $P=0.003$). Among 1,033 IFX biosimilar users included in the separate analysis of switching patterns, 20.7% switched to any biologic within the first 6 months post-index: 17.3% of 302 patients naïve to originator IFX at baseline and 22.6% of 663 patients with prior experience with originator IFX in the 6 months pre-index. More specifically, 16.1% of 1,033 switched to originator IFX: 10.3% of 302 patients naïve to originator IFX and 19.3% of 663 patients with prior experience with originator IFX in the 6 months pre-index.

CONCLUSIONS: New users of originator IFX were less likely to discontinue treatment compared to new users of an IFX biosimilar. More than 20% of IFX biosimilars users switched within 6 months to another biologic, especially those previously treated with originator IFX.

M4 Impact of a Mandatory Specialty Pharmacy Benefit on Rheumatoid Arthritis Medication Adherence Among Members of a Commercial Client

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BACKGROUND: Patients with rheumatoid arthritis (RA) have benefitted from the introduction of tumor necrosis factor (TNF) inhibitors, however multiple studies have reported that rates of medication adherence are suboptimal. Specialty pharmacies offer various management strategies to improve adherence in patients with RA. Adherence to biologics for RA has been poorly studied, and limited studies exist that measure the impact of a mandatory specialty pharmacy benefit on adherence.

OBJECTIVE: To determine the impact of a mandatory specialty pharmacy benefit on RA medication adherence eight months after transitioning members of a commercial client to the specialty pharmacy.

METHODS: A retrospective analysis was conducted using an internal pharmacoadherence application. Members with claims for TNF inhibitors (adalimumab, etanercept, certolizumab pegol, golimumab) were included, provided they received at least two fills within the study time periods of May 2017 through December 2017 and January 2018 through August 31, 2018 (time period 1), and June 2017 through January 2018 and February 2018 through September 2018 (time period 2). Pharmacy claims were analyzed to calculate proportion of days covered (PDC), medication possession ratio (MPR), and gap in therapy (GIT) in each time period. Members with a baseline Health Assessment Questionnaire II (HAQ-II) score after the transition were compared to subsequent HAQ-II scores for a correlation with adherence.

RESULTS: 137 members with RA were included for both time periods. Prior to transition, 34% of members were filling at non-specialty pharmacies and 66% of members were filling at specialty pharmacies. In time period 1, there were no statistically significant differences in MPR or GIT pre- and post-transition, however there was a statistically significant improvement in PDC for members who were filling at a non-specialty pharmacy before transition (0.836 vs. 0.893, $P = 0.03$). In time period 2, there were no statistically significant differences in MPR pre- and post-transition, however there was a statistically significant improvement in GIT (36.500 vs. 26.457, $P = 0.035$) and PDC (0.823 vs. 0.873, $P = 0.017$). HAQ-II scores did not significantly improve after six months post-transition compared to baseline.

CONCLUSIONS: PDC significantly improved after mandating specialty pharmacy for RA members taking TNF inhibitors who were previously filling at non-specialty pharmacies. Patient-reported outcomes regarding disability and physical function did not show significant improvement. Future studies with more robust HAQ-II data is warranted.

SPONSORSHIP: Navitus Health Solutions.

M5 A Systematic Review of the Association Between Patient Out-of-Pocket Costs and the Non-Initiation of Biologics Used to Treat Rheumatoid Arthritis

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BACKGROUND: Annual expenditures for biologics that treat inflammatory disorders have steadily increased and patients' out-of-pocket (OOP) costs for these therapies are also rising. Previous systematic reviews have described an association between patient OOP costs and adherence to biologics. However, a review that evaluates the association between OOP costs and whether patients initiate treatment with biologics has not been conducted.

OBJECTIVE: To conduct a systematic review of studies that evaluated the association between OOP costs and the non-initiation of biologics used to treat inflammatory disorders.

METHODS: We searched Embase and Medline for peer-reviewed studies published between 1974-2018 that analyzed the association between OOP costs and biologic treatment initiation for inflammatory diseases using insurance claims or electronic health record data. To be included in this review, studies must be empirical research using quantitative methods. Surveys and qualitative studies were excluded. Results were summarized by describing the metrics used to define OOP and treatment non-initiation as well as the association between the two within each study.

RESULTS: Out of 519 unique articles identified through the search criteria, a total of seven published from 2009-2018 met the inclusion criteria for analysis. All were retrospective studies conducted in patients with rheumatoid arthritis (RA). The studies defined biologic non-initiation as: (a) the absence of a claim for a biologic or (b) the reversal of an adjudicated claim with no subsequent claims for the therapy. OOP costs were described in terms of: (a) insurance type or proportion of drug costs covered by insurance (3 studies); (b) presence or absence of low-income subsidies (2 studies); and (c) dollar amounts paid by the patient (2 studies). All studies showed a relationship between higher OOP costs and greater rates of biologic non-initiation. Four studies found that this relationship occurred with self-administered biologics covered through the prescription benefit and not with facility-administered biologics (which are covered through the medical benefit).

CONCLUSIONS: Higher out-of-pocket costs are associated with non-initiation of biologics used to treat RA. This is specifically true for biologics covered through the prescription benefit and higher OOP costs may shift biologic utilization towards the medical benefit. More follow-up studies investigating the impact of OOP costs with health outcomes are needed.

SPONSORSHIP: Sandoz.

M6 U.S. Rheumatology Practice-Based Real-World Evidence of Methotrexate Utilization and Response to Therapy in Rheumatoid Arthritis Patients Treated with Intravenous Golimumab

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BACKGROUND: AWARE (Comparative & Pragmatic Study of Golimumab [GLM] IV Versus Infliximab in Rheumatoid Arthritis) is an ongoing Phase 4 study designed to provide a real-world assessment of intravenous GLM and intravenous infliximab (IFX) in patients with rheumatoid arthritis (RA). The primary objective is to assess incidence of infusion reactions. Concomitant use of methotrexate (MTX) is also reported. In the FDA-approved label, GLM is indicated for treatment of patients with moderately to severely active RA in combination with MTX; however prospectively obtained real world evidence on the rate of GLM use without MTX has not been reported.

OBJECTIVE: To compare patient demographics, disease characteristics, response to therapy and discontinuation of GLM in patients with and without concomitant MTX from an interim analysis (IA) of the AWARE study.

METHODS: In this prospective, noninterventional, observational, multicenter 3-year study conducted in the U.S., RA pts (1,200 adults) were enrolled at the time of initiating treatment with GLM or IFX. All treatment decisions including MTX utilization are made at the discretion of the treating rheumatologist. Imputations of Clinical Disease Activity Index (CDAI) data were not performed at this IA.

RESULTS: 678 GLM pts were enrolled (71.8% GLM Plus-MTX, 28.2% GLM No-MTX). Baseline (BL) characteristics among the two groups were similar in terms of age (total mean = 61 y), gender (86% female), disease duration (9.2 y), race (86.5% white), weight (83.7 kg), and BMI (30.9 kg/m2). At BL, 92.6% of GLM Plus-MTX and 91.5% of GLM No-MTX pts had categorical CDAI activity of moderate or high; 7.4% and 8.5%, respectively, of low or remission. CDAI scores (mean ± SD) for GLM Plus-MTX and GLM No-MTX, respectively, were 30.9 ± 14.6 and 33.2 ± 16.6 at baseline, 21.3 ± 15.0 and 20.7 ± 14.4 at 3 months, and 19.4 ± 14.6 and 18.1 ± 14.4 at 6 months. Discontinuation from the study was similar between the GLM Plus-MTX (173/487; 35.5%) and GLM No-MTX (64/191; 33.5%). 7.9% of GLM No-MTX pts reported leflunomide use.

CONCLUSIONS: At BL, 28.2% of pts on GLM did not report concomitant MTX use. The demographics of the GLM Plus-MTX pts and GLM No-MTX pts were similar. Early response to treatment, assessed by CDAI score after 3 months and 6 months, was similar in the two groups. These preliminary data suggest that in a real-world rheumatology practice setting, use of GLM with or without concomitant MTX led to similar CDAI scores at 3 and 6 months in RA pts with predominantly moderate to high BL CDAI disease category.

SPONSORSHIP: Janssen Scientific Affairs.

M7 Age and Gender Differences in Comorbidities Among Patients with Rheumatoid Arthritis in a Large U.S.-Based Real-World Cohort

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BACKGROUND: Treatment decision for rheumatoid arthritis (RA) are complex due to patients' underlying disease conditions.

OBJECTIVE: To characterize key patient characteristics that influence treatment decisions and outcomes.

METHODS: The OM1 RA Registry (OM1, Boston, MA) follows more than 100,000 patients longitudinally with deep clinical data, including laboratory, symptom, patient-reported and disease activity information. The OM1 Data Cloud collects, links and leverages additional structured and unstructured data from electronic medical records (EMR), claims and other sources in an ongoing and continuously updating manner. These linkages provide ongoing data from rheumatologists, primary care and other specialties, which is important in understanding the multi-systemic burden of the disease. For this analysis, patients were required to have at least 1 of the following: 1+ RA diagnosis code from a rheumatology EMR, 1+ inpatient RA diagnosis code or 2+ outpatient RA diagnosis codes at least 30 days but less than 1 year apart. Data from January 2013 through November 2018 were used.

RESULTS: There were 1,190,615 RA patients identified, with an average observation time in the cohort of 4.5 years (standard deviation 1.4). Average age at cohort entry was 63.1 years for women (n = 980,356) and 65.4 years for men (n = 282,259). Men had lower Charlson scores (2.2 vs. 1.9), more hypertension (59.7% vs. 53.3%), more diabetes (27.6% vs. 24.1%), higher mean C-reactive protein (1.3 vs. 0.9), but had fewer extra-articular oral manifestations (2.2% vs. 6.9%), lower mean Functional Assessment of Chronic Illness Therapy (FACIT) fatigue score (5.9 vs. 6.8), and lower multidimensional Health assessment questionnaire visual analog scale (MDHAQ VAS) pain scores (5.3 vs. 5.8). Although a similar proportion had joint exam data, 54.8% of men with scores had a tender joint count = 0-4, compared to 48.4% for women. Similar proportions of patients were on biologic disease-modifying anti-rheumatic drugs (bDMARDs; 21% male, 23% for females). In comparisons across age groups (18-64 vs. 65+ years), older patients had higher ESR scores (68.1% of older males had ≤20 vs. 77.3% for younger male, and 74.8% of older women vs. 81.2% for younger women). Older patients had more cardiovascular and respiratory comorbidities, and higher Charlson scores (2.2 vs. 1.7), but lower fatigue scores (6.4 vs. 6.7) and MDHAQ VAS pain scores (5.8 vs. 6.1).

CONCLUSIONS: The high cost and complexity of RA treatments necessitates full assessment of the impact of patient characteristics should be part of the evaluation of treatment choice and outcomes.

SPONSORSHIP: OM1.

M8 Serum Uric Acid and Health-Related Quality of Life in Patients with Gout and Hypertension

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BACKGROUND: Gout is a chronic inflammatory disorder associated with elevated serum uric acid (sUA). Although increasing evidence suggests sUA is a risk factor for hypertension, there is limited data on the relationship between sUA and gout with comorbid hypertension and associated quality of life.

OBJECTIVE: To use nationally representative patient-reported outcome (PRO) survey data linked with clinical data from electronic health records (EHR) to evaluate differences in serum uric acid (sUA) levels and health-related quality of life (HRQoL) in patients with gout and hypertension (GwH).

METHODS: Patient-Centered Research (PaCeR) U.S. data (2015-2018; N = 345,184) consisting of patient-reported survey data were included in a HIPAA-compliant linking methodology with a large U.S. ambulatory EHR database (2012-2018; N = 50 million+). Linking was performed by comparing Protected Health Information from EHR and Personal Identifiable Information from PaCeR. Linked PaCeR-EHR respondents were included in the study if they had at least one sUA test result in the EHR taken within 18 months of survey completion. Gout and hypertension patients were identified through self-report in PaCeR. One-sample ANOVA and Kruskall Wallis tests were used to compare sUA and HRQoL between groups. HRQoL measures included SF-36v2 metrics, and work and activity impairment (Work Productivity and Activity Impairment Questionnaire).

RESULTS: A total of 231 PaCeR-EHR respondents had valid sUA test results in the EHR, of which 5.2% had gout only, 16.5% had gout and hypertension, 27.7% had hypertension and 50.6% had neither. Gout patients were more likely to be male (74.0% vs. 26.0%, $P < 0.001$), older (65.6 vs. 57.0 years, $P < 0.05$), and unemployed (70.0% vs. 30.0%, $P = 0.02$) compared with non-gout patients. Patients with gout (6.6 mg/dL), hypertension (5.8 mg/dL), or both had (6.1 mg/dL) significantly higher sUA levels compared with those with neither condition (5.2 mg/dL; $P < 0.05$). Patients with hypertension (44.4) or GwH (44.3) had lower physical SF-36v2 scores compared with those with neither condition (50.6; $P < 0.05$). Patients with hypertension (34.8%) or GwH (35.8%) reported higher work activity impairment than those with neither condition (21.9%; $P < 0.05$).

CONCLUSIONS: Linking sUA test results with patient-reported data enabled assessment of the relationship between sUA and HRQoL among gout patients with and without comorbid hypertension. sUA levels were consistently higher with lower HRQoL among patients with GwH.

SPONSORSHIP: Kantar Health.

M9 Understanding the Impact of Dose Escalation on the Cost-Effectiveness of Etanercept Among Patients with Rheumatoid Arthritis

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BACKGROUND: Tumor necrosis factor inhibitors (TNFi) have transformed the course of disease for patients with moderate to severe rheumatoid arthritis (RA), with adalimumab (ADA) and etanercept (ETN) being the most commonly prescribed. Dose escalation to maintain efficacy may lead to unpredictable dosing and higher than expected costs. Previous analysis examined the cost-effectiveness of TNFi by means of a simulation model but did not consider the impact of dose escalation on economic outcomes. Here, we examine the potential impact that dose escalation of etanercept and adalimumab has on the cost-effectiveness of these medications.

OBJECTIVE: To estimate the cost-effectiveness of ETN and ADA for patients with moderate to severe RA and inadequate response to conventional disease-modifying antirheumatic drugs (cDMARDs) who are naïve to TNFi from a U.S. societal perspective.

METHODS: We used the Innovation and Value Initiative RA (IVI-RA) decision model to calculate lifetime total quality-adjusted life years (QALY) and total costs (direct medical and productivity costs) associated with ETN or ADA treatment sequences after inadequate response to cDMARD. We derived the time to dose escalation (days' supply/quantity ≥ initial dose) and magnitude of dose escalation (any increase in dose) from a retrospective analysis of the IBM MarketScan Commercial and Medicare Supplemental Databases between January 2010 to March 2017. We adapted the IVI-RA model dosage to incorporate dose escalation, which varies across treatments. Specifically, we simulated time to dose escalation from the time-to-event models and adjusted dosage by the magnitude of the dose escalation. Costs and outcomes were discounted at 3% per year.

RESULTS: Among 22,608 patients with RA identified in MarketScan, 6,586 (29.1%) received ADA and 6,390 (28.3%) received ETN. Over a lifetime, simulations predicted 17.3% and 11.4% of patients receiving ADA and ETN, respectively, would dose escalate at some point. The IVI-RA model predicted lifetime costs (without dose escalation) for ADA and ETN as $276,701 and $288,689, respectively. Mean lifetime costs and outcomes with dose escalation for ADA and ETN were $295,987 and $294,606, and 6.28 and 6.50 QALYs, respectively.

CONCLUSIONS: Simulation model results showed ETN was both more effective and less expensive than treatment with ADA when accounting for dose escalation. Over a lifetime, ETN is predicted to be more cost-effective than ADA in RA when real-world dose escalation data are considered.

SPONSORSHIP: Amgen.

M11 Curbing the Opioid Epidemic: 20% Reduction by 2020

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BACKGROUND: Americans suffering from chronic pain deserve safe and effective relief. Opioids can help manage some types of pain in the short term, however, there are serious risks of opioid use disorder and overdose particularly with high dosages and long-term use. Per the CDC, 115 Americans die daily from an opioid overdose. In 2016, the number of overdose deaths involving opioids was 5 times higher than in 1999. In April of 2018, NYSDOH passed an initiative to Reduce Opioid Dispensing by 20% by 2020. This NYS health plan will implement a UM edit and a standardized process of reviewing opioid requests in accordance with CDC guidelines to decrease opioid usage in members.

OBJECTIVE: To describe and evaluate the impact of a UM edit that requires prior authorization (PA) when exceeding a daily dosage of 90 MME (Morphine milligram equivalents) and utilize newly created clinical criteria per CDC recommendations when reviewing requests that exceed this limit.

METHODS: Answering New York State's call to combat the opioid epidemic and to decrease opioid use by 20% by 2020, a NYS based Managed Medicaid health plan implemented a UM edit that requires PA when exceeding 90 MME per day, effective 6/1/2018. Evidence based criteria was created to ensure appropriate prescribing of opioids and used to gather information to ensure consistency with CDC guidelines. Members with pain diagnoses relating to cancer, sickle-cell, or palliative care/hospice were excluded. Clinicians were requested to submit a urine drug screen when clinically indicated and acknowledge or review concurrent use of a benzodiazepine with an opioid. The plan is placing an emphasis on safety; members are never mandated to lower or stop opioids. This reduces the risk of destabilization, withdrawal symptoms, and members seeking illicit drugs. The health plan will evaluate the program's impact by comparing the total MME dispensed by month before and after implementation. This program does not affect substance abuse medication availability or opioid treatment programs in any way.

RESULTS: Four months post implementation, there was a 23.6% decrease in monthly dispensed MME, which correlates to a decrease of 10,032,577 total monthly MME dispensed (May vs. September 2018). The health plan will also examine data relating to medical claims and alternative medications.

CONCLUSIONS: The results constitute a decrease of over 10 million MME of opioids dispensed to members monthly. The health plan anticipates to have a more complete picture of the program impact by March 2019, however, the early data is encouraging.

SPONSORSHIP: Fidelis Care.

M12 An Analysis of the Burden of Illness and Treatment in Knee Osteoarthritis in a U.S. Administrative Claims Database

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BACKGROUND: Knee osteoarthritis (OA), the most common type of OA, is a disabling joint disease with rising prevalence and is commonly associated with aging. Pain is the predominant symptom and pharmacological therapies are often utilized initially for patient treatment.

OBJECTIVE: To describe knee OA prevalence, treatment trends, and associated all-cause- and knee-OA-related healthcare utilization and costs from a U.S. administrative claims database.

METHODS: U.S. administrative claims data from 2013-2018 (IBM MarketScan) were used to perform a retrospective cohort study. Inclusion criteria included ≥ 18 years old and (a) ≥ 1 claim with an ICD-9 diagnosis of lower-leg OA prior to 10/2015, followed by a confirmatory ICD-10 diagnosis of knee OA, or (b) ≥ 1 claim with an ICD-10 diagnosis of knee OA. The index date was the earliest claim date. Patients had to have ≥ 12 months of continuous enrollment prior to and 24 months following the index date. Healthcare utilization and costs were measured during the post-index period. Cost was estimated as per-patient-per-year (PPPY) to account for variable-length follow-up. Prevalence was calculated as the number of patients with a knee OA diagnosis divided by the total number of patients with continuous enrollment in 2017.

RESULTS: 273,079 knee OA patients met inclusion criteria. Estimated 2017 prevalence in the eligibility-matched cohort was 5.0%, and for patients ≥ 60 years old, 14.3%. Mean age was 60.6 years (SD 11.9; range 18-103), and 61.6% were female. Mean total all-cause annual healthcare cost per patient was $20,275 (SD $33,730), whereas knee-OA-related cost was $6,414 (SD $8,294). All-cause and knee-OA-related healthcare utilization, respectively, were: 39.1% (mean $15,918; SD $23,269) and 19.2% (mean $11,922; SD $10,069) for inpatient admissions; 99.7% (mean $10,327; SD $ 21,944) and 99.7% (mean $1,160; SD $2,354) for outpatient services; 98.3% (mean $3,704; SD $10,210) and 89.6% (mean $367; SD $1,538) for medication claims. Of patients prescribed a medication, 84.1% received corticosteroids, 33.1% hyaluronic acid, 69.1% prescription NSAIDS and 36.5% opioids (≥ 30 days supply). The mean PPPY cost associated with each drug above was $209 (SD $1,353), $498 (SD $548), $242 (SD $1,302) and $537 (SD $3,056), respectively.

CONCLUSIONS: This descriptive claims analysis provides updated healthcare resource utilization and costs for patients with knee OA. Further research will explore the significance of these findings on total cost of care for knee OA patients in the U.S.

SPONSORSHIP: Samumed.

M13 Impact of Intra-Articular Corticosteroid Injections on Opioid Utilization Patterns in Patients with Knee Osteoarthritis

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BACKGROUND: Symptomatic knee osteoarthritis (OA) is typically managed with analgesics including oral agents as well as intra-articular corticosteroid (IACS) injections. In light of the ongoing opioid crisis in the United States, the potential opioid-sparing effects of non-addictive medications used to treat OA pain are of great interest.

OBJECTIVE: To assess the impact of IACS injection on opioid utilization and associated treatment patterns among patients with knee OA.

METHODS: Patients aged ≥40 years with incident knee OA diagnosed 1/2012-6/2016 were identified in IQVIA's Real-World Adjudicated Claims-U.S. Database. Patients with IACS use were identified by procedure codes for CS injection within 12-months post-OA diagnosis. Patients with non-IACS management had ≥1 pharmacological therapy for knee OA but no CS injections within 12 months post-OA diagnosis. The date of first injection (for IACS cohort) or pharmacy treatment (for non-IACS cohort) served as the index date. All patients had ≥360 days of follow-up pre- and post-index date. IACS (N=23,777) and non-IACS (N=23,377) cohorts were directly matched 1:1 by age group, sex, index year, Charlson comorbidity index, and days between OA diagnosis and index date.

RESULTS: Mean age was 55.3 years and 46% were female. Pre-index opioid use and hospitalizations were higher in the non-IACS cohort (62.2% and 13.2%) than the IACS cohort (43.4% and 5.2%; $P<0.0001$). Most frequent post-index treatments in the non-IACS cohort were opioids (48.0%) and nonsteroidal anti-inflammatories (44.7%); post-index treatment in the IACS cohort included additional IACS injections (67.5%) and hyaluronic acid injections (29.5%). Comparing IACS and non-IACS cohorts, median time to post-index opioid prescription was longer (86 days vs. 41 days; $P<0.0001$), and mean number of days supplied for all opioid prescriptions was lower (69 days vs. 84 days; $P<0.0001$). Post-index arthroscopy and total knee replacement were higher in the IACS cohort: (10.97% vs. 7.96% and 7.55% vs. 6.07%, respectively; $P<0.0001$ for both).

CONCLUSIONS: This retrospective analysis found that patients receiving initial IACS to manage their knee OA had a longer time to opioid prescription following diagnosis and fewer opioid prescriptions compared with patients who did not receive IACS. Early utilization of IACS treatment may help reduce the use of opioid analgesics. Additional research is needed to assess if long-acting IACS can influence subsequent treatment patterns and clinical outcomes among patients with knee OA.

SPONSORSHIP: Flexion Therapeutics.

M14 Healthcare Costs Among Patients with Ankylosing Spondylitis or Psoriatic Arthritis Who Switch or Discontinue Biologics

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BACKGROUND: Costs associated with biologic switching and discontinuation can be high in chronic inflammatory diseases and inappropriate use of medications may have cost implications for both payers and patients. There is a lack of understanding of biologic utilization and switching rates among patients with ankylosing spondylitis (AS) or psoriatic arthritis (PsA).

OBJECTIVE: To compare direct costs of treatment switchers, non-switchers, and discontinuers among patients with AS or PsA who newly initiated a biologic.

METHODS: Patients aged ≥18 years with an AS or PsA diagnosis and ≥1 pharmacy claim for a FDA-approved subcutaneous biologic for AS or PsA between 01/01/2016 and 12/31/2016 were identified from the Truven Health MarketScan Databases. At the time of biologic initiation (index date), eligible patients were continuously enrolled with medical and pharmacy claims ≥1 year before (baseline period) and ≥1 year after the index date (follow-up [FU] period). Patients with AS or with PsA were categorized into 3 mutually exclusive groups of switchers, non-switchers, and discontinuers based on their biologic utilization pattern during the 1-year FU period. Healthcare costs during FU were described across the 3 groups separately and by disease.

RESULTS: A total of 788 patients with AS, newly initiating a biologic, were categorized as switchers (15.7%), non-switchers (52.9%), and discontinuers (31.3%); and a total of 2656 patients with PsA were categorized as switchers (18.6%), non-switchers (54.7%), and discontinuers (26.7%). Switchers with AS had higher mean total healthcare costs than non-switchers ($72,562 vs. $66,555), due to increased medical ($14,423 vs. $10,988) and pharmacy costs ($58,139 vs. $55,567). Switchers with PsA also had higher mean total healthcare cost than non-switchers ($80,451 vs. $69,985), driven by increased medical ($13,728 vs. $13,181) and pharmacy costs ($66,724 vs. $56,804). Discontinuers with AS or PsA had the lowest total healthcare costs (AS, $39,028; PsA, $52,247) but had the highest medical costs ($16,651; $23,390).

CONCLUSIONS: Biologic switching resulted in higher total healthcare costs than remaining on the same biologic. For payers, biologic discontinuation may impose economic burden due to medication wastage. While reasons for switching and discontinuation are unknown, these findings may impact formulary decisions due to the potential cost implications of biologic switching and discontinuation in patients with AS or PsA.

SPONSORSHIP: Novartis Pharmaceuticals.

M15 Morphine Milligram Equivalent Reductions in a Multidisciplinary Chronic Pain Management Program

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BACKGROUND: The pharmacodynamic component of chronic pain has a significant impact on individual's quality of life and often medications to address chronic pain are not assessed appropriately. It is now evident that the United States is suffering from an opioid crisis due to overuse and overprescribing patterns. This has led to such issues as addiction, misuse, severe drug interactions, and a trend of increasing morphine milligram equivalents (MME) without improving the patients functional status which increases their risk of an adverse event. The Chronic Pain Program was created as a member-facing, multidisciplinary care management and coaching program that provides support and resources to members with chronic pain.

OBJECTIVE: The goal of the program is individualized to improve function. The pharmacist component of the program focuses on appropriate pharmacotherapy for the pain condition, tapering down opioid therapy when clinically appropriate, and decreasing inappropriate opioid utilization. The analysis conducted measured opioid days supply and MME's as a marker of decreasing inappropriate opioid utilization.

METHODS: Members from a commercial health plan enrolled in the program and had been contacted by March 31, 2018. Propensity Score Matching (PSM) was conducted and included relevant musculoskeletal ICD-10 categories, opioid drug classes, age, and gender. Those in moderate and high tiers were included in the PSM as well as all those who were contacted but not enrolled. The members in the low tier group were excluded from the PSM but were added back as a second comparison group. The PSM used Logistic Regression as the estimation algorithm.

RESULTS: The change in opioid days supply decreased by a mean of 15 in the intervention group as compared to a mean of 2 in the control group. The MME in the intervention group had a mean decrease of 57 compared to the control group which had a mean increase of 53. The lowest tier group had a mean of a 28 days supply decrease and a MME decrease of 57.

CONCLUSIONS: The analysis demonstrates a clinically significant reduction in opioid utilization and morphine milligram equivalents. While limited by a small sample size, the multidisciplinary approach to chronic pain management shows promise in reducing inappropriate opioid use and tapering down the MME to decrease the potential of serious side effects. The member is supported throughout their enrollment in the program and are able to consult with a clinical pharmacist to discuss medication concerns.

SPONSORSHIP: Magellan Health.

M17 Characterization of Medicare Patients with a Fragility Fracture

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BACKGROUND: Osteoporosis and associated fractures are an important public health burden. In addition to increased morbidity, the downstream effect of fractures includes functional decline, loss of independence, nursing home admissions and mortality.Due to an increasing aging population, the number of Americans at risk of fractures is projected to increase by 33% by 2030. Current data on burden of fractures in a population of Medicare enrollees will contribute to increased awareness among healthcare providers to facilitate appropriate care and access to therapy.

OBJECTIVE: To examine baseline characteristics of Medicare patients who experienced a fragility fracture.

METHODS: The current study included Medicare fee-for-service (FFS) members with a closed fragility (or osteoporosis-related) fracture between January 1, 2010 and September 30, 2014 (identification period). Additional inclusion criteria included age ≥ 65 as of the index date, continuous enrollment in Medicare FFS with medical and pharmacy benefits (parts A + B + D - C) for a minimum of one year prior to the index date. Patients with Paget's disease or malignancy (except for non-melanoma skin cancer) at baseline were excluded. Patients were classified into four cohorts based on the observed diagnoses and/or treatment of osteoporosis at baseline. Diagnoses of osteoporosis could be in any position on the medical claim.

RESULTS: Of 18,936,386 total beneficiaries, 885,676 met the eligibility criteria. The average age was 80.5 (± 8.4) years, 90.9% were white, and 93.8% were female. The most commonly observed fracture sites were: spine (n = 239,807; 27.1%), hip (n = 206,298; 23.3%), and radius or ulna (n = 137,939; 15.6%). Of all patients with a qualifying fracture,

approximately 77% (n = 683,465) were neither diagnosed nor treated for osteoporosis at baseline. 2.5% (n = 21,803) were diagnosed but not treated, 17.4% (n = 153,659) were treated but not diagnosed, and only 3.0% (n = 26,749) were diagnosed and treated. Nearly 87% of patients (n = 768,328) had a comorbidity or were on a medication that is associated with increased fall risk.

CONCLUSIONS: The current study findings confirm a consistent high level of underdiagnosis and undertreatment of osteoporosis in Medicare population. Further documentation of cost of illness following an osteoporosis-related fracture, including identification of high cost drivers who may benefit from earlier targeted therapies, will be of value.

SPONSORSHIP: Radius Health.

M20 The Impact of Prescription NSAIDs on Opioid Use in Opioid-Naïve Patients Following Orthopedic Surgery

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BACKGROUND: Opioids are the cornerstone of pain relief following orthopedic surgery, but they can lead to several complications and long-term dependence. Consequently, the development of multimodal pain management strategies which include both an opioid and nonsteroidal anti-inflammatory drugs (NSAIDs) are an attractive alternative.

OBJECTIVE: To determine how multimodal outpatient pain management utilizing opioid and NSAID therapy compares to opioid monotherapy in regards to the duration of opioid use and average morphine equivalent daily dose (MEDD) during the postsurgical period. Risk of developing chronic opioid use and long term opioid use disorder were secondary efficacy outcomes. Adverse drug reactions that were compared across groups were a combined endpoint of mechanical/inflammatory complications after the surgery, new onset anxiety, new onset depression, acute kidney injury, gastric ulcers, hemorrhages, and constipation.

METHODS: Retrospective observational cohort study utilizing paid claim data from PharMetrics from 2001-2015. The opioid + NSAID and opioid only arms included 5,432 and 26,576 patients, respectively. Patients were followed for 12 months after their surgical index date. Primary outcomes were analyzed using multivariate linear regression with statistically significant variables based on backward elimination of likely confounders that have previously been documented in the literature. Secondary outcomes and safety measures were analyzed using similar logistic models.

RESULTS: The opioid + NSAID group had a lower MEDD (m = -0.838 [-1.64, -0.038]) than the opioid alone group. There was no statistically significant difference between the groups in regard to duration of opioid therapy (m = -0.148 [-0.411-0.095]), chronic opioid use (OR = 1.03 [0.92-1.16]), or development of substance abuse disorder (OR = 1.14 [0.84-1.56]). The opioid+NSAID group was less likely to have mechanical/inflammatory complications (OR = 0.81 [0.70-0.93]). The opioid + NSAID group was also more likely to develop new onset depression (OR = 1.46 [1.24-1.71]) and anxiety (OR = 1.39 [1.13-1.71]). No other safety outcomes were statistically significant.

CONCLUSIONS: NSAIDs prescribed post-surgery can lower the average MEDD but not duration of opioid therapy, risk of chronic use, or risk of substance abuse disorder. The addition of an NSAID decreased the risk of mechanical/inflammatory complications but also increased the incidence of new onset depression/anxiety. Further research is needed to fully characterize the costs and benefits of the opioid-sparing effects of NSAIDs.

SPONSORSHIP: None.

M21 Improving Quality of Care in Rheumatoid Arthritis Utilizing Hospital-Based Specialty Pharmacies in Monitoring Disease Activity

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BACKGROUND: The American College of Rheumatology (ACR) guidelines recommends a treat-to-target approach to managing patients to a goal of remission/low disease activity, yet many rheumatology practices do not routinely assess or document rheumatoid arthritis (RA) disease activity due to time constraints and uncertainty about which measure to use.

OBJECTIVE: To leverage the capabilities of hospital-based specialty pharmacists and software to capture patient reported disease activity to collaborate with rheumatologist and enhance treatment management.

METHODS: TherigySTM is a therapy management software to deliver/document specialty therapy care. The Routine Assessment of Patient Index Data (RAPID3), an ACR recommended patient reported disease activity measure, was integrated into the TherigySTM RA module. Assessments were conducted telephonically during scheduled patient engagement and frequency of follow-up was performed based on patient's disease activity per ACR guidelines.

RESULTS: Five hospital-based specialty pharmacies collected data from 12/1/17 through 8/5/18. A total of 889 patients ≥ 1 RAPID3 score were evaluated during the review period; 306 patients had ≥ 3 RAPID3 scores over the 9-month evaluation. The average age of the patients was 56 years and 82% were females. Of those 306 patients, baseline disease activity was classified as 65% high, 30% moderate, 3% low, and 2% near remission. During the analysis period, 32% of patients improved by at least one disease activity level and 22% of patients ended in low or near remission. Sensitivity to change of the RAPID3 scores may be affected in patients with comorbidities and non-English speaking patients may be interpreting questions differently based on the translation provided. Specialty pharmacists stated having an increased awareness of their patients with high disease activity.

CONCLUSIONS: Enabling pharmacists to assist in monitoring RA patients can enhance quality of patient care and potentially improve outcomes. Pharmacists were able to follow up with patients more frequently to reassess disease activity per ACR guidelines. The best interval for RAPID3 reassessment needs to be re-evaluated to avoid survey fatigue and patient abrasion. Software enabled pharmacists engagement with rheumatologist is an emerging opportunity in optimizing treatment management for RA patients.

SPONSORSHIP: Pfizer.

N00-N99 Diseases of the Genitourinary System (e.g., ESRD)

N2 Burden of Complicated Urinary Tract Infections: Epidemiology, Health Care Resource Utilization, and Readmission Rates

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BACKGROUND: Complicated urinary tract infection (cUTI) include UTIs that occur in patients with structural or functional abnormalities of the urinary tract, immunosuppression, and significant comorbidities. Despite their frequency, limited data areavailable on the incidence and healthcare burden associated with cUTIs.

OBJECTIVE: To estimate the epidemiology and health care resource utilization (HCRU) associated with cUTI in the U.S.

METHODS: Retrospective study of insurance claims (PharMetrics Plus) from 1/1/13 to 12/31/17. Inclusion criteria: age ≥18 years, ICD-9/10 cUTI diagnosis (first diagnosis defined the index date), and continuous plan enrollment for ≥6 months pre- and ≥30 days post-index date. Patients were stratified into cohorts based on initial care setting: inpatient (IP) and outpatient (OP). Incidence of cUTI was determined. Outcomes for the 30-days post-index date included costs, admission/readmissions, emergency department (ED) visits, and subsequent antibiotic treatment.

RESULTS: In total 543,502 adults with cUTI met the inclusion criteria (104,866 IP cohort; 438,636 OP cohort). Mean (SD) age was 48.1 (16.5) years and 68.1% were female. The overall incidence of cUTI in the PharMetrics database was 1.01%. In the IP cohort, overall median (IQR) 30-day health care costs were $13,028 ($4,855-$26,781). Median (IQR) costs for the initial admission were $9,441 ($2,079-$19,027), with median (IQR) length of stay of 4 (3-8) days. Of IP patients, 12,933 (12.3%) and 8,345 (8.0%) had a subsequent all-cause and UTI-related readmission, respectively; 30,558 (29.1%) and 17,567 (16.8%) had an all-cause and UTI-related ED visit, respectively; and 16,926 (16.1%) received antibiotics and had a UTI diagnosis post discharge. In the OP cohort, median (IQR) 30-day health care costs were $1,531 ($305-$4,998). Of OP patients, 40,457 (9.2%) and 35,869 (8.2%) had a 30-day all-cause and UTI-related inpatient admission, respectively; 210,784 (48.1%) and 192,900 (44.0%) had an all-cause and UTI-related ED visit, respectively; and 57,505 (13.1%) had a subsequent antibiotic and a UTI diagnosis after their initial antibiotic course.

CONCLUSIONS: This is the first study to elucidate the incidence of cUTI. We found that cUTI is associated with substantial economic burden, especially among patients requiring hospitalization. As hospital reimbursement and antimicrobial stewardship programs are increasingly tied to quality and efficiency of care, the findings highlight the need for new treatment approaches and antibiotics that reduce hospitalization rates, facilitate early discharge, and avoid readmissions and ED visits.

SPONSORSHIP: Achaogen.

O00-O99 Pregnancy, Childbirth, and the Puerperium (e.g., Abortion, Eclampsia, and Maternal Care)

O2 The Change in Prescription of Pregnancy-Contraindicated Drugs in Korea

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BACKGROUND: Korean nationwide computerized Drug Utilization Review (DUR) system provides safety information to physicians and pharmacist by generating a pop-up window on a real-time basis when prescribing or dispensing. In 2012, 88 drugs were newly announced as pregnancy-contraindicated on September 25 (21 drugs), November 21 (49 drugs) and December 13 (18 drugs) by Ministry of Food and Drug Safety (MFDS). The information were provided through the DUR system afterwards.

OBJECTIVE: To evaluate changes in use of 88 contraindicated drugs during pregnancy in Korea using the nationwide Health Insurance and Assessment Service (HIRA) database.

METHODS: The study population consisted of pregnant women who gave birth in 2012-2016 in Korea. We extracted prescription data for 273 days before delivery. Given the rapid decline in births, we calculated the number of prescriptions per day per 100,000 pregnancy women in each month, not just the number of prescriptions. Also, we analyzed the change in the average number of prescriptions for each pregnancy-contraindicated drug before and after the DUR information was provided.

RESULTS: The average number of pregnancy-contraindicated prescriptions per day per 100,000 pregnant women slightly increased by 0.82% from 2,329.00 to 2,348.07, though DUR information was provided. However, it was much less than the 9.65% increasing rate for the average number of total prescriptions per day per 100,000 pregnant women (from 42,236.44 to 46,310.65). Among 88 contraindicated drugs, analgesics and anti-inflammatory agents (34 drugs) had decreased from 1,631.52 to 1,540.34, a 5.59% reduction. However, anti-diabetes agents (15 drugs) showed the largest change with a jump of 25.54%, from 418.66 to 525.58.

CONCLUSIONS: The use of pregnancy-contraindicated drugs was slight increased after DUR information was provided, however it was much less when compared to the increase rate in the total prescriptions during pregnancy. Further research is needed to investigate the reason of a large increase of anti-diabetes use in pregnancy.

SPONSORSHIP: None.

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

T1 Opioid Misuse-Related Health Care Resource Utilization and Costs in Texas

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BACKGROUND: Opioid misuse has become a national public health crisis, which leads to significant health care resource utilization and imposes significant cost burdens to the health care system and greater society.

OBJECTIVE: To evaluate health care resource utilization and costs associated with opioid misuse in Texas hospitals.

METHODS: A retrospective observational cross-sectional study was conducted using 2016 Texas Inpatient, Outpatient, and Emergency Department Public Use Data Files. ICD-10-CM codes related to opioid abuse, adverse effects, dependence and poisoning were used to identify clinical encounters related opioid misuse. Two definitions were used. The first definition (Definition 1) only included encounters with principal diagnosis codes related to opioid misuse. The second definition (Definition 2) included encounters with either principal or secondary diagnosis related to opioid misuse. Multivariate logistic regression models were applied to identify the association between visits and patients' demographic and socioeconomic characteristics.

RESULTS: Using Definition 1, there were 10,423 outpatient and 7,444 inpatient visits related to opioid misuse. Approximately 90% of outpatient and 50% of inpatient visits were through the emergency department (ED). Using Definition 2, there were 31, 901 outpatient and 47,021 inpatient visits related to opioid misuse. Approximately 90% of outpatient and 60% of inpatient visits were through the ED. Patient characteristics were comparable between the two definitions, with the majority being ages 18-44 years, female, white, and non-Hispanic. Patients who were ages 18-44 years, white, non-Hispanic, uninsured, and residing in metro areas were significantly most likely to experience opioid misuse related clinical encounters in Texas. The annual health care costs related to opioid misuse was estimated to be $3.2 billion using Definition 2 compared to $0.27 million using Definition 1.

CONCLUSIONS: Using two definitions, our findings indicate clinical encounters related to opioid misuse impose significant clinical and economic burdens in Texas. By examining opioid misuse health care utilization more broadly, the results suggest the clinical and economic burdens may be significantly higher than previously reported.

SPONSORSHIP: None.

T3 Opioid Overdose Incidence Among Medicaid Members Receiving Opioids with and Without Mental Illness Diagnosis

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BACKGROUND: We are continuing to understand factors driving opioid overdose. The more we understand, the more likely we are to identify possible solutions. Substance use disorders (SUD) and mental illness frequently coexist. Although there is debate about the nature of any cause and effect relationship, there is a high rate of comorbidity between SUD and mental illness. This study was designed to identify relationships between opioid overdose with various mental illness diagnoses.

OBJECTIVE: To determine the frequency of opioid overdose in Medicaid members with mental illness receiving opioids.

METHODS: Using a Medicaid claims database, 141,637 members were identified who filled an opioid prescription between 10/01/2017 and 09/30/2018. Prescriptions for less than 10 days' supply and members with a cancer diagnosis in the past two years were previously excluded. Members were stratified into four groups based on history of mental illness and number of prescribers. The control group contained 46,332 members using opioids with no mental illness and two or fewer prescribers (group 1). 19,700 members had no mental illness and three or more prescribers (group 2), 35,428 had mental illness and two or fewer prescribers (group 3) and 40,177 members had mental illness and three or more prescribers (group 4). Opioid overdose frequency by mental illness and count of prescribers were analyzed.

RESULTS: Overall there were 1,778 (1.26%) overdoses. Group 1 had 79 overdoses for a rate of 0.17%, 85 in group 2 (0.43%, a 153% increase over the control), 683 in group 3 (1.93%, a 1031% increase over control), and 931 in group 4 (2.31%, a 1259% increase over control). Of the members with no mental illness 29% had 3 or more prescribers, while 51% of members with mental illness had 3 or more prescribers. Patients with SUD had a higher rate of overdose (7.2%) compared to other mental illnesses, (schizophrenia 4.0%, bipolar 3.2%, depressive disorder 2.6%, anxiety disorder 2.1%, and ADHD 1.2%).

CONCLUSIONS: Members with mental illness had the highest incidence of overdose among opioid users and that was compounded in those with three or more prescribers. Potential coordination of care issues were increased by the presence of a mental illness (MH) diagnosis. Opioid management programs targeting substance use disorders have the potential to lower overdoses, as do programs that encourage treatment of schizophrenia, bipolar and depressive disorders.

SPONSORSHIP: Conduent.

U00-U99 Codes for Special Purposes and AMCP Unclassified Abstracts

(e.g., Care Management, Specialty Pharmacy, Rare Diseases, Star Ratings, Pharmacist Services, MTM, Outcome Analyzers, Part D, Multidisease Studies, ACO, ACA)

U1 Clinical Adherence Programs at a Specialty Pharmacy: A Quantitative Analysis

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BACKGROUND: Specialty pharmacies often use clinical programs to promote patient adherence for select medications. These clinical adherence programs include ongoing education and other strategies for managing patient challenges with therapy. Although the programs are widely used today, there are limited data available on their quantitative and qualitative outcomes.

OBJECTIVE: To evaluate the relationship between patients' participation in a clinical adherence program and their quantitative and qualitative outcomes.

METHODS: The study population included patients ($\geq$ 18 years of age) taking one of four oncolytic medications. Patients were identified using data from the patient care management system. A survey was mailed to a separate cohort. Each of the four medications had an associated clinical adherence program. These programs consisted of phone calls varying in volume, content, and timing. The primary endpoints included duration of therapy (DoT), persistency, capped medication possession ratio (C-MPR), and proportion of days covered (PDC). Given the complexity of determining the threshold that indicates patient participation, our analyses focused on patients who took no calls ("non-participants") vs. patients who took every call ("full participants"; results in this format below). Qualitative findings from the survey were presented at a previous conference, and the quantitative results are presented here.

RESULTS: For the seven-call program, DoT was 293.0 days vs. 393.3 days ($P < 0.001$), persistency was 202.5 days vs. 270.9 days ($P < 0.001$), C-MPR was 0.94 vs. 0.95 ($P < 0.05$), and PDC was 0.94 vs. 0.94 ($P = 0.06$). For the five-call program, DoT was 118.9 days vs. 189.1 days ($P < 0.001$), persistency was 103.5 days vs. 143.3 days ($P < 0.001$), C-MPR was 0.93 vs. 0.92 ($P = NS$), and PDC was 0.93 vs. 0.92 ($P = NS$). For the three-call program, DoT was 172.1 days vs. 213.3 days ($P < 0.05$), persistency was 145.0 days vs. 193.5 days ($P < 0.05$), C-MPR was 0.96 vs. 0.97 ($P = NS$), and PDC was 0.95 vs. 0.97 ($P = NS$). For the one-call program, DoT was 155.8 days vs. 159.4 days ($P = NS$), persistency was 101.5 days vs. 125.1 days ($P = NS$), C-MPR was 0.88 vs. 0.93 ($P = NS$), and PDC was 0.86 vs. 0.93 ($P = NS$).

CONCLUSIONS: Patients who participated fully in a clinical adherence program had favorable DoT and persistency outcomes compared to patients who did not participate. PDC and C-MPR values were high for both groups and comparable across all four programs (potential ceiling effects). Clinical adherence programs continue to be a promising strategy for providing effective patient support.

SPONSORSHIP: Diplomat Pharmacy.

U2 A Motivational Factors Assessment Instrument for Employees Providing Medication Therapy Management Services: A Rasch Analysis

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BACKGROUND: The 2003 Medicare Prescription Drug, Improvement, and Modernization Act lead to implementation of Medicare medication therapy management (MTM) services. Telephonic medication management centers (MMCs) provide MTM services, including detailed review of patients' medication use with the goal of improving health outcomes and alleviating potential medication-related issues. Motivation factors driving the performance of MMC personnel are key components in achieving these goals; yet, motivation aspects affecting personnel performance are not well reported in literature.

OBJECTIVE: To assess validity and reliability of the Employee Motivation Questionnaire (EMQ), a 19-item measure of barriers and facilitators to motivation associated with work performance among MMC employees.

METHODS: All pharmacist, nurse, technician, and intern employees (N = 534) of a telephonic MMC were invited to complete the electronic EMQ, developed based on focus groups held among stratified groups of MMC employees, in April-June 2018. Rasch analysis of the EMQ was conducted in WINSTEPS software. Given the items' polytomous response structure, 4-point Likert scale (strongly disagree to strongly agree), the rating scale model was used. Construct and content validity and reliability were analyzed with employee and item separation index (SI) and reliability coefficient (RC).

RESULTS: A total of 319 employees completed the EMQ, 59.7% response rate, at the Arizona, Florida, and Ohio MMCs. Employee and item Infit and Outfit mean-squared values fell within recommended fit criteria (0.5 to 1.5), suggesting measurement of the same construct. Item-person map identified items that were easiest (joy of helping patients) and hardest (motivated to work harder if incentives were tied to goal achievements) for employees to agree with. Missing items in the middle and top of the measurement continuum (-1 to 0.92 logits) indicated need for additional items that employees perceive as more difficult to agree with. Per Rasch analysis, the employee RC was 0.81 and SI was 2.04, while the item RC was 0.97 and SI was 5.94.

CONCLUSIONS: Although improvements can be implemented in content validity, the EMQ illustrated some content validity, good construct validity and reliability evidence when used to measure motivation factors among MMC employees. Consideration of motivation factors may help in better meeting program goals, improving patient outcomes, and alleviating potential medication-related adverse events.

SPONSORSHIP: SinfoniaRx.

U3 Impact of a Pharmacy Lock-In Program in a Medicaid Managed Plan

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BACKGROUND: The Arizona Health Care Cost Containment System (Arizona's Medicaid Agency) set forth a policy for monitoring controlled and non-controlled medication utilization. In response, Health Net Access, a managed Medicaid plan in Arizona, implemented a pharmacy lock-in program triggered by member claims, physician

prescribing patterns and use of multiple pharmacies. Interestingly, studies have suggested that lock-in programs may simply shift cost burden to other payers rather than addressing potential abuse concerns.

OBJECTIVE: To provide a foundation of data regarding the utilization outcomes post pharmacy lock-in with the future intent of assessing patient outcomes versus merely shifting the cost-burden.

METHODS: Lock-in was implemented (post case management evaluation) for members using ≥4 different abuse/misuse potential drugs, prescribed by ≥4 physicians and filled at ≥ 4 pharmacies or if there had been ≥12 claims for abuse/misuse potential drugs during each quarter. Targeted medication classes were benzodiazepines, hypnotics, muscle relaxants, opioids and stimulants. Patients with pharmacy and medical benefits 6 months pre/post lock-in were evaluated. Utilization outcomes measured included average number of prescribers, number of different drugs, total claim count, morphine milligram equivalent (MME) and medical claim costs. A paired t-test was performed to compare the difference between mean utilization outcomes before and after lock-in.

RESULTS: A total of 124 patients in the lock-in program met eligibility criteria. With the exception of medical claim costs, all utilization outcomes tested were significantly lower after the lock-in. Specifically, the average number of prescribers was significantly lower after lock-in (mean reduction = 2.2 [95% CI: 1.7-2.6]). The number of different drugs used was 2.8 lower post lock-in (95% CI: 2.4-3.3), and the average claim count was 6.2 less after the lock-in (95% CI: 5.3-7.0). For opioids, the average daily MME dose decreased from 104mg to 64mg (mean reduction = 40.2 mg, 95% CI: 26.7-53.7). Although average medical claim costs were lower after lock-in, the change did not reach statistical significance.

CONCLUSIONS: The significant change in utilization measures suggests an association between pharmacy lock-in programs and reduced utilization. A future study should assess shifts in drug use patterns to non-monitored drug classes post lock-in to better understand the clinical benefit of the program. Future interventions for consideration may include a physician lock-in program.

SPONSORSHIP: Envolve Pharmacy Solutions.

U5 Evaluation of Providers' Response to Statin Re-Challenge Intervention

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BACKGROUND: As supported by The American Diabetes Association and included in the Statin Use in Persons with Diabetes (SUPD) Medicare Star measure, statins are recommended for patients with diabetes to help prevent cardiovascular disease. Unfortunately, many patients who could benefit from statin therapy stop taking their medication due to muscle pain. The American College of Cardiology reports that less than 5% of patients who experience statin associated muscle symptoms have a true statin intolerance.

OBJECTIVE: To determine the effectiveness of pharmacists' phone calls to provider offices to increase statin prescribing in patients with a history of reported statin side-effects.

METHODS: A total of 663 patients with diabetes and no statin claims were enrolled in the provider phone call outreach program after receiving a response from the initial letters that were faxed to the provider offices. The majority of the letter responses stated that patients were not taking a statin due to reports of muscle pain or intolerance associated with statins. Two pharmacists called these provider offices and recommended statin re-challenge, if appropriate. The statin

re-challenge strategies included asking providers to consider prescribing a lower dose statin or a more hydrophilic statin (e.g. pravastatin, fluvastatin) that may have a lower risk of muscle pain side effects.

RESULTS: Out of the 663 patients in the program, 209 (31.5%) patients filled a statin after the provider phone call outreach. Many of the provider office staff members were open to relaying the statin re-challenge recommendation to the providers if the providers were unavailable to take the phone call.

CONCLUSIONS: When contacting providers for the SUPD program, it is pivotal to follow-up with education and recommendation of statin re-challenge guidelines published by the American College of Cardiology. This helps ensure that patients who can benefit from statins are properly receiving statins and managing their side effects without unnecessarily ending their therapy. As a result, better health outcomes can be achieved by lowering patients' risk of heart disease in the future.

SPONSORSHIP: Envolve Pharmacy Solutions.

U6 ICER: Payer Use and Perspective

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BACKGROUND: As the U.S. health care market shifts from fee-for-service to value-based payments, value frameworks have emerged and are being adopted by payers and other decision makers to assist with measuring value and supporting reimbursement and coverage decisions. ICER has emerged in the U.S. as a key value framework and decision makers are using these reports to inform their formulary and reimbursement decisions.

OBJECTIVE: To better understand the payer perspective on using ICER to inform reimbursement and coverage decisions.

METHODS: Dymaxium reviewed syndicated survey responses from their active payer community, FormularyDecisions.com. The review included surveys completed between November 2017 and October 2018 from 171 respondents who reviewed products that had corresponding ICER reports. The FormularyDecisions.com platform connects payers/health care decision makers to evidence, resources and their peer community to support their drug formulary review processes.

RESULTS: Dymaxium reviewed syndicated surveys from 450 respondents who represented 125M managed care and 239M pharmacy benefit covered lives. Of those, 171 respondents were identified that reviewed products with a corresponding ICER report. Most respondents (65%) indicated they have used or will use ICER in their formulary review. Of those that had used ICER Reports (n = 111), over half indicated their primary use was as a secondary source of evidence and/or to inform/validate their own research. Participants found ICER reports useful (weighted score 4.17 out of 5) and would recommend ICER to their peers (86.8%). Report and model quality and satisfaction rated highly (over 4 out of 5 for each ICER report reviewed). Key words that have been used to describe the ICER reports are objective, clear, concise and easy to understand; key words used to describe the ICER model is that the methodology is clear and comprehensive. 14% of respondents indicated they did not use ICER reports as part of their review. Of those that did not use ICER in their product review indicated the primary reason was the timeliness of report availability in relation to their formulary review (38.3%).

CONCLUSIONS: The research supports the growing use of ICER among payers and other U.S. decision makers. Payers find the reports useful

and of high quality but recognize they are not always available in time for their formulary review. Additional analysis could be conducted on the difference between MCOs and PBMs with respect to their attitudes and usage of ICER Reports. Further research is needed regarding ICER's recommendations versus real-world coverage decisions.

SPONSORSHIP: Dymaxium.

U7 Accuracy and Efficiency: Validating the Financial Impact of Pharmacist Interventions

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BACKGROUND: Pharmacists are integral to successful managed care (MC) programs. Previously, we demonstrated that a pharmacist-driven intervention program in a Florida MC plan resulted in an actuarial validated return on investment (ROI) of 10:1 (Khazraee et al. JMCP (23):S112). In that program, ~1.5 million dollars in identified savings were not validated due to time constraints on the actuarial team.

OBJECTIVE: To create an accurate and efficient pharmacist-driven process for validating cost-saving interventions.

METHODS: An eight member team of pharmacists in the Florida Blue (FB) MC plan reviewed reports targeting medications with potentially meaningful optimization opportunities. These reports encompassed 1.8 million FB members, including fully insured and Medicare. Pharmacists intervened with the member or provider to modify the drug regimen. Cost savings were quantified by the intervening pharmacist using pre and post-intervention claims data. Pharmacists were paired to review and validate cost-savings interventions of two other pharmacists on an assigned monthly rotation. This schedule allowed each pharmacist to partner with and review interventions by every team member throughout the year. During reviews, claims data was utilized to determine if the intervention was accepted and length of impact. Questions and discrepancies that arose were referred back to the intervening pharmacist, full team, or actuary for further discussion. The FB actuarial team performed a secondary review on all high dollar interventions, defined as >$50,000, as well as a random selection of 5% of remaining cases.

RESULTS: From 1/1/2018-11/30/2018, FB pharmacists reviewed 8279 unique cases. Savings were internally assigned and validated for 415 interventions. Actuary completed a secondary validation on 52 (12.5%) successful cases. When compared to actuary, 41 cases (78.8%) were assigned the same savings using the internal pharmacist validation process, and 49 cases (94.2%) were within 5% of calculated actuarial savings. 3 cases (5.8%) differed by >5%. These three cases were complex, with unique reasons for each discrepancy. Time spent validating team members' work averaged 8.75 minutes per case, extrapolated to 7.57 hours per pharmacist over the 11 month period.

CONCLUSIONS: MC clinical pharmacists are capable of accurately assigning a dollar value to medication related interventions and efficiently validating those results. Internal pharmacist team validation allows for comprehensive review of all cases and lessens the time commitment of valuable actuarial resources.

SPONSORSHIP: Florida Blue and Prime Therapeutics.

U8 The Benefits of Pharmacist-Led Interventions in the Health Plan Setting

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BACKGROUND: There are several publications assessing the value of pharmacist involvement with patient care. Results from studies have illustrated that pharmacist intervention with patient care improves outcomes or results in cost savings and reduced medical expenses in several disease states across different practice settings. An area that is lacking in this type of review is within managed care organizations. As the number of high-cost specialty drugs and the complexity of these regimens continues to grow it is more critical than ever to have a trained health plan pharmacist involved in the evaluation and management of the patient's drug therapy. Health plan pharmacists are in a unique position to improve both the quality and cost-effectiveness of drug therapy regimens.

OBJECTIVE: To evaluate pharmacist impact through patient directed interventions conducted at an Ohio-based health plan serving more than 1.4 million members.

METHODS: The population for this observational review was identified using pharmacy and medical claims data from February 2018 to January 2019 with a focus on members using high cost medications or members with high medication utilization. Members from Medicare, commercial, and Health Insurance Marketplace lines of business were identified and their claims were reviewed for drug therapy optimization opportunities by one full-time clinical pharmacist. The means of intervention was through communication with members, pharmacies, and prescribers. The pharmacist recorded notes for each intervention made during the review period and cost savings for the health plan were calculated.

RESULTS: As of November 2018, the pharmacist has recorded interventions on 19 members which included recommendations for lower cost medication alternatives and addressing medication therapy issues as determined on patient interview. The realized savings of all interventions made based on medication cost for the health plan was $1,806,222 with an annualized savings of $6,219,245.

CONCLUSIONS: This review examined the impact of pharmacist intervention within a health plan. Through communication with members, pharmacies, and prescribers; one pharmacist generated a cost savings of over $1.8 million. There are limitations to the study that may affect the generalization of these results to other settings. Despite the limitations, this study demonstrates a cost savings impact and improvement in patient outcomes. More studies are needed to address the limitations of this review and to provide further support for the value of a pharmacist within health plans.

SPONSORSHIP: Medical Mutual of Ohio.

U9 Redesigning a Value-Based Formulary to Address Current Pharmaceutical Spending Trends: Changes in Drug-Tier Classifications

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BACKGROUND: Having an implementable, value-based method to determine coverage and cost-sharing for prescription drugs shows promise for managing drug spending. In 2010, a large not-for-profit plan implemented a pharmacy benefit known as the Value-Based Formulary that aligned cost-sharing for medications with their value, estimated using cost-effectiveness analysis. Prior analyses demonstrated that this pilot formulary shifted medication use towards higher-value medications and reduced pharmacy expenditures by 9% over 3 years. But employer understanding and adoption of this formulary was low due to its complexity and changes in the pharmaceutical market such as the rising use of specialty drugs. The program was substantially redesigned to be more easily understood and

implementable and to more explicitly address specialty drugs and renamed value-based formulary-essentials (VBF-e). Consequently, the VBF-e has experienced a 10-fold the uptake in among employers compared to the original pilot.

OBJECTIVE: To describe how the formulary was designed and the change in drug tier assignment moving from a traditional cost-based formulary to a more salient VBF-e.

METHODS: We obtained a dataset with drug-level tier designations for the VBF-e and the standard 4-tier formulary in use prior to the VBF-e. We applied the Wilcoxon signed rank test to evaluate the movement of drugs into value-based tiers.

RESULTS: Qualitative Results the VBF-e is a 5-tier formulary that includes two notable innovations: (a) a coinsurance tier (tier 4) for any drug that has a value estimate above $150,000/QALY and (b) coverage exclusion for drugs that are economically dominated. Tiers 1-3 are determined generic, brand, and preferred specialty status. This allows greater flexibly to assign any drug, whether specialty drugs or inflationary generics to tiers according to value but still be easy to understand. Quantitative Results Relative to the prior 4-tier formulary, the VBF-e significantly changed the assignment of medications to tiers with 45% and 3% of medications moved into higher and lower tiers, respectively ($P < 0.001$). By prior tier status, the greatest changes were in tiers 3 and 4; 98% of tier 3 drugs moved up while 5% and 28% of tier 4 (i.e., specialty) drugs moved up and down, respectively. By therapeutic class, dermatological and multiple sclerosis agents experienced the greatest movement up (71%) and down (59%) respectively.

CONCLUSIONS: The VBF-e is a promising formulary that addresses current issues in drug spending in an explicitly value-based framework.

SPONSORSHIP: None.

U10 Managed Care Pharmacists and Top of License Practice: Understanding the Perceptions, Barriers, and Readiness

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BACKGROUND: Although there is no universal definition for top of license, it is generally considered to mean practicing to the full extent of ones' education and training, versus performing activities that could be completed by someone with less training. For this survey, we defined top of license as the practice of pharmacy organized and prioritized based on better patient outcomes.

OBJECTIVE: To determine the relationship between top of license practice and impact on outcomes, with results serving as a baseline to determine the future impact of efforts to advance top of license practice.

METHODS: We emailed a 30-question survey to all licensed pharmacists working in any role (e.g., dispensing, front-end review, prior authorizations, grievance/appeals) as of 06/01/2018 (N = 823). The survey included 16 seven-point Likert questions, 7 multiple-choice questions and 7 open-ended response questions. Results were summarized using descriptive statistics. Questions pertaining to the impact of work on outcomes (defined as health outcomes, patient experience, and healthcare costs) were stratified by pharmacists working at top of license. Pharmacists working at top of license were defined as those who strongly agreed or agreed with the following statement: In my day-to-day activities, I am currently practicing at the top of license. Their results were compared to those who strongly disagreed or disagreed with the same statement using Chi-Square.

RESULTS: 593 surveys were completed (72% response). 66% had ≥ 10 years of experience; 71% were in production roles, defined as ≥ 80% of their time in operations work. Most respondents reported practicing at top of license (27.8% = strongly agree, 33.8% = agree, 14.3% = somewhat agree, 13.1% = neither agree nor disagree, 3.5% = somewhat disagree, 3.1% = disagree, 1.7% = strongly disagree, 2.8% = not applicable). 75.1% strongly agreed/somewhat agreed/agreed with the statement "The concept of top of license motivates me". Nearly all respondents felt their daily work was directly tied to improving health outcomes (91.2%), the overall patient experience (92.5%), and lowering healthcare costs (90.0%). Significantly more pharmacists practicing at top of license (vs. those that did not) reported that their work affected outcomes (97.9% vs. 64.9% health outcomes; 97.0% vs. 84.6% patient experience; 96.7% vs. 76.9% healthcare costs, respectively, $P < 0.001$).

CONCLUSIONS: These findings suggest that advancing the daily work of pharmacists to the full scope of their license may improve outcomes.

SPONSORSHIP: None.

U11 Results of Using Integrated Healthcare Data with a Clinical Safety Program to Improve Health Outcomes

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BACKGROUND: Disparate healthcare data systems may inhibit a provider's ability to identify and prevent potential adverse health events due to drug interactions or contraindications for a diagnosis made by another healthcare provider. An integrated health safety solution with clinical rules to identify these potential health hazards would help prevent unnecessary medical costs and utilization by alerting health care providers in order to prevent these events before they occur.

OBJECTIVE: To asses the impact of an integrated clinical safety program on healtch outcomes in a commercially insured population.

METHODS: A retrospective analysis using a matched case/control study design comparing pre and post period healthcare costs and utilization. The analysis compared intervention patients who were enrolled in a client with a clinical safety program with those in a client that was not enrolled in the program. Patients in the intervention group were selected if they were identified by an adverse drug clinical rule. These patients were matched to the control cohort on demographics and pre-period medical utilization. Pre and post period cost and utilization were assessed for primary care, emergency room and inpatient visits. Difference in difference metrics were used to assess the effect of the program.

RESULTS: The intervention and control samples consisted of 53,339 patients that were 45.8% and 45.6% male, and 49.4 and 49.2 years of age respectively. Intervention patients had average number of primary care, ER and inpatient visits in the pre period of 4.65, 0.25 and 0.05 respectively. Control patients had average visits of 4.64, 0.25 and 0.05. The average number of primary care visits in the intervention sample, increased by 0.54 ($P < 0.0001$) visits in the post period compared to the control group. ER and inpatient visits declined for the intervention group by 0.02 ($P = 0.0003$) and 0.03 ($P < 0.0001$) respectively. The decreases in average ER and inpatient visits contributed to lower average associated plan costs of $526.30 and $1,197.40 respectively.

CONCLUSIONS: Utilizing a clinical rules based system in an integrated pharmacy and medical claims repository to identify and alert healthcare providers to potential adverse drug events can improve health outcomes and improve utilization of ER and inpatient facilities.

SPONSORSHIP: Express Scripts.

U12 Improving Continuity of Care for Patients on High-Risk Medications

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BACKGROUND: Inadequate transitions of care (TOC) is a significant safety issue causing upwards of $40 billion per year in wasteful medical spending attributable to avoidable complicationsand unnecessary hospital readmissions. Pharmacist-led TOC services can improve patient safety and limit excess healthcare expenditure via performance of medication reconciliation, medication access resolution and patient education.

OBJECTIVE: To evaluate the impact of integrating a TOC pharmacist within a multidisciplinary inpatient care team on patient care delivery and safe transitions for patients on discharge.

METHODS: A TOC pharmacist was embedded within an inpatient general cardiology team at a tertiary academic medical center. On admission, the TOC pharmacist was responsible for completing admission medication reconciliation within 24-48 hours. Throughout admission, the TOC pharmacist completed medication education for all new start high-risk medications defined as antiplatelet agents, anticoagulants and insulin. These medications were also reviewed for access issues such as formulary step therapy, need for prior authorization, and affordable copayments. On discharge, medication lists and changes were reviewed with both the physician and patient, education provided and a post-discharge phone call completed. Metrics collected included average number of medication discrepancies per patient, number of medication access issues resolved, and 30-day medication-related hospital readmissions.

RESULTS: Over a 17-week period, a total of 247 patients received the TOC intervention. On admission, an average of 5 medication errors per patient were identified, the majority involving high-risk medications. An average of 1.8 medication reconciliation discrepancies were identified per discharge summary among the 147 discharge summaries reviewed, with incorrect prescribing being the most common. Twenty-eight prior authorizations were avoided by recommending formulary alternatives and 9 were completed by the TOC pharmacist. Eighteen patients were provided with copay assistance cards and 140 medications were provided via bedside delivery program. There were no medication-related readmissions within 30-days of discharge.

CONCLUSIONS: This quality improvement initiative supports the need for TOC services at institutions to ensure safe discharges and enhancement of medication access and education that often leads to costly delays in discharge time and readmissions.

SPONSORSHIP: Brigham and Women's Hospital.

U13 Analysis of Anti-Narcotic Therapy Across a Self-Insured Population

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BACKGROUND: Per the FDA, the opioid epidemic is the "most profound crisis facing the United States." Opioid addiction is a chronic medical illness for which abstinence based treatments have a 90% relapse rate. The Drug Addiction Act of 2002 requires physicians treating opioid abuse to undergo additional training, obtain a special waiver, and provide counseling and referral to psychosocial therapy, if needed. Buprenorphine allows for stabilization of opioid receptors and can be an effective tool to treat opioid addiction. As of 2015, The American Society of Addiction Medicine stated that there is not sufficient evidence on outcomes to make a recommendation on buprenorphine taper duration.

OBJECTIVE: To assess buprenorphine/naloxone use in a self-insured population, identify utilization trends, and assess appropriateness of therapy based on current recommendations.

METHODS: A retrospective evaluation of buprenorphine/naloxone utilization was conducted analyzing all members with at least one buprenorphine/naloxone product (Suboxone, Zubsolv, or Bunavail) claim from 1/1/2017-9/30/2018. Primary outcomes assessed included duration of therapy, use of opioids during therapy, rate of therapy completion, and avg. cost per prescription. Secondary outcomes included new or existing therapy during review period, usage of prescription opioids prior to or after therapy, avg. dosage/day, and concurrent Benzodiazepine use. Medical data was not available, limiting insight into counseling/other psychosocial therapy and non-prescription opioid use.

RESULTS: The avg. length of buprenorphine/naloxone therapy for all members analyzed was 10.4 months with 13% extending more than 5 years. 7.5% of members used prescription opioids during therapy while 15.8% used a benzodiazepine. Therapy was completed by 20.3% of members treated with an avg. duration of 24.9 months, though 14.5% used a prescription opioid after completion. The avg. dose was 16mg/day with 52.7% experiencing a dosage decrease during therapy. The avg. cost was $253.28/Rx, of which employers paid 72.2%.

CONCLUSIONS: Treatment of opioid use disorders requires a multi-faceted approach which includes long-term maintenance therapy of a buprenorphine/naloxone product. Drug therapy alone is not the answer. Substituting one pill for another does not address the underlying addiction component. There must be a mental health component, lifestyle modification, and strategy for weaning off buprenorphine. Tapering must be highly individualized, and when the member is ready as forced tapering is associated with high relapse rates and mortality.

SPONSORSHIP: Employee Health Insurance Management.

U14 An Evaluation of Value-Based Frameworks for Non-Small Cell Lung Cancer Drug Regimens: ASCO Value Framework, ESMO Magnitude of Clinical Benefit Scale, ICER Report, and NCCN Evidence Blocks

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BACKGROUND: To combat rising prescription drug costs, the American Society of Clinical Oncology (ASCO), European Society for Medical Oncology (ESMO), Institute for Clinical and Economic Review (ICER), and National Comprehensive Cancer Network (NCCN) created value-based frameworks (VBFs) to inform clinical treatment and payer decision-making processes. Due to the increasing need to redefine the value of medications, it is important to understand the varying attributes of each VBF.

OBJECTIVE: To (a) compare four VBFs for treatments indicated for non-small cell lung cancer (NSCLC) and (b) explore similarities and differences across VBFs in defining value.

METHODS: To perform a test case analysis for the VBFs in NSCLC, two classes of drugs were examined: tyrosine kinase inhibitors (TKIs), including afatinib (AFA), erlotinib (ERL), and gefitinib (GEF), and anti-programmed death receptor-1 and ligand-1 antibodies (PD1s) including atezolizumab (ATE), nivolumab (NIV), and pembrolizumab (PEM). The clinical trials evaluated TKIs for first-line treatment and PD1s for subsequent therapy. The ASCO 2016 updated framework was used to generate a net health benefit (NHB) score for all six drugs. The investigators generated ESMO Magnitude of Clinical Benefit Scale (MCBS) scores for ATE only, while ESMO reported the remaining drugs' MCBS scores. Value assessments for each drug from the 2018 NCCN Evidence Blocks and the 2016 ICER Report were extracted for the test case analysis. Results from each VBF for all six drugs were evaluated and compared.

RESULTS: Among the TKIs, the ASCO VBF results demonstrated significant value of ERL versus GEF and AFA (NHB scores of 77.14, 47.52, and 13.6, respectively). Meanwhile, the ICER VBF suggested that GEF was more cost-effective than AFA and ERL ($110,840/QALY, $135,095/QALY, and $147,244/QALY, respectively). The NCCN VBF valued both ERL and GEF over AFA due to safety concerns. In contrast, the ESMO VBF valued all TKIs equally. Among the PD1s, both ASCO and ICER VBFs reported superior values with ATE (NHB score of 57.89; $219,179/QALY) and PEM (NHB score of 57.57; $240,049/QALY) over NIV (NHB score of 39.64; $415,950/QALY). Both ESMO and NCCN VBFs valued all three PD1s equally. Large differences were seen across the VBFs, such as their value calculations and parameters assessed.

CONCLUSIONS: Among all four VBFs, there was no clear dominating drug. The high heterogeneity in results suggest that a 'one size fits all' approach may not exist when defining drug value. Further enhancements of VBFs are necessary.

SPONSORSHIP: None.

U15 Management of Specialty Drugs, Specialty Pharmacies, and Biosimilars in the United States

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BACKGROUND: Specialty medicines continue to increase as a percent of net and invoice-price basis spending. Biologics are a large portion of specialty spending and health plans are expected to adjust their formularies to maximize expected savings from biosimilars.

OBJECTIVE: To provide a better understanding of health plan management of specialty pharmacy (SP), SP products and biosimilars.

METHODS: Online survey of health plan exec on: roles+plan information, specialty pharmacies and specialty pharmaceuticals, expected biosimilar coverage/restrictions/copays. Results were compared with prior surveys (changes > 2% reported).

RESULTS: Survey completed by 85 respondents. 42.9% were senior officers, 13.1% regional, 8.3% payor specific, 1.2% therapeutic area specific. 36.9% worked for health plans, 13.1% PBMs, 9.5% IDNs, 2.4% PPOs/IPAs, 1.2% Government Plans were National = 29.9%, Regional = 24.7% or Local = 22.1% and cover multiple member types: commercial(58.6% = FFS,77.8% = HMO/PPO), Medicaid (Traditional = 27.8%, HMO/PPO = 72.3%), Medicare (71%, PDP-only = 51%), Employer/Self-funded = 79% and IDN (43.6%, 340B Qualified = 43.8%). 45.6% reported the plan's PBM as their SP provider and providers were restricted by 58%↓23% with plans restricting products: 58% to those under contract, 11.6% for those available through multiple SPs, 10.1% allow any SP handling a product, and 4.4% carving out their SPs. Compared with last year, providers shifted approximately

6% from independents to internally provided and currently 45.6% are PBM-owned, 38.2% health plan-owned, 25% independent and 13.2% hospital/IDN-owned. SP products continue to move from fixed to %copays with more plans determining by group+benefit design . Plans covered clinician-administered products under the medical benefit (36.8%↓7.3%), 2.9% under the pharmacy benefit the remainder used price+plan design. Biosimilar use expected for all reference product indications 58.8%↓5.7%, 31.4%↓13.5% will restrict to approved indications, and 9.8% will use indication as the basis for copay. 10%↓15% expect the biosimilar to be the only product available, copays are expected to be discounted off the innovator 58%↓10.1%, and 32%↓4.9% to vary based on approval timing. Biosimilar education provided through: different copays = 64.7%, prescriber+patient mailings (76.5%↓4.2% + 58.8%), prescriber+patient calls (51%↓10.6% + 27.5%↑4.1%). Expected biosimilars savings: 66%↑20.9% expect 20% 5 years from now.

CONCLUSIONS: Costs associated with SPs+SP products have shifted and are expected to grow with some relief coming from biosimilars.

SPONSORSHIP: TPG-National Payor Roundtable.

U16 The 2019 United States Payor Landscape: Trends and Results from Surveys on Formulary Management

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BACKGROUND: Phamacy and Therapeutics (P&T) committees use an assortment of tools to manage product availability within health plans.

OBJECTIVE: To provide a better understanding of formulary management issues, reviews/coverage and changes.

METHODS: Online survey of senior officers from health plans, insurers, and PBMs. Changes (> 2%) from prior surveys reported.

RESULTS: Survey completed by 85 respondents from health plans, IDNs, ACOs, PPOs, and SPs. Respondents served on a variety of advisory committees. Advisors/plans covered multiple member types: Commercial FFS = 41%, Medicaid = 70%, IDN = 57%, HMO/PPO = 22%, Employer self-funded = 22%. Accountable care/disease mgmt programs included primary care, Hep C, Lipid management, diabetes, and joint replacement. Plans cover rare diseases restricting use thru PAs = 54.7%, based on: risk/benefits = 20.3%, safety&efficacy = 18.8%; contracting = 3.1%, cost = 1.6%, # of members with the condition = 1.6%. Clinician administered agents were always under the medical benefit (37.7%↓6.3%), 2.9% exclusive under the pharmacy benefit, 46%↓8.2% was mixed, and 5.8%↓4.4% plan-design mandated. Changes were not anticipated by 57%↓15.9% of respondents. SP product member co-pays for fixed vs. percent with minimal changes with 36% using co-pay accumulator programs (36%). Approximately 65% of oral biologics and self-injected products were covered under the pharmacy benefit, with no changes anticipated in the benefit (68%). Based on therapy cost, on-going monthly = 43.5%, annual = 30.5%, and "one and done" (26%) treatments were preferred. Respondents involved in decisions for Rx drugs (all 64%, some 27%) and medical devices (all 33%, some 50%), and only 65% require submission of AMCP dossier for Rx products (all 34%, some 28%). Budget impact models (BIMs) were used in 77%↓11% of pharmaceutical products, and in 63%↑18%. Most BIMs were developed internally = 38%, others with manufacturers. 86% indicated they would cover preventative medications for conditions. Rebate disclosures were supported from pharmaceutical manufacturers = 60%, health plans = 59%, and through total cost publications = 61%.

CONCLUSIONS: The managed care P&T Committee decision-making process is undergoing a series of changes and will continue to establish standards for therapeutics and continue to ensure high quality drug therapy for its members in a cost-effective manner. Medical and pharmacy directors have distinct opinions as to how to alter the process to adapt to these influences and cover new therapies with different administration schedules and for rare disorders.

SPONSORSHIP: TPG-National Payor Roundtable.

U17 Identification of Exposure to Reference Biologics and Biosimilars: Use of Medical Claim Line, NDC Code, and HCPCS Code Modifiers

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BACKGROUND: Optimal post-approval surveillance of biologics (reference and biosimilar) requires the accurate identification of the specific product used in administrative claims databases when billed using Not Otherwise Specified (NOS) Healthcare Common Procedure Coding System (HCPCS) codes or HCPCS codes that are not specific to a single product (e.g., biosimilars of the same reference biologic administered by a healthcare provider between 1/1/2016 and 3/31/2018).

OBJECTIVE: To assess the capture of biologic dispensings in the claims databases of the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) Distributed Research Network (DRN) partners, with a focus on the utilization of medical claim National Drug Code (NDC), a novel data field, and HCPCS modifiers.

METHODS: A cross-sectional observational study was conducted among patients with medical and pharmacy benefits enrolled in participating insurance plans of the BBCIC DRN between 1/1/ 2013 and 9/30/2017. We calculated the proportion of medical claims with ≥ 1 NDC code. For select biologics (insulin glargine, anti-inflammatory biologics, erythropoiesis-stimulating agents, granulocyte colony-stimulating factors, and biosimilars), dispensings were identified using 4 different approaches: (a) specific HCPCS alone, (b) specific HCPCS and NDC, (c) NOS HCPCS with NDC, and (d) HCPCS with modifiers (applicable to biosimilars). Numbers of dispensings were calculated for each biologic by the approach and by select patient and health plan characteristics.

RESULTS: The study identified >1.5 million eligible participants who contributed approximately 4 million person-years of data. Among 1.2 billion medical claims analyzed, 2.3% included an NDC code overall; the percentage increased from 1.2% in 2013 to 3.0% in 2017. The NOS HCPCS plus NDC codes in medical claims identified 2,074 dispensings of vedolizumab in 2014 and 2015 (FDA approved vedolizumab in 2014), accounting for 39% and 28% of all vedolizumab dispensings identified from the claims during the two years. A total of 26,381 dispensings of filgrastim biosimilars (Zarxio) were identified from medical claims; 51% of the biosimilar dispensings had a HCPCS modifier and an additional 12% had a medical claim NDC code. We identified 1,244 dispensings of infliximab biosimilars from medical claims; the manufacturer was confirmed for 38% of the biosimilar dispensings using HCPCS modifier, and an additional 3% using NDC code.

CONCLUSIONS: Use of medical claim NDC codes and HCPCS modifiers improves identification of exposure to select biologics that do not have a product-specific HCPCS code.

SPONSORSHIP: Biologics and Biosimilars Collective Intelligence Consortium.

U18 Payer Perceptions on Access to Breastfeeding Support in the United States

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BACKGROUND: In 2015, 25% of infants born in the United States (U.S.) met the American Academy of Pediatrics' recommendation to be exclusively breastfed for the first 6 months of life. Increasing utilization of pain relievers during delivery, increasing number of mothers in the work force, high cost of breast support supplies, and inadequate access to lactation counseling are identified as barriers to breastfeeding.

OBJECTIVE: To survey pharmacy and medical directors with regards to their perceptions on breastfeeding support provided by their organization.

METHODS: A survey was administered to pharmacy and medical directors within Xcenda's Managed Care Network (MCN). The survey assessed the scope of coverage for breastfeeding support supplies and services (e.g., breast pumps, lactation counseling) provided by insurers in the U.S., including timing and frequency of benefit availability.

RESULTS: Forty advisors completed the survey, 60% of whom were pharmacy directors and 40% were medical directors from both regional (75%) and national (25%) managed care organizations (MCOs). Advisors represented commercial plans (62.5%), integrated healthcare delivery systems (30%), and pharmacy benefit managers (7.5%). Approximately 53% of the respondents provided breast pump coverage when the baby was born, while the remaining 47% covered for breast pumps purchased some point during pregnancy to one year after childbirth. Moreover, 71% of the national MCOs covered one breast pump for each pregnancy, while the rest covered one breast pump per every three or more years. All but 32% of respondents required cost-sharing for electric breast pump purchase. Respondents that did not provide full coverage for electric breast pumps (68%) perceived the currently available breastfeeding support as adequate, and 52% of them believed that 0-25% of their plan members utilized the services. When the respondents were asked how proactive they were in disseminating information on the plan benefits to expecting mothers, 9% of the payers that provided full coverage for electric breast pumps responded to be very proactive.

CONCLUSIONS: This survey demonstrates a disconnect between payers and patients. While payers perceive the currently available breastfeeding support as adequate, a large percentage of women do not take advantage of the support, possibly because they are not aware of the services and supplies their plans cover. Further research may be conducted to understand how to effectively deliver the available services and supplies to eligible plan members.

SPONSORSHIP: Xcenda.

U19 Impact of Non-Medical Switching Among Ambulatory Patients: Results of a Systematic Literature Review

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BACKGROUND: Non-medical switching is typically defined as a change in a patient's medication to a clinically similar but chemically distinct (i.e., not a bioequivalent generic) medication for reasons apart from lack of clinical effectiveness, tolerability or adherence.

OBJECTIVE: To perform a systematic review evaluating the impact of non-medical switching on clinical and economic endpoints, resource utilization and medication taking behaviors.

METHODS: We performed a systematic literature search from January 2000-September 2018 in Medline and Web of Science. Studies evaluating ≥25 patients and measuring the impact of non-medical switching of drugs on ≥1 clinical, economic, resource utilization or medication taking behavior endpoint were included. The direction of association between non-medical switching and endpoints was classified as negative or positive, if a statistically significant worsening or improvement was reported; or neutral if no significant difference was observed.

RESULTS: Thirty-eight studies contributed 154 endpoints (60.4% clinical; 21.4% resource utilization; 15.6% economic; 21.6% medication taking behavior). The direction of association was negative (n = 48; 31.2%) or neutral (n = 91; 59.1%) more often than it was positive (n = 15; 9.7%). Stratified by endpoint type, non-medical switching was associated with a negative impact on clinical, economic, healthcare utilization and medication-taking behavior in 26.9%, 41.7%, 30.3% and 75.0% of cases; with a positive effect seen in 3.0% (resource utilization) to 14.0% (clinical) of endpoints. Of the 92 endpoints from studies performed by the entity dictating the non-medical switch, 88.0% were neutral or positive; whereas, only 40.3% of endpoints from studies conducted separately from the interested entity were neutral or positive. Endpoints from studies with a duration of follow-up ≥6 months were more frequently negative than in studies with <6 months follow-up (35.1% vs. 23.2%).

CONCLUSIONS: Non-medical switching was commonly associated with either negative or neutral endpoints and was seldom associated with positive ones. Among the subset of studies conducted by groups that performed/dictated the non-medical switch, endpoints were mostly neutral and positive, and the possibility of reporting bias cannot be ruled out.

SPONSORSHIP: Janssen Scientific Affairs.

U20 Patterns of On-Demand Medication Use Among Patients with Hereditary Angioedema Treated Long-Term with Prophylactic Subcutaneous C1-Inhibitor

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BACKGROUND: Hereditary angioedema (HAE) is characterized by recurrent, debilitating attacks of angioedema that may require immediate (on-demand) treatment with acute medications. HAE prophylactic therapy has the potential to reduce the need for on-demand treatment by decreasing the frequency and severity of attacks, which may in turn impact treatment costs. Subcutaneous C1-inhibitor (C1-INH [SC] 60 IU/kg, HAEGARDA, CSL Behring) is indicated as routine prophylaxis to prevent attacks in adolescent and adult patients with HAE. In the pivotal phase III COMPACT trial, the median reduction in attack rate relative to placebo was 95% with twice-weekly C1-INH (SC) 60 IU/kg, and median reduction in on-demand medication use was >99%.

OBJECTIVE: To examine patterns of on-demand medication use among patients treated with C1-INH (SC) 60 IU/kg in a long-term, open-label extension (OLE) of the COMPACT trial.

METHODS: The OLE of the COMPACT trial was a multicenter, international, randomized, parallel-arm study that evaluated patients aged ≥6 years with ≥4 attacks over 2 consecutive months before enrollment. The trial included patients from the COMPACT trial and C1-INH (SC)-naïve patients. All patients were randomly assigned to receive C1-INH (SC) 40 IU/kg or 60 IU/kg twice weekly for 52 weeks or up to 140 weeks (for U.S. patients only). The time-normalized number of uses of medication for the treatment of HAE attacks was an exploratory endpoint.

RESULTS: Of the 63 subjects in the 60 IU/kg group, 35 had a total of 371 attacks, of which 229 (61.7%) were treated with on-demand medication—84% of attacks (192/229) were treated with 1 medication, 62% with C1-INH (IV) and 38% with icatibant. The majority of treated attacks (113/229) were severe. A total of 28 subjects (44.4%) had no attacks, 11 (17.5%) had no treated attacks, and 24 (38.1%) had at least 1 treated attack. Post-hoc analysis of annualized on-demand medication use showed that 39 subjects (61.9%) treated with C1-INH (SC) 60 IU/kg used no on-demand medication; 66.7% used it less than once per year (mean [SD]: 3.8 [9.6] uses/yr; median: 0.0 uses/yr). Between months 25 and 30, 87% of patients (20/23) used no on-demand medication (mean: 0.08/month, or ~1 use/yr).

CONCLUSIONS: The use of on-demand medication remained consistently low during prophylactic therapy with C1-INH (SC) in the OLE study, with two-thirds of patients using medication less than once per year. The reduction in on-demand medication use over time should be considered in cost-effectiveness analyses of HAE prophylactic therapies.

SPONSORSHIP: CSL Behring.

U21 Evaluating the Impact of a Targeted Program Tailored to Address Patients' Specific Medication Adherence Barriers

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BACKGROUND: Adherence to medication treatment regimens is essential to managing and limiting progression of chronic diseases. However, there are multiple barriers to adherence; cost, forgetfulness, and safety concerns, that must be addressed at the patient level in order to affect change. A proactive, innovative, and tailored approach to identifying and treating non-adherence is the best solution to address the dilemma of medication nonadherence.

OBJECTIVE: To measure the impact of the program on medication possession ratio (MPR) after implementation for three main therapy classes: antihyperlipidemics, antihypertensives, and antidiabetics.

METHODS: A retrospective analysis using a matched case/control study design comparing the pre and post period therapy level MPR of members. The analysis compared the patients from clients who opted for the targeted solution (case sample) to patients from clients who did not opt for the targeted solutions. Patients from both groups were selected based on their predictive score identifying them for possible intervention. Therapy adherence was based on MPR at the therapy class level, assessed 365 days before (pre-period) and after (post period) the program targeting date. The control and test populations were matched by age, gender, and MPR in pre period.

RESULTS: The final sample consisted of 1,611 diabetes, 3,242 hypertension patients and 777 dyslipidemia patients. MPR for lipid medications increased between the pre and post period for the intervention group (0.852 to 0.871) compared to control patients (0.845 to 0.850). A similar pattern was observed for antihypertensive medications. Although, MPR for diabetes medications declined for intervention group and control group, the decrease was less in the intervention group (0.854 to 0.843) compared to those patients in (0.856 to 0.840). Results from multivariate analyses assessing impact on MPR show that patients in the intervention group were 23.5%, 21.5% and 29.1% more likely to be adherent in 2017 controlling for age, gender and pre-period adherence for lipid, hypertension and diabetes classes respectively.

CONCLUSIONS: Utilizing a targeted and tailored prescription adherence program helps to maintain therapy adherence. When compared to patients enrolled in payers that have not implemented the adherence program, adherence showed smaller declines in the post period. This may contribute to an increase in pharmacy related costs, but these may more than account for by increased medical cost savings associated with better management of the patient's chronic health condition.

SPONSORSHIP: Express Scripts.

U22 Forces Driving Change in Healthcare: Payer Insights on Key Trends

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BACKGROUND: A variety of interwoven trends are changing the face of healthcare. These trends include, but aren't limited to, drug affordability, innovative and curative therapies, industry consolidation, optimal health coverage, population health management, and accelerated drug approvals. Payers are one key group working towards viable solutions to the aforementioned trends.

OBJECTIVE: To understand payer insights into key healthcare trends and to identify the most promising potential solutions to foster wider implementation of innovative strategies.

METHODS: A 33-item web-based survey (9/19/18-10/6/18) was conducted with U.S. pharmacy, contracting, and medical directors and clinical pharmacists across national and regional ACOs, IDNs, health plans, and PBMs (N = 70). Respondents were asked about their familiarity with trends outlined above. For each trend that respondents had some familiarity, they were asked about the barriers and solutions to addressing these issues.

RESULTS: Of the 6 key trends studied, drug affordability was ranked most impactful on the future of healthcare with 93% of respondents classifying it as extremely/very impactful, followed by innovative and curative therapies (88%) and industry consolidation (80%). Affordability faces many barriers, with lack of pricing transparency being most prominent (49%). The top barrier facing innovative and curative therapies is cost, which 99% of respondents believe is extremely/very challenging even while 69% believe it will be addressed in 6-10 years. Nearly all (91%) respondents indicated that industry consolidation could harm patient choice. The topics rated as relatively less impactful, though still perceived as extremely/very impactful on the future of healthcare, were optimal health coverage (76%), population health management (73%), and expedited drug approvals (47%).

CONCLUSIONS: Of those examined, the trends most impactful to future healthcare, according to payers, are drug affordability, innovative and curative therapies, and industry consolidation. Cost, lack of transparency, and misaligned incentives are often rated as extremely/very challenging barriers. Given the complexity of these trends and barriers, their respective solutions must be multifaceted. Healthcare IT, artificial intelligence, and big data are instrumental to craft innovative solutions. Social determinants of health should also be considered to drive meaningful change.

SPONSORSHIP: Academy of Managed Care Pharmacy Foundation and Pfizer.

U23 Payer Perceptions of Patient-Reported Outcomes and Other Clinical Outcome Assessments in the United States

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BACKGROUND: Patient-reported outcomes (PROs), and more broadly, clinical outcome assessments (COAs), can measure a patient's symptoms, mental state, and/or the effects of a disease or condition on patient function. Frequently, COAs are utilized to determine whether a drug has demonstrated treatment benefit(s). A previous survey conducted in 2014 assessed United States (U.S.) managed care pharmacy decision makers' familiarity, interest, and utilization of PROs vs. other types of COAs in decision making.

OBJECTIVE: To understand and evaluate trends in U.S. managed care pharmacy and medical directors' familiarity, interest, and utilization of COAs in decision making.

METHODS: An online survey containing multiple choice, open-ended, and Likert scale rating questions was fielded to members of Xcenda's Managed Care Network, a panel of managed care professionals, between November and December of 2018. These survey responses were compared to the previous survey responses to assess changes in payer perceptions of COAs.

RESULTS: 43 respondents, covering more than 300 million lives across the U.S., completed the survey representing primarily regional plans (63%). Similar to the 2014 survey, 70% of the respondents reported being very or extremely familiar with PRO data. In the current survey, more respondents (95%) responded affirmatively towards the credibility of clinician-reported outcomes (ClinROs) compared to any other COA; PROs had the lowest credibility rating of all COAs (77%). Similarly, more respondents confirmed that ClinROs are the most impactful COA on tier placement and utilization management (72%), as well as having the highest overall value (93%). These findings closely reflect the results of the 2014 survey. Current respondents rated PRO endpoints within clinical trials most relevant in psychiatry (79%) and least relevant in immunology (56%). Respondents also indicated that although they infrequently use PROs in managed care activities, they are most often used to improve patient care (60%) through disease management programs and quality metrics (both 54%). Notably, a majority of respondents (72%) indicated never or seldom using PROs to determine product access and/or coverage.

CONCLUSIONS: Despite increased efforts to include the patient voice in healthcare decision making, the impact of PROs and other COAs on payer decision making within the U.S. is low. There is a need for further efforts to better define the role of COAs, specifically PROs, in payer decision making so as to increase utilization.

SPONSORSHIP: None.

U24 Listening to the Medicare Beneficiaries: Findings from a National Survey on the Medication Therapy Management Standardized Format

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BACKGROUND: The Medication Therapy Management (MTM) Standardized Format's (SF) length, cost, static nature of the

document, as well as lack of integration into the beneficiaries' electronic health records have been identified as areas that need improvement. However, limited research exists on the beneficiaries' opinion and perceptions of the SF.

OBJECTIVE: To evaluate beneficiaries' perspective regarding SF utility to inform potential modifications for its optimal use.

METHODS: A national survey for the evaluation of the MTM SF was designed on the basis of qualitative findings from previous research. This structured survey, with 42 multiple choice questions, was distributed through Medicare Part D plans to beneficiaries who had received a Comprehensive Medication Review (CMR) in the previous 12 months. Descriptive statistics are reported for demographic information, health status, the perceived value and helpfulness of the SF and its three components (cover letter [CL], Medication Action Plan [MAP], Personal Medication List [PML]), updates to the SF, alternate formatting, and integration of the SF into health records.

RESULTS: A total of 9,975 surveys were sent electronically to beneficiaries by four different Medicare Part D plans. Of the 434 unduplicated survey respondents, 58.5% were 65-84 years, 60% identified as white and 49.1% had at least a college education. Beneficiaries rated how well the SF helped improve different aspects of their medication management with 40.8%-44.9% choosing very good to excellent. Helpful sections of the MAP included "What we talked about" and "What I need to do", and for the PML, medication name, strength, dosage form and, how and why I use the medication. Less helpful were the fill-in sections of the MAP, with 48.6% reporting that they did not write in any information. A wallet card version of the PML, if available, would be used by 54.6% of participants. About 30% of beneficiaries shared the SF with their doctor and 26% gave copies of their medication summary to their relatives.

CONCLUSIONS: Fewer than half of the Medicare beneficiary respondents perceived the SF as very good or excellent for managing their medications. This national survey provides Medicare beneficiary focused evidence that more work is needed to improve the utility as well as the integration of the SF into healthcare delivery. This can be achieved by allowing flexibility in the design of the SF while keeping the essential elements identified as helpful by the beneficiary.

SPONSORSHIP: Academy of Managed Care Pharmacy.

U25 Changing Prescriber Use of Pharmaceutical Manufacturer Coupons Within a Clinically Integrated Healthcare System

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BACKGROUND: Pharmaceutical manufacturer coupons are commonly marketed to patients and prescribers. These coupons insulate patients from higher copay costs incurred when using higher-priced brand name drugs. In value-based payment models the prescription cost per member per month can impact shared savings. In this setting, manufacturer coupons reduce generic utilization thereby increasing costs to payers, providers and the clinically integrated healthcare system.

OBJECTIVE: To evaluate coupon card utilization after implementing mandatory provider education and prescribing policy changes within a clinically integrated healthcare system.

METHODS: Two pharmacists provided education to primary care providers and care managers on the implications of manufacturer coupons. This asynchronous, fifteen-minute video with subsequent electronic newsletter was assigned as required continuing medical education to 163 primary care providers. Additional changes were also made in the organizations policies for using manufacturer coupons.

Claims data on prescriptions processed using manufacturer coupons was provided by a large chain pharmacy. The data compared pre-education and policy change between September 2015 to September 2016 versus post-education implementation and policy changes between June 2017 to June 2018.

RESULTS: Coupon utilization dropped 50% (713 to 356) and was correlated with a 67% drop in coupon prescription expenditure ($243,019 to $79,594).

CONCLUSIONS: Educating providers on the cost implications of pharmaceutical manufacturer coupons and implementing policies to limit the use of coupons promotes prescribing of more cost-effective formulary alternatives. This improves generic dispensing ratio and per member per month pharmacy cost, and ultimately reduces the overall cost of healthcare.

SPONSORSHIP: Hartford Healthcare Integrated Care Partners and University of Connecticut School of Pharmacy.

U26 Differences on Work Productivity Loss, Healthcare Resource Utilization, and Costs by Patient Activation Level

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BACKGROUND: Patient activation refers to an individual's knowledge, skill, and confidence in managing their health, which can lead to better outcomes. However, more research is needed to understand whether patient activation may impact economic outcomes.

OBJECTIVE: To examine the associations between patient activation level and economic outcomes among U.S. adults.

METHODS: Data from Kantar Health's 2018 PaCeR (Patient-Centered Research) database in the U.S. were utilized. Adults age 18 and over (N = 74,977) were surveyed using stratified random sampling based on gender, age, and race/ethnicity to ensure representativeness to the adult population (based on U.S. Census data). Patient activation was assessed using the Patient Activation Measure (PAM; 4 levels [L1-L4]; higher levels represent higher activation). Economic outcomes included work productivity and activity impairment (assessed with the WPAI questionnaire), health resource utilization (HRU) in the past 6 months, and estimated mean annual direct and indirect costs. Bivariate analyses were performed using independent sample t-tests or chi-square tests to examine differences between activation level groups.

RESULTS: Among 63,522 respondents with PAM scores, mean age was 48 years old; 55.8% female. Lower PAM levels were associated with younger age, being male, being single/never married, and having lower educational attainment. Lower PAM levels were associated with greater overall work impairment (Means: L1 = 33.6%, L2 = 25.5%, L3 = 20.24%, L4 = 15.6%, all pair-wise $P < 0.05$) and higher annual indirect costs (Means: L1 = $7,586, L2 = $5,726, L3 = $4,296, L4$ = 3,127, all pairwise $P < 0.05$). Adults with lower PAM levels incurred greater numbers of healthcare provider visits (Means: L1 = 4.25 vs. L4 = 3.84, $P < 0.05$), ER visits (Means: L1 = 0.41 vs. L4 = 0.20, $P < 0.05$) and hospitalizations (Means: L1 = 0.24 vs. L4 = 0.13, $P < 0.05$) in the past 6 months than those with higher PAM levels. As a result, annual directs costs were higher among those with lower PAM levels than those with higher PAM levels (L1 = $9,491, vs. L4 = $6,129, $P < 0.05$).

CONCLUSIONS: Lower patient activation was associated with greater work productivity loss, HRU, and annual direct and indirect costs. Future research should identity interventions which can move individuals from lower to higher levels of activation as it could potentially help reduce healthcare costs.

SPONSORSHIP: Kantar Health.

U27 Hereditary Angioedema C1-Inhibitor Replacement Therapy and Coexisting Autoimmune Disorders: Findings from a Claims Database

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BACKGROUND: Autoimmune diseases are a leading cause of morbidity and mortality in the U.S. (estimated prevalence: 4.5%) and often associated etiologically with dysregulation of the complement system (innate and adaptive immune response). The classic complement pathway, one of 3 biochemical pathways that activate the complement system, is regulated by C1-inhibitor (C1-INH), which binds to C1 to prevent its activation. Hereditary angioedema with C1-INH deficiency (C1-INH-HAE) may be linked with increased autoimmunity due to secondary deficiency of C1r, C1s, and other components.

OBJECTIVE: It was hypothesized that increased regulation of the complement system via C1-INH replacement therapy may reduce autoimmunity in patients with C1-INH-HAE. We compared coexisting autoimmune disease claims frequency between C1-INH-HAE patients treated with plasma-derived (pd) C1-INH versus other "non-C1-INH" treatments.

METHODS: C1-INH-HAE patients were identified in the IMS Health PharMetricsPlus claims database between January 2012 and December 2015 by International Classification of Diseases (ICD) 9/10 diagnosis code, and classified by their HAE treatment into "pdC1-INH" or "Other (non-C1-INH)". Index date was the first claim for HAE treatment. For patients using pdC1-INH, the first fill was the index date even if other HAE medications had been used previously. Frequency of visit claims for autoimmune conditions was identified by diagnostic codes (primary or secondary). Mean visits per patient per year by treatment group, gender, and age (<50 vs. ≥50 years) were summarized for autoimmune conditions.

RESULTS: Of the 589 HAE patients identified (69% female, 38% aged ≥50 years), 276 (729 patient-years) received pdC1-INH and 313 (860 patient-years) received "other (non-C1-INH)" treatments. In this cohort, 12.9% of patients had at least 1 visit associated with a coexisting autoimmune disorder—the most common were lupus, alopecia, rheumatoid arthritis, sicca (Sjögren) syndrome, and connective tissue disorders. The mean (95% CI) number of visits for autoimmune diagnoses per patient per year were 1.37 (0.56, 2.19) for patients treated with pdC1-INH versus 2.28 (0.83, 3.73) for those treated with non-C1-INH treatments.

CONCLUSIONS: Treatment of C1-INH-HAE with pdC1-INH may have a positive impact on coexisting autoimmune conditions by normalizing complement. Confirmation with larger independent samples and further research are needed. If confirmed, there are implications for healthcare resource utilization among patients with HAE and coexisting autoimmune disorders.

U28 A Framework for Vetting "Good" Outcomes-Based Measures in Alternative Payment Models

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BACKGROUND: Alternative payment models (APMs) are part of a growing trend to shift away from volume-based, traditional fee-for-service payment models toward payment for value. In the broadest sense, APMs generally seek to achieve high-value care and reduce high cost, low-value care by incentivizing providers and their clinicians to make economical care decisions while a) maintaining or improving the quality of care delivery, and b) linking pre-specified outcomes to quality measures related to financial performance-based payments. Value is defined by outcomes achieved per dollar spent. But how can stakeholders be confident we are truly measuring value? Many clinical stakeholders worry current quality measures do not adequately reflect the quality of care they provide their patients. A major concern is that current measures lack the patient voice, instead emphasizing utilization, cost and short-term complications.

OBJECTIVE: To explore how high quality, patient-informed core outcome sets (COS) developed for research might help improve the patient-centeredness of APMs. In doing so, we engaged a multi-stakeholder working group to identify and prioritize characteristics of "good" outcomes-based quality measures.

METHODS: We conducted a directed literature review, key informant interviews, web-based multi-stakeholder workgroup discussions and a COS vetting and prioritization exercise using the web-based survey platform Qualtrics.

RESULTS: The following characteristics of "good" outcomes or outcomes-based quality measures in APMs were identified and include (in order of priority): clinically relevant, meaningful to patients, actionable, inclusive of important patient populations, feasible to observe (and measure) from data, associated with observable differences in a reasonable amount of time, associated with cost savings, and associated with minimal burden on providers.

CONCLUSIONS: Based on our exploration of how COS can help improve the patient-centeredness of APMs, we propose a framework to guide future discussions engaging providers, payers, clinicians and patients to select appropriate and relevant outcomes-based measures for APMs and other value-based payment initiatives. This framework is intended to connect what patients value in research to the systems that are shaping reimbursement policies and influencing the experience and decision-making of the patient-clinician encounter.

U29 Pharmacists in ACOs and Roles for Managed Care Pharmacists

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BACKGROUND: One of the ways accountable care organizations (ACOs) aim to improve patient care while reducing the total cost of care is to focus on pharmacy costs and quality. However, anecdotally, pharmacy services and priorities vary greatly among ACOs. It is a challenge to support several ACOs from a central managed care position, such as from within one of the multiple payers that contract with ACOs.

OBJECTIVE: To describe the prevalence of employed pharmacists among ACOs, the pharmacists' roles, and opportunities for optimizing the support of pharmacy initiatives for ACOs with and without pharmacists, from a managed care perspective.

METHODS: A voluntary online questionnaire survey was conducted in August 2018 by a national payer's clinical consultants who work directly with ACOs' clinical leadership. Question types included were dichotomous (yes/no), multiple choice, or open-ended. Categorical and discrete variables were analyzed using univariate analysis. Free

text responses were analyzed using deductive coding. Provider groups with multiple ACO contracts (e.g., for multiple lines of business) were counted once, as pharmacist resources are typically shared within a provider group regardless of line of business or contracted payer.

RESULTS: Survey responses were received for 233 of the 529 ACOs for which a survey request was made (46% response rate). Among the ACOs with responses, 57% were Medicaid, 28% Medicare, and 25% commercial, where 10% had contracts for multiple lines of business. Pharmacists were employed by 81 ACOs (35%), with more commercial and Medicare ACOs having pharmacists (47% and 45%, respectively) than Medicaid (29%). The number of pharmacists employed ranged from 0.5 to 10, with most ACOs employing 1-2. Reported key responsibilities of the ACO pharmacists included patient care (79%), population health (59%), collaborative practice (53%), dispensing (2%), or unknown (15%). For commercial ACOs that use a monthly pharmacy report provided by the payer with lower cost alternative prescribing opportunities and opioid utilization data (29 ACOs), the majority used the reports for monitoring trends and savings opportunities. Other report uses included provider and member outreach.

CONCLUSIONS: The majority of surveyed ACOs do not employ pharmacists, and pharmacist responsibilities vary among ACOs. Our results provide insights into opportunities for enhanced pharmacy support from managed care entities that contract with ACOs, especially payers where pharmacy education and analytics could be provided to drive savings and quality improvement opportunities.

SPONSORSHIP: UnitedHealthcare.

Z00-Z99 Factors Influencing Health Status and Contact with Health Services

Z1 Unmet Needs in the Diagnosis and Treatment of Women with Hypoactive Sexual Desire Disorder

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BACKGROUND: Hypoactive sexual desire disorder (HSDD) is defined as persistent diminished or lack of sexual desire accompanied by distress, and affects approximately 10% of U.S. women aged 18-44 years. However, there is limited awareness of validated HSDD screening instruments and treatment options among physicians.

OBJECTIVE: To understand the unmet needs in diagnosis and treatment for patients with HSDD through a medical chart review.

METHODS: Data from 268 medical charts from 103 U.S. board-certified obstetricians/gynecologists (OB/GYNs), psychiatrists, and primary care physicians (PCPs), which included family medicine and internal medicine physicians, were analyzed using an IRB-approved case report form that mimicked a typical patient chart. Physicians also completed an IRB-approved web-based questionnaire. Screening criteria required physicians to manage ≥2 patients diagnosed with HSDD and ≥5 patients diagnosed with female sexual dysfunction (FSD) each month. Inclusion criteria for medical charts were females ≥18 years old who had been diagnosed with HSDD.

RESULTS: Physicians who contributed medical charts included OB/GYNs (41%), PCPs (31%), and psychiatrists (28%); only 16% reported a subspecialty in sexual medicine. Medical charts for premenopausal (57%) and postmenopausal patients (43%) were included; their mean age was 45 years. The Decreased Sexual Desire Screener (DSDS), a validated HSDD screening questionnaire, was not used in 81% of medical charts to diagnose HSDD. The duration from first HSDD symptoms

recognition to treatment was approximately 2.5 years. The most commonly prescribed medications were flibanserin (53%) and bupropion (46%). The most frequently prescribed nonpharmacological treatments included lubricants/moisturizers (60%), referral to a therapist (55%), and relaxation/meditation (49%). There was a lower discontinuation rate of nonpharmacologic versus pharmacologic treatments. Physicians reported treatment ineffectiveness as the most common reason for treatment discontinuation, and only moderate levels of satisfaction with pharmacological and nonpharmacological treatments.

CONCLUSIONS: Most physicians who participated in this study did not use a validated HSDD screening and diagnostic instrument, such as the DSDS, and there was approximately a 2.5-year delay from recognition of HSDD symptoms to treatment by the physician. Moderate levels of satisfaction with treatments indicate a high level of unmet needs regarding efficacious treatments for HSDD.

SPONSORSHIP: AMAG Pharmaceuticals.

Z3 A Discrete Choice Experiment on Payer Preferences for Innovative Payment Schemes Aimed at Financing High-Cost, Potentially Curative Therapies

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BACKGROUND: As the number of potentially curative therapies in the drug development pipeline grows, stakeholders are proposing innovative payment schemes (IPSs) to mitigate budgetary strain and hedge against healthcare payer uncertainty. While risk-sharing agreements have exhibited popularity in recent years, many other IPSs remain to be investigated for their appeal and feasibility.

OBJECTIVE: To understand, by means of direct and indirect preference elicitation (i.e., discrete choice experiment [DCE]), health care decision maker (HCDM) preferences for traditional payment schemes and IPSs (i.e., amortization [AA], milestone [MA], risk-sharing [RSA], and securitization agreements [SA]) aimed at financing high cost, potentially curative therapies nearing market authorization.

METHODS: An online survey was conducted via Xcenda's Managed Care Network, a panel of U.S. HCDMs. Responders were probed via DCE to assess preferences for drug-disease profiles comprising cost of therapy, expected clinical and humanistic benefit, probability of experiencing benefit, and payment scheme. From responder tradeoffs, part-worth utilities were derived for payment schemes; responder preferences for payment schemes as well as profile characteristics were also directly elicited, while statistical significance of such was assessed by analysis of variance.

RESULTS: Responses from 35 HCDMs were collected. Twenty respondents (57%) represented a health plan, 10 (29%) represented a pharmacy benefits manager, and 5 (14%) represented an integrated delivery network. DCE revealed that MAs had greater utility than RSAs, followed by fee-for-service (FFS), while AAs and SAs had less utility than FFS arrangements. Likewise, upon direct elicitation, MAs and RSAs were stated as the most favorable payment schemes. The most impactful characteristics in the choice between drug-disease profiles as determined through DCE were cost of therapy followed by payment scheme, for which a significant difference was not detected. Respondents also directly rated cost of therapy and payment scheme as the most impactful characteristics when choosing a drug-disease profile. Nearly three-quarters of respondents expressed that IPS implementation was "extremely concerning" or "very concerning."

CONCLUSIONS: IPSs are of notable importance to HCDMs. Concordance was observed across indirect and direct elicitation methods, with MAs and RSAs being preferable to FFS contracting. Future

multi-stakeholder partnerships should be aimed at further developing IPSs that best meet HCDM needs for funding high-cost, potentially curative therapies.

SPONSORSHIP: None.

Z4 Analysis of Pharmacogenomics Program with Pharmacy Benefit Manager Intervention

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BACKGROUND: Genetic makeup affects medication metabolism. Pharmacogenomics (PGx) testing is a tool that may assist in providing safe and effective medications to individual patients. While some studies have shown the benefit of PGx testing, the effect on medication changes and costs is not well described.

OBJECTIVE: To determine user experience with the PGx process, to assess medication changes after testing, and to evaluate pharmacy costs associated with medication changes after testing.

METHODS: Participants obtained an order from their provider for the PGx test, and collected their own buccal swab sample. Participants and prescribers were then mailed a letter with the test results and notable gene-drug interactions with medications the participants were currently taking. Participants were asked to complete a user experience survey at the end of the pilot. Pharmacy prescription claims data was obtained for two successive 8-month time periods: July 1, 2017-February 28, 2018 (pre-PGx test) and March 1, 2018-October 31, 2018 (post-PGx test). The sample was divided into 2 groups; the intervention group included members who followed the recommended changes and the non-intervention group included members who continued therapy without making the recommended changes.

RESULTS: There were 54 gene/drug interactions among 80 participants (mean age 44). Follow up was not possible with 5 of the gene/drug interactions due to insurance coverage differences. Out of 49 gene/drug interactions, there were 15 medication changes and 9 PRN medication discontinuations. Repeated measures ANOVA with post hoc comparisons of significant mean effects indicated a significant interaction was detected in all three cost variables: plan paid per day, member paid per day, and total cost per day of therapy. Post hoc analysis of total cost per day of therapy indicated the intervention group decreased from 1.05 ± 0.31 to 0.17 ± 0.25 (-83%). The non-intervention group did not change their cost per day of therapy 0.89 ± 0.30 to 0.91 ± 0.25 (+2%). The intervention group declined significantly at post-PGx test to a point where their values were significantly less than the non-intervention group. The survey results showed that 94.4% of the members agreed with the statement "I was overall satisfied with the program as whole".

CONCLUSIONS: Incorporating PGx testing in prescribing practices may result in cost-savings. On average, the members in the intervention group saved 88 cents cost per day of therapy. Further studies are needed to support PGx testing for prescribing medications and overall cost avoidance.

SPONSORSHIP: Navitus.

Z5 Adherence to Specialty Medications: Assessing Rates and Correlates of Nonadherence at an Integrated Specialty Pharmacy

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BACKGROUND: Nonadherence to specialty medications leads to worse patient health outcomes and higher financial burden on the healthcare system. Identifying rates and predictors of nonadherence can improve adherence intervention design.

OBJECTIVE: To analyze rates and correlates of medication nonadherence in patients prescribed specialty medication at an integrated specialty pharmacy in an academic health center.

METHODS: We conducted a single-center retrospective review of pharmacy claims at Vanderbilt Specialty Pharmacy (VSP) for patients treated in 20 specialty clinics. Patients receiving at least three medication fills from VSP during the study period (November 2016 to December 2017) were included. We excluded patients whose medications had disparate administration schedule and days' supply claim submission. Data were analyzed on the patient plus generic product identifier (GPI) level. We calculated medication adherence using proportion of days covered (PDC); nonadherence was defined as PDC<80%. We collected patient demographics (age, race, and gender), and summarized the sample using descriptive. Using Chi-square tests, we compared rates of non-adherence (PDC<80%) between gender (male vs. female) and race (White vs. non-White). An independent samples t-test compared average age between adherent and non-adherent patients. Multivariable logistic regression was used to assess whether nonadherence was associated with patient gender, race, or age (per 10-year increase).

RESULTS: We included 7297 unique patient/GPI identifiers. Most were female (56%) and White (86%), with an average age of 51 years (SD = 19.8). Clinics with the most patient/GPI identifiers were rheumatology (24%), oncology (15%), and multiple sclerosis (10.8%). Median PDC of the sample was 99%; 14% of the sample (n = 1,027) was classified as nonadherent. Nonadherence was more common in women than men (15.1% vs. 12.8%, χ^2 = 7.54, P = 0.006), and nonadherent patients were significantly younger than adherent patients (46.2 vs. 52.5 years, t = 9.36, P < 0.001). In multivariable logistic regression, non-adherence was associated with female gender (B = -0.22, SE = 0.07, P = 0.002), and older age (B = -0.15, SE = 0.17, P < 0.001). Race was not associated with adherence in univariate or multivariable analysis.

CONCLUSIONS: Our results show a low rate of nonadherence among patients using an integrated specialty pharmacy but highlight improvement potential. Data suggest younger patients and female patients are at risk for nonadherence. These results aid in identifying and addressing patients at risk of nonadherence to specialty medication.

SPONSORSHIP: Vanderbilt University Medical Center.

Z8 Quantifying the Healthcare Burden Associated with Opioid Use After Discharge Following Inpatient and Outpatient Surgery Among Previously Opioid-Naïve Patients

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BACKGROUND: The treatment of post-surgical pain with prescription opioids has been associated with new chronic use, opioid use disorder, and increased healthcare utilization and costs.

OBJECTIVE: To compare the healthcare burden between opioid-naïve patients prescribed opioids after discharge from surgery vs. opioid-naïve patients who were not prescribed opioids.

METHODS: From 2010-2016, opioid-naïve adult patients with inpatient or outpatient major surgery were identified in the MarketScan Commercial, Medicare, or Medicaid claims databases. Enrollment before (≥1 year) and after (≥1 year) surgery was required. Cohorts were defined based on opioid pharmacy claim(s) within 7 days before to 1 year after index surgery (opioid use during surgery and inpatient use were not available). Patients with such claims from 365 to 8 days before surgery were excluded. All-cause healthcare utilization and costs were measured during the post-period (index surgery hospitalization/day of index outpatient surgery not included). Predicted costs were estimated from adjusted log-linked gamma generalized linear models.

RESULTS: There were 1,174,905 opioid-naïve patients with an inpatient surgery (73% commercial, 20% Medicare, 7% Medicaid) and 2,930,216 opioid-naïve patients with an outpatient surgery (74% commercial, 23% Medicare, and 3% Medicaid) during the study period. Opioid use post-discharge was common among all cohorts, but less common among Medicare patients (inpatient = 63%; outpatient = 43%) than patients with commercial (inpatient = 80%; outpatient = 75%) or Medicaid insurance (inpatient = 86%, outpatient = 81%). Most patients in the opioid cohorts filled a prescription within ±7 days of surgery (59%-91%). Opioid cohorts were younger, had a larger proportion of female patients, and had higher preoperative comorbidity burden than the non-opioid cohorts. Hydrocodone and oxycodone were the most commonly used opioids. In unadjusted analyses, opioid groups generally had more hospitalizations, emergency room visits, and pharmacy claims. Adjusted predicted 1-year post-period total healthcare costs were significantly higher ($P<0.001$) for opioid groups than non-opioid groups for commercial (inpatient: $22,209 vs. $14,439; outpatient: $13,897 vs. 8,825), Medicare (inpatient: $31,721 vs. $26,761; outpatient: $24,529 vs. $15,225) and Medicaid (inpatient: $13,512 vs. $9,204; outpatient: $11,975 vs. $8,212) patients.

CONCLUSIONS: Filling an opioid prescription in the 1 year after inpatient or outpatient surgery was independently associated with increased healthcare costs.

SPONSORSHIP: Heron Therapeutics.

Z9 Cost-Effectiveness Analysis of a Community Pharmacy-Enhanced Service Program: Should the Managed Care Organization Reimburse Enhanced Pharmacy Services?

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BACKGROUND: The Joint Commission of Pharmacy Practitioners (JCPP) recognizes the need for pharmacist involvement in improving the quality of care in community pharmacies. However, no studies have been published on the cost-effectiveness of the Community Pharmacy Enhanced Service program (CPESP), which offers additional communications and establish professional relationship with the patient, provide more intensive review of patient medication regimens and work with patients to resolve concerns with the patient's medications.

OBJECTIVE: To determine the cost-effectiveness of Community Pharmacy Enhanced Services Program (CPESP) provided by independent pharmacies vs. traditional services provided by chain pharmacies from the payer's perspective using claims data, and to apply the results to guide third-party payers' decision-making.

METHODS: A Markov Cost-Effectiveness model with annual cycles and 10-year time horizon was run from a U.S. managed care perspective. Both a cohort-based analysis and bootstrap simulation were implemented for the incremental cost-effectiveness ratio (ICER) of the CPESP program in terms of survival time and patient clinical outcomes. The modeled population were based on the real-world claims data from either independent pharmacies that provide CPESP or traditional services by chain pharmacies. The comparative effectiveness of pharmacy services was obtained from a longitudinal observational cohort from January 1, 2017 to December 31, 2017. The Markov model was implemented to simulate patients receiving either CPESP or traditional pharmacy services moving between healthy status, stable to mild disease, advanced disease, and death. Transition probabilities, survival time (in life years) and costs were derived from the claims data and the literature, where appropriate.

RESULTS: From the managed-care perspective, the Community Pharmacy Enhanced Service program could extend patients survival time by 0.12 years/person over a 10-year period (The incremental cost-effectiveness ratio, ICER, for enrollees was $16,809 per life year gained) and could reduce hospitalizations by 6.9/person over a 10-year period (ICER = $290.61 per hospitalization reduced). As a result, a cost offset of $19,99.4/ person could be obtained for patients receiving CPESP vs. those who did not over 10 years.

CONCLUSIONS: Community Pharmacy Enhanced Service Network is a cost-effective or even a cost-saving program in the managed care perspective. Third-party payers should consider reimbursing fully or partially the cost of these community pharmacy enhanced services, which would result in cost-savings over the long run.

SPONSORSHIP: University of South Carolina Kennedy Center.

Z14 Healthcare Resource Utilization and Direct Healthcare Cost Related to Peanut Allergy in Medicaid Patients

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BACKGROUND: Peanut allergy (PA) is one of the most common forms of food allergy, with reactions due to accidental exposure to peanut accounting for the majority of severe and sometimes life-threatening events in food-allergic patients. There are limited data assessing the real-world cost of care for patients with PA.

OBJECTIVE: To evaluate the cost of care associated with PA among Medicaid-insured patients.

METHODS: This retrospective, matched cohort study used Medicaid administrative claims data from 6 U.S. states (Iowa, Kansas, Missouri, Mississippi, New Jersey, and Wisconsin; 01/01/2007-03/31/2017). Patients were classified into 2 mutually exclusive cohorts, the PA cohort (patients with confirmed PA and evidence of severe allergic reactions, including a diagnosis for anaphylactic reaction due to peanut or an emergency department [ED] visit with a PA diagnosis) and the PA-free cohort (patients without a PA diagnosis). PA patients were matched 1:10 to PA-free patients based on age, sex, race, health-plan type, and state. The index date of PA-free patients was set to the index date of the matched PA patient, which was the date of the first evidence of a severe reaction. All subjects were required to have ≥12 months of data after the index date. Patient comorbidity profile, healthcare resource utilization (HRU), and direct healthcare costs (2017 USD; public payer's perspective) were analyzed.

RESULTS: A total of 2,799 PA patients were matched to 27,990 PA-free patients; the mean age was 8 years and 56.9% were male. The proportion of patients with comorbidities frequently associated with PA was higher in the PA vs. PA-free cohort (asthma: 58.0% vs. 20.1%; atopic dermatitis/eczema: 59.7% vs. 23.4%; other food allergies: 44.1% vs. 0.5%; allergic rhinitis: 64.6% vs. 26.1%; depression: 13.6% vs. 11.2%;

anxiety: 8.5% vs. 6.1%; all $P<0.01$). On average, PA and PA-free patients had 1.2 and 0.6 ED visits per patient-year (PPY), respectively (incidence rate ratio [IRR] = 2.08; $P<0.01$). PA and PA-free patients had 0.7 and 0.4 inpatient admissions PPY, respectively (IRR = 1.95; $P<0.01$). The mean annual direct healthcare costs per PA patient were $6,706 (15% were related) vs. $3,592 (4% were asthma-related) per PA-free patient. PA patients incurred higher costs by $3,114 PPY; this cost difference was $2,261 PPY when excluding asthma-related costs (all $P<0.01$).

CONCLUSIONS: Medicaid patients with PA and evidence of severe allergic reactions had significantly higher HRU and direct healthcare costs, regardless of asthma-related costs, compared to those without PA.

SPONSORSHIP: Aimmune Therapeutics.

Z15 Comorbidity and Economic Burden of Peanut Allergy in Privately Insured Patients in the United States

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BACKGROUND: Peanut allergy (PA) is a condition for which there are currently no curative therapies. Reactions triggered by accidental exposure to peanut are common and can be life-threatening. As the prevalence of PA continues to increase, a better understanding of cost of care associated with PA is warranted.

OBJECTIVE: To assess the cost of care associated with PA among privately insured patients in the U.S.

METHODS: A retrospective, matched cohort study comprising patients from a large U.S. administrative claims database (01/01/2007-03/31/2017) was conducted. Patients were classified into 2 mutually exclusive cohorts, the PA cohort (patients with a confirmed PA diagnosis and evidence of severe allergic reactions, including anaphylactic reaction due to peanut or an emergency department (ED) visit with a PA diagnosis) and the PA-free cohort (patients without PA diagnoses). PA patients were matched 1:10 to PA-free patients based on age, sex, health-plan type, and region of residence. For PA-free patients, the index date corresponded to that of the matched PA patient, which was the date of first evidence of a severe reaction. Comorbidity profile, healthcare resource utilization (HRU), and direct healthcare costs (2017 USD; private payer's perspective) were observed for ≥ 12 months after the index date and compared between cohorts.

RESULTS: A total of 6,971 patients with PA were matched to 69,710 PA-free patients; mean age was 9 years and 59.0% were male. The proportion of patients with comorbidities frequently associated with PA was higher in the PA vs. PA-free cohort (asthma: 49.0% vs. 12.8%; atopic dermatitis/eczema: 43.3% vs. 16.2%; other food allergies: 44.0% vs. 1.0%; allergic rhinitis: 61.6% vs. 19.2%; depression: 11.2% vs. 8.1%; anxiety: 8.9% vs. 6.2%; all $P<0.01$). On average, PA and PA-free patients had 0.6 and 0.3 ED visits per patient-year (PPY; incidence rate ratio [IRR] = 1.90; $P<0.01$). PA and PA-free patients had 0.06 and 0.04 inpatient admissions PPY, respectively (IRR = 1.54; $P<0.01$). The mean annual total direct healthcare costs per PA patient were $4,342 (14% were asthma-related) vs. $2,570 (4% were asthma-related) per PA-free patient. PA patients incurred higher costs by $1,772 PPY; this cost difference was $1,269 PPY when excluding asthma-related costs (all $P<0.01$).

CONCLUSIONS: Privately insured patients with PA and evidence of severe allergic reactions had significantly higher HRU and direct healthcare costs, regardless of asthma-related costs, compared to those without PA in the U.S.

SPONSORSHIP: Aimmune Therapeutics.

Z16 Development of a Collaborative Pharmacy Practice Agreement to Improve Efficiency and Management of Prescribing in a Renal Transplant Clinic

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BACKGROUND: Post-transplant patients require complex medication regimens to ensure the survival of the transplanted organ and patient overall well-being. These regimens are frequently adjusted, initiated, or discontinued after transplantation. Pharmacist (PharmD) expertise can be utilized to optimize post-transplant medication use.

OBJECTIVE: To describe the creation and corresponding outcomes of a Collaborative Pharmacy Practice Agreements (CPPA) between PharmDs and physicians within a renal transplant clinic.

METHODS: After the Tennessee (TN) Pharmacist Association and TN Medical Association finalized legislation approving CPPAs for licensed PharmDs in TN (effective July 1, 2014), the Vanderbilt Renal Transplant Clinic and Vanderbilt Transplant Pharmacy (VTxP) began developing a CPPA, which was approved by the Vanderbilt University Medical Center (VUMC) Pharmaceutical and Therapeutics Committee and VUMC Medical Board. To evaluate the outcomes of the CPPA, we assessed the type of authorizer for immunosuppressant (IS) prescriptions (nurse, physician, or PharmD; measured as % of IS prescriptions) and the volume of IS prescriptions across three 7-month intervals: (a) before PharmD clinic integration (11/1/14-5/31/15), (b) with PharmD integration without a CPPA (12/1/15-6/30/16), and (c) with PharmD integration and a CPPA (4/1/17-10/31/17). Adult patients with at least one IS prescription generated in each time interval were included. Frequency of safety concerns and staffing requirements resulting from the CPPA were collected. Finally, we assessed the total volume of prescriptions filled by VTxP.

RESULTS: Following PharmD prescription management under a CPPA, physician and nurse refill workload for IS prescriptions reduced from 42.7% and 57.3% to 8.7% and 5.9%, respectively. Overall prescription generation to VTxP increased from 13,523 prior to PharmD integration to 45,320 after integration with a CPPA. No safety concerns were reported in any of seven quarterly reviews. Due to the drastic increase in prescription volume, VTxP has grown from a team of eight in 2015 to 23 team members in 2018.

CONCLUSIONS: Implementing a CPPA resulted in increased IS and non-IS prescription generation and reduced physician and nurse burden. It facilitated close monitoring of post-transplant medication regimens with no patient safety concerns. Additionally, VTxP benefitted from an increase in prescription volume and revenue.

SPONSORSHIP: None.

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