AMCP Abstracts Program

AMCP Nexus 2019: The Intersection of Value and Care, in National Harbor, MD, is expected to attract more than 2,400 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 Thursday, October 31, from 12:30 pm to 2:00 pm. For each poster, at least 1 author will be available during the poster presentations to discuss findings. Posters will also be displayed on Wednesday, October 30, from 4:30 pm to 6:30 pm, during the opening night reception in the Exchange. Podium presentations for the Platinum award-winning abstracts are Thursday, October 31, from 10:00 am to 11:30 am.

Professional abstracts that have been reviewed are published in the Journal of Managed Care & Specialty Pharmacy’s (JMCP) 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

Fifty-eight reviewers and 3 JMCP editorial reviewers were involved in the abstract review process for Nexus 2019. 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 Nexus 2019 are listed below.

**Reviewers**

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- Brandon Bellows, PharmD, MS
- Justin Boc, PharmD, BCPP, BCAG, RPh
- Eric Borrelli, PharmD, MBA
- Ami Buikema, MPH
- Sara Carruth, PharmD
- Vivien Chan, PharmD
- Satabdi Chatterjee, Postdoc Fellow
- Chanadda Chinthammit, BSPharm, MS, PhD
- Desola Davis, PharmD, BCPP, BCACP
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- Jennifer Friderici, MS
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- Prabhash Reddy, PharmD
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- Rolin Wade, RPh, MS
- Yan Wang, PhD
- James Wilson, PhD, PharmD
- Jun Wu, PhD

**JMCP Reviewers**

- Donald G. Klepser, PhD, MBA
- Melissa S. McCart, PharmD, MS
- Karen L. Rascati, PhD
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*Academy of Managed Care Pharmacy*

*Nexus 2019, National Harbor, Maryland*

*October 29-November 1, 2019*

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I10 Real-World Dosing for Oral Treprostinil and Selexipag Using Administrative Claims Data

I11 Real-World Comparison of Healthcare Costs Among Nonvalvular Atrial Fibrillation Patients Treated with Warfarin and Direct Oral Anticoagulants

I12 Using Real-World Evidence to Design Value-Based Contracts for the Real World

I13 Patient-Reported “Good” Days During a Prospective Study of the Treatment of Neurogenic Orthostatic Hypotension with Droxidopa

I14 Can Real-Time Pharmacy Benefits Improve Adherence? A Descriptive Analysis Using Prescriptions for Antithrombotic Medications

J1  Cost-Effectiveness of Baloxavir Marboxil Among Otherwise Healthy Individuals with Influenza


J3  Impact of Omalizumab Treatment on Asthma-Related Healthcare Resource Utilization in a Real-World Dataset from a Managed Care Plan

J4  Association of Opioid Use and COPD Exacerbation: A Cohort Analysis Among Elderly Medicare Advantage Plan Beneficiaries

J5  Reduced Asthma Exacerbations and Asthma-Related Healthcare Resource Use with Omalizumab from the Real-World PROSPERO Study

J6  A Predictive Model for Clinical Asthma Exacerbations Using Albuterol eMDPI (ProAir Digihaler): A 12-Week, Open-Label Study

J7  Inappropriate Triple Therapy: A Budget Impact Cost Calculator to Identify Avenues for Potential Savings in Patients with COPD

J8  Durability of Culture Conversion in Patients Receiving Amikacin Liposome Inhalation Suspension for Treatment-Refractory Mycobacterium avium Complex Lung Disease in the CONVERT Study

J9  An Open-Label Extension Study of Amikacin Liposome Inhalation Suspension for Treatment-Refractory Lung Disease Caused by Mycobacterium avium Complex

J10 An Early View of Characteristics and Treatment Patterns of Patients Initiated on Tezacafitor/Ivacaftor in the United States: An Administrative Claims Data Analysis

J11 Burden of Illness Among Children Aged <12 Years with Cystic Fibrosis

J12 Making the Case for EGFR TKI Sequencing in EGFR-Mutated NSCLC: A GioTag Study U.S. Patient Analysis

J13 Evaluation of Asthma Medication Ratios in African American Children with Uncontrolled Asthma

K1  Impact of Infliximab-dyyb (Infliximab Biosimilar) on Patient-Reported Outcomes: 3-Month Follow-Up Results from an Observational Real-World Study Among Patients with Inflammatory Bowel Disease in the U.S. and Canada (the ONWARD Study)

K2  Development and Validation of an Administrative Claims-Based Inflammatory Bowel Disease Severity Index

K3  Direct and Indirect Costs Associated with Crohn’s Disease in the United States

K4  Work Productivity Loss and Associated Indirect Costs by Severity for Patients with Ulcerative Colitis in the U.S.

K5  Work Productivity Loss and Associated Indirect Costs for Patients with Crohn’s Disease in the U.S.

K6  Plecanatide-Improved Patient Global Rating of IBS Symptoms in Adult Patients with IBS-C
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Exhibit Hall Map and All Poster Titles
(Student, Encore, and Professional Reviewed)

M10 Characterization of Patients New to Osteoporosis Therapies
M11 Economic Burden of Osteoporosis-Related Fractures in Medicare Patients
M12 Retrospective Analysis of Claims Utilization Data of Medications Indicated to Treat Osteoporosis in the Medicare Part D Population
M13 Characterizing RA Medication Use Patterns of Immunomodulators and dMARDs in a National Pharmacy Benefit Manager Population
N1 Metabolic Acidosis Is Associated with Higher Costs in Patients with Chronic Kidney Disease: A Longitudinal Analysis from Electronic Medical Records of >50,000 Patients
N2 Disparities in Real-World Utilization Patterns of Potassium Binders in U.S. Veterans with Hyperkalemia
N3 Impact of Comorbid Overactive Bladder on Healthcare Resource Utilization and Costs in Patients with Depression: A Retrospective, Matched Case-Control Cohort Analysis
N4 Antibiotic Utilization Associated with Treating Pediatric Urinary Tract Infections in Texas Medicaid Patients
O1 Updates and Future Directions: Development of a Pharmacoeconomic Registry to Evaluate the Risks of Unintended Pregnancies Resulting from Drug Interactions with Hormonal Contraceptives
Q1 Pilot Study to Estimate the Healthcare Cost Associated with Clinical Events in Vascular Ehlers-Danlos Syndrome
R1 Using Pharmacy Claims to Measure Opioid Misuse and Prospectively Identify At-Risk Patients
R2 Costs of Mandating Blister Packaging for Solid-Dose Opioids in the U.S. Retail Setting
R3 Current Lung Nodule Management and the Use of Risk Prediction Models
T1 Opioid Overdose Deaths and Political Party Control of State Governments
U1 Use of Biosimilar and Specialty Generic Medication in Medicaid: Differences Between Managed Care and Fee for Service
U2 Trends in List Prices, Net Prices, and Discounts for Branded Prescription Drugs in the U.S., 2007-2018
U3 Trends in Payer Experiences, Attitudes, and Perceptions of Pre-Approval Information Exchange
U4 Differences in Dose Intensity of Benzodiazepine Prescriptions Dispensed by Pharmacies in Rhode Island in 2018
U6 Inclusion of Real-World Evidence and Patient Input by U.S. Value Assessment Organizations
U7 Medicaid Missed Refill Letter Intervention Impact on Refill Rate Versus Randomized Controls
U8 Drug Super Spenders: 2016-2018 Growth in Number of Members and Total Pharmacy Plus Medical Benefit Drug Cost for Members with Extremely High Annual Drug Cost in a 17 Million-Member Commercially Insured Population
U10 A Descriptive Analysis of 2016 Medicare Part D Medication Therapy Management Comprehensive Medication Review Completion Rates
U11 Evaluating the Relationship Between Increased Patient Engagement and Adherence to Specialty Medications
U12 Patient Characteristics and Outcomes Following 6 Orthopedic Procedures Performed at Different Surgical Venues in the United States: Findings from a Large National Health Plan
U13 Are Payers Using Value Assessment Frameworks in the United States?
U14 Development of a Tool to Assess Community Pharmacist Ability to Impact Quality Measures
U15 Proactive Pharmacist Call Program: Assessing the Impact of a Predictive Model-Driven Medicare Member Outreach on Adherence and Star Ratings
U16 A Review of the Use of Work Productivity Endpoints in Clinical Trials
U17 Has There Been a Change in the Payer Perspective on the Academy of Managed Care Pharmacy Format Version 4.0 Pre-Approval Dossier?
U18 Quantitative Perceptions of Budget Impact Thresholds Among U.S. Payers
U19 Impact of Specialty Pharmacist Integration on Time to Medication Access for Pimavanserin
U20 Lessons Learned from Hurricane Maria: Continuity of Prescription Benefits Programs During Natural Disasters
U21 Misclassification of Case-Control Studies in PubMed
U22 A Thematic Analysis of Barriers to Safe and Appropriate Opioid and Non-Opioid Pain Management by Primary Care Providers
U23 Improving Pharmacotherapies for Hypertension and Diabetes Among Hispanics
U24 Impact of Prostate Cancer Comorbidity and Treatment on Arthritis Patients’ Health-Related Quality of Life
U25 Factors Associated with CMS 30-Day Hospital-Wide Risk-Adjusted All-Cause Readmission Rates: 2014-2017
U26 Deprescribing in an Ambulatory Care Setting to Improve Quality and Reduce Cost of Care
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<td>A Targeted Literature Review on the Impact of the Oncology Care Model</td>
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<td>Z1</td>
<td>Impact of Shingrix (Recombinant Zoster Vaccine) Second Dose Reminder Member Calls by a Commercial Health Plan</td>
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<td>Z2</td>
<td>Pharmacist-Led Transitions of Care Service for Congestive Heart Failure Patients and All-Cause 30-Day Readmission Rates</td>
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<td>Z3</td>
<td>The Impact of Manufacturers’ Copay Card Ban Lift on Disease-Related Hospitalizations and Medical Costs in Massachusetts in Six Disease Areas</td>
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<td>Comparison of Pharmacy Benefit and Medical Benefit Sites of Service for Appropriateness of Shingrix (Recombinant Zoster Vaccine) Administration</td>
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<td>Z5</td>
<td>Evaluating a Telehealth Model of Transitional Care Management at a University Setting to Reduce Hospital Readmission Rates</td>
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<td>Z6</td>
<td>Outcomes of Health Plan-Initiated Text-Based Medication Refill Reminders in Medicare Patients</td>
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<td>Z7</td>
<td>Anticoagulation in the DOAC Era: Ambulatory Care Characteristics with Warfarin and DOACs from 2007-2016</td>
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# Student Poster Titles and Presenters

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<td>Human Papillomavirus Vaccine Hesitancy: Barriers to and Facilitators of Dose Initiation and Completion Among Young Adults</td>
<td>Meredith Douglas, Justin Gatwood, PhD; m <a href="mailto:dougl15@uthsc.edu">dougl15@uthsc.edu</a></td>
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<tr>
<td>B2</td>
<td>Pharmacist-Driven Shingrix Follow-Up: A Randomized Controlled Trial</td>
<td>Michael D. Stapley, PharmD Candidate, Sarah Nestlehan, PharmD, Jonathan Magness, PharmD; <a href="mailto:michael.stapley@gmail.com">michael.stapley@gmail.com</a></td>
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<td>B7</td>
<td>Cost-Effectiveness of Triumeq, a Combination of Dolutegravir, Abacavir, and Lamivudine Drugs, for the Treatment of HIV Infections</td>
<td>Miriam Mlabasati, Rana Y. El-Sheikh-ali, Ellen Loh, BPharm, PhD; mm <a href="mailto:labas@student.touro.edu">labas@student.touro.edu</a></td>
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<td>C14</td>
<td>Characteristics and Treatment of Lung Cancer Patients in the Emergency Department and Ambulatory Settings</td>
<td>Emily Oliphant, PharmD, Michael Peercy, MPH, MT (ASCPH), Mark P. Doescher, Bobby Szaunkeah, RN, MSHE, CIP, Grant H. Skrepnek, PhD; <a href="mailto:emily-oliphant@ouhsc.edu">emily-oliphant@ouhsc.edu</a></td>
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<td>C30</td>
<td>Primary Care Versus Specialist Management of Pediatric and Adolescent Cancer Cases in U.S. Ambulatory Care Settings</td>
<td>Elizabeth A. Goetzinger, PharmD, Michael Peercy, MPH, MT (ASCPH), Bobby Szaunkeah, RN, MSHE, CIP, Mark P. Doescher, Grant H. Skrepnek, PhD; <a href="mailto:elizabeth.goetzinger@ouhsc.edu">elizabeth.goetzinger@ouhsc.edu</a></td>
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<td>C36</td>
<td>Leading Causes for and Associated Cost Burden of Hospitalizations Among Patients with Chronic Lymphocytic Leukemia in the United States</td>
<td>Tyler Mantaiian, BSPS, Ami Vyas, PhD, MBA; Stephen J. Kogut, PhD, MBA; <a href="mailto:tylermanthaia@my.uri.edu">tylermanthaia@my.uri.edu</a></td>
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<td>D4</td>
<td>A Case Study on Filgrastim Biosimilar and Originator Biologic Pricing Behavior to Assess the Validity of Assumptions Used in Budget Impact Analyses</td>
<td>Anna R. Dizik, PharmD Candidate, T. Joseph Mattingly, PharmD, MBA; Joseph Levy, PhD; <a href="mailto:adizik@umaryland.edu">adizik@umaryland.edu</a></td>
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<td>E12</td>
<td>Regional and National Real-World Healthcare Resource Utilization, Clinical, and Cost Outcomes of Type 2 Diabetes Patients Treated with SGLT2i</td>
<td>Mina A. All, PharmD, MPH, Sebastian Schneeveiss, MD, SM, ScD, Ajinkya Pawar, PhD, MS; Elisabetta Patorno, MD, DrPH; <a href="mailto:mina.52100@gmail.com">mina.52100@gmail.com</a></td>
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<td>E13</td>
<td>Longitudinal Assessment of Patterns of Diet and Exercise Regimens</td>
<td>Congjian Zhou, PharmD, Joelle Jo, PharmD, Ashley Tang, PharmD, Daniel Mesa, PharmD, Sung Jae Lee, PharmD, Mohit Trivedi, PharmD; <a href="mailto:congjian.zhou@rutgers.edu">congjian.zhou@rutgers.edu</a></td>
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<td>E14</td>
<td>Effect of Clinical Pharmacist-Led Medication Therapy Management Encounters on Diabetes Medication Regimens and Medication Adherence</td>
<td>Kanya Shah, PharmD, David Ahern, PhD, Joe Wroblewski, MBA, Qinhe Zheng, Christine Dyer; <a href="mailto:kanya_shah@my.uri.edu">kanya_shah@my.uri.edu</a></td>
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<td>E15</td>
<td>Leveraging Ambulatory Care Pharmacy to Drive Diabetes Control and ACO Performance</td>
<td>Adam B. O’Neil, PharmD Candidate, Marie Waddles, PharmD, BCACP; adam_ o <a href="mailto:neil@unc.edu">neil@unc.edu</a></td>
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<td>E16</td>
<td>Impact of Mail Order Pharmacy on Adherence Rates to Antidiabetic Medications in Patients in Rural Tennessee</td>
<td>Kayla Owens, BS, Justin Gatwood, PhD; k <a href="mailto:owens19@uthsc.edu">owens19@uthsc.edu</a></td>
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<td>E17</td>
<td>Trends in List and Net Prices of Novel Non-Insulin Antidiabetic Agents, 2007-2018</td>
<td>Terri V. Newman, PharmD, Alvaro San-Juan-Rodriguez, PharmD, Waldid Gellad, MD, MPH, Chester Good, MD, MPH, Inmaculada Hernandez, PharmD, PhD; <a href="mailto:tvn6@pitt.edu">tvn6@pitt.edu</a></td>
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<td>E23</td>
<td>Health Outcomes and Reimbursement Analysis in OECD Countries for Cystic Fibrosis Patients</td>
<td>Siddharth Jain, PharmD Candidate, Palna Mehta, PharmD Candidate, Richard Ko, PharmD Candidate, Amy Hu, PharmD Candidate, Maureen Ahn, PharmD Candidate, Young Kim, PharmD Candidate, Susanna Bae, PharmD Candidate; <a href="mailto:siddharth.jain@rutgers.edu">siddharth.jain@rutgers.edu</a></td>
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<td>F4</td>
<td>Characteristics of Concurrent Users of Opioid and Benzodiazepine Versus Opioid-Only Users in the North Carolina Medicaid Population</td>
<td>Anna Hung, PharmD, PhD, MS; Christopher Bush, MPH, Melissa Greiner, MS, Hilary Campbell, PharmD, JD, Bradley Hammill, DrPH, Matthew Maciejewski, PhD, Aaron McKeithan, PhD; <a href="mailto:anna.hung@duke.edu">anna.hung@duke.edu</a></td>
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<td>F5</td>
<td>Budget Impact Analysis of Novel Abuse Deterent Opioids in a Population of Chronic Opioid Use</td>
<td>Andrew Descoteaux, MS, Ami Vyas, PhD, MBA; Stephen J. Kogut, PhD, MBA; r adesco <a href="mailto:teaux@my.uri.edu">teaux@my.uri.edu</a></td>
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<td>F20</td>
<td>Marijuana and Its Effect on Weight Gain for People with Anorexia</td>
<td>Marzia Tsitarava, BS Biology, PharmD Candidate; <a href="mailto:msitarava@student.touro.edu">msitarava@student.touro.edu</a></td>
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<td>F21</td>
<td>A Systematic Review of the Efficacy and Tolerability of Flibanserin in the Treatment of Hypoactive Sexual Desire Disorder in Premenopausal Women</td>
<td>Page J. Briggs, Kayla Broomfield, Ariana Miranda, Gloria Paulina; p <a href="mailto:Briggs@student.touro.edu">Briggs@student.touro.edu</a></td>
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<td>F26</td>
<td>Healthcare Costs of Major Depressive Disorder Patients over Multiple Lines of Therapy and Major Depressive Episodes</td>
<td>Ryan Thalifdeen, PharmD Candidate, Amy Tung, PharmD, MS, Patrick Gillard, PharmD, MS, Katelyn Keyloun, PharmD, MS, Sara Higa, PharmD, MS; <a href="mailto:ryan.thalifdeen@ucsf.edu">ryan.thalifdeen@ucsf.edu</a></td>
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<td>G14</td>
<td>A Medication Use Evaluation of Edaravone in the Treatment of Amyotrophic Lateral Sclerosis</td>
<td>Dharti Patel, PharmD, MBA, Stephen Batt, PharmD, Philip Schwieterman, PharmD, MHA; dharti pal <a href="mailto:et2@uky.edu">et2@uky.edu</a></td>
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Student Poster Titles and Presenters

G15 A National Assessment of the Association Between Alzheimer’s Disease and Antipsychotic Prescriptions in Ambulatory Care Settings
Laura M. Sidmore, PharmD, Shelli L. Keast, PharmD, PhD, MS; Grant H. Skrepnek, PhD; lmbergs@gmail.com

G38 The Clinical and Financial Impact of Brand to Generic Switch for NTI Medications
Jessica S. Jay, PharmD Candidate, Alice Cheng, PharmD Candidate, Nicholas Schnarr, Jay Vora; jessicasjay@gmail.com

G39 Differentiation of Human Mesenchymal Stem Cells into Schwann-Like Cells by Electrical Stimulation In Vitro
Pranita Chilakamarri, Shaine Ninan, Sangamesh Kumbar, Sweetha Rudraiah, PhD; pchilakamarri@usj.edu

I14 Can Real-Time Pharmacy Benefits Improve Adherence? A Descriptive Analysis Using Prescriptions for Antithrombotic Medications
Taryn Sohal, PharmD Candidate, Leann McDowell, PharmD, Peter Marshall, PharmD; tsohal3@mail.umkc.edu

J1 Cost-Effectiveness of Baloxavir Marboxil Among Otherwise Healthy Individuals with Influenza
Julia A. Mahler, BS, Zafar Zafari, MSc, PhD, C. Daniel Mullins, PhD; jmahler@umaryland.edu

J13 Evaluation of Asthma Medication Ratios in African American Children with Uncontrolled Asthma
Kathy Hsieh, Anh Thai, Uche Nwofy, PharmD, Portia Davis, PharmD, Lilalyn Punsalan, PharmD, MPH; k.hsieh7627@student.tsu.edu

L6 Effectiveness of Crisaborole 2% in Treating Atopic Dermatitis in Individuals Aged 2 Years and Up: A Systematic Review
Ahmad Naeem, PharmD, Maria Shah, PharmD, Jermin Ashrawy, PharmD, Lilaan Chamalov, PharmD; anaeem@student.touro.edu

M5 Evaluation of a Provider Outreach Pilot Program to Increase Uptake of Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis in the Ambulatory Medicare Population
Max Lee, BS, Tina Mody, PharmD; lee7829@pacificu.edu

M6 Comparative Effectiveness of Disease-Modifying Anti-Rheumatic Drug Combination Therapy: Methotrexate/Leflunomide Versus Methotrexate/Sulfasalazine in Patients with Rheumatoid Arthritis
Mary Zhang; mary.zhang@umaryland.edu

M12 Retrospective Analysis of Claims Utilization Data of Medications Indicated to Treat Osteoporosis in the Medicare Part D Population
Kyle D.Krudsen, PharmD, MBA, S. Russell Spjut, PharmD, Julia Farnosko, PharmD, MBA; kkrudsen@student.roseman.edu

M13 Characterizing RA Medication Use Patterns of Immunomodulators and tDMARDs in a National Pharmacy Benefit Manager Population
Aisha Fowler, PharmD Candidate, Alex Peaslee, PharmD; aishafowler@gmail.com

N4 Antibiotic Utilization Associated with Treating Pediatric Urinary Tract Infections in Texas Medicaid Patients
Alana M. Coleman, PharmD Candidate, Karen L. Ruscati, PhD, RPh; coleman.alana@gmail.com

T1 Opioid Overdose Deaths and Political Party Control of State Governments
Dana Prozementer, Jonathan Thigpen, PharmD; dprozementer1@live.umd.edu

U21 Misclassification of Case-Control Studies in PubMed
Stephen Kim, BS, Aubrey Jones, PharmD, Gregory Stoddard, MS, MBA, MPH, Esther Aguilar, Joanne Lafleur, PharmD, MSPH; Stephen.Kim@pharm.utah.edu

U22 A Thematic Analysis of Barriers to Safe and Appropriate Opioid and Non-Opioid Pain Management by Primary Care Providers
Sarette T. Tilton, PharmD Candidate, Lisa K. Sharp, PhD; Christopher D. Salfore, PharmD, Mary Smart, PharmD, Todd A. Lee, PharmD, PhD, A. S. Pickard, PhD; stilto2@uic.edu

U23 Improving Pharmacotherapies for Hypertension and Diabetes Among Hispanics
Amy Nguyen, Benjamin Donovan; amy.nguyen14@stjohns.edu

U24 Impact of Prostate Cancer Comorbidity and Treatment on Arthritis Patients’ Health-Related Quality of Life
Anna Chen, Monica Hwang, PhD; anna.chen14@stjohns.edu

U25 Factors Associated with CMS 30-Day Hospital-Wide Risk-Adjusted All-Cause Readmission Rates: 2014-2017
Michael M. Nguyen, PharmD, Michael Peercy, MPH, MT (ASCPH); Bobby Saunthak, RN, MSHECE, CIP, Mark P. Doeschler, Grant H. Skrepnek, PhD; michael-m-nguyen@ouhsc.edu

U26 Deprescribing in an Ambulatory Care Setting to Improve Quality and Reduce Cost of Care
Shweta Shah, PharmD, Alexandra Watson, PharmD, Michele Sager, PharmD; sshah924@gmail.com

U27 Concurrent Medication Adherence Among Chronic-Condition Patients in the Medicaid Coverage Gap
Gina No, PharmD Candidate, Yiran Zhang, PhD, Julie Urmie, PhD; Jayoung Han, PhD, noxgina@student.fdu.edu

U28 Characterize Specialty Medication Users with Four Chronic Conditions
Karen Balangkig, PharmD Candidate, Nellopar Ahad, PharmD; Adam Pennoyer, PharmD, Jayoung Han, PhD; kbalangk@student.fdu.edu

U29 Evaluating Naloxone-Furnishing Models of San Francisco Community Pharmacies
Andy M. Nguyen, PharmD Candidate, Dorie Apollonio, PhD, MPP, Thomas Kearney, PharmD; andy.mp.nguyen@gmail.com

U30 Do the Institute for Clinical and Economic Review’s Comparative Clinical Effectiveness Ratings Align with Those of International Health Technology Assessment Bodies?
Jaymin Patel, PharmD Candidate, Brian Snow, PharmD Candidate, Julie Patterson, PharmD, PhD; snowbl@vcu.edu
Student Poster Titles and Presenters

**U31** Identifying Barriers to Medication Adherence Among Latinxs in New Brunswick, NJ
Daniel A. Mesa, PharmD Candidate, Ashley Tang, PharmD, Palma Mehta, PharmD Candidate, Congjian Zhou, PharmD, Serena Lam, PharmD Candidate, Mohil Trivedi, PharmD; daniel.a.mesa42@gmail.com

**U32** Analysis of Medication Medication Adherence When Using a Mail Order Pharmacy
Kishan T. Patel, Hilary Shin, Yiehyun Yi, Young Kim, PharmD Candidate, Sumie Kakehi, Maureen Ahn, Joelle Jo, PharmD; kishant.patel@rutgers.edu

**U33** Impact of Value-Based Insurance Design on Adherence and Total Cost of Care
Katrina S. Zywiec, PharmD; katrina.zywiec@tu.edu

**U34** Evaluating the Use and Perception of E-Cigarettes/Vaping Among College Students at Rutgers University (Continued)
Serena Lam, PharmD Candidate, Congjian Zhou, PharmD, Samuel Golbin, Soomin Jin, PharmD Candidate, Mohil Trivedi, PharmD, Sumie Kakehi, PharmD Candidate; serenalam08@gmail.com

**U35** Measuring What Matters: What does that Mean to Patients?
Thelma R. Love, MPH, Elisabeth M. Oehrlein, PhD, MS, Eleanor M. Perfetto, PhD, MS; troseganser@umaryland.edu

**U36** The Inclusion of Economic Endpoints as Outcomes in Clinical Trials Reported to ClinicalTrials.gov
Jordan Mitchell, Julie Patterson, PharmD, PhD; mitchellj7@mymail.vcu.edu

**U37** Electronic Nicotine Delivery Systems: Impact of Recent FDA Regulations
Lam Ho, Pauline Mock, Nikitha Pathuri, Shivani Vaidya; ldh60@rutgers.edu

**U38** The Effect of Direct Interaction with Managed Care Pharmacists on the Understanding of Managed Care Pharmacy for Student Pharmacists
Uzoamaka Uwechia; uzoamaka.uwechia@bison.howard.edu

**U39** Real-World Treatment Patterns with CoolSculpting: Electronic Health Record Review
Wilson Haong, BS, Sara Higa, PharmD, MS, Vaishali Patel, PharmD, MS, Sarah Baradaran, PharmD, MS; wilson.haong@wne.edu

**U41** Value-Based Agreements Algorithm Based on an AMCP Membership Survey
Amy Hu, PharmD Candidate, Denise Rotella, PharmD, Mark Wrobel, PharmD, Jean McGrath Brodeur, PharmD, Walter McClain, PharmD, MBA; hu.amy09@gmail.com

**U42** Assessing Barriers to Inclusion of Digital Therapeutics on Formulary: A Cross-Sectional Study Across Health Plans, PBMs, and IDNs
Shyra Bias, PharmD Candidate, John Spain, PharmD, BCPS, Annesha White, PharmD, MS, PhD, Terry Richardson, PharmD, Paula Eichenbrenner, MBA, CAE; shyra.washington@bison.howard.edu

**U43** Impact of Implementing a Narrow 90-Day Pharmacy Network Within an Integrated Delivery System on Drug Utilization
Rachael K. Lai, BS, Curtis Wander, PharmD, BCPS, Natalia Ruiz-Negron, PharmD; rachaelklai@gmail.com

**U44** A Targeted Literature Review on the Impact of the Oncology Care Model
Gilbert C. Ko, MBA, Krupa Parekh, PharmD, MPH, Sheila Shapouri, PharmD, MS; gilbko@uw.edu

**Z2** Pharmacist-Led Transitions of Care Service for Congestive Heart Failure Patients and All-Cause 30-Day Readmission Rates
Connor McKay, PharmD, MBA Candidate, Jongwha Chang, PhD, Chanhyun Park, PhD, Marcia Brackbill, PharmD, Sean H. Kim, PharmD, MS; cmckay16@su.edu

**Z5** Evaluating a Telehealth Model of Transitional Care Management at a University Setting to Reduce Hospital Readmission Rates
Balsam Elajouz, Akilah Fuller, Daisy Vargas, Jennifer Tejeda, Tricia Gangoo-Doohkan, BSPharm, PharmD; bc312@mymsu.nova.edu

**Z6** Outcomes of Health Plan-Initiated Text-Based Medication Refill Reminders in Medicare Patients
Benjamin Ham, PharmD, Jonathan Magness, PharmD, hamfl300@gmail.com

**Z7** Anticoagulation in the DOAC Era: Ambulatory Care Characteristics with Warfarin and DOACs from 2007-2016
Matthew C. Dickson, PharmD, Nicholas C. Schwier, PharmD, BCPS, David Hawkins, PharmD, Grant H. Skrepnek, PhD; matthew-dickson@ouhsc.edu
Encore Poster Titles and Presenters

B6 High Levels of Patient Satisfaction and Virologic Suppression at 48 Weeks in Newly Diagnosed Black/African American Individuals Rapidly Initiating Darunavir/Cobicistat/Etritricabine/Tenofovir Alafenamide in the DIAMOND Study
Keith J. Dunn, PharmD, BCP, AHAIVHE, Richard Bruce Simonson, BS, Donghan Luo, PhD, Wing Chow, PharmD, MPH, Eric Y. Wong, PhD, MBA, Debra Israel, PharmD, MBA, Sarah Seyedkazemi, PharmD, AHAIVHE, Hélène Hardy, PharmD, MPH, MSC; WChow3@its.jnj.com

B8 Healthcare Resource Use, Costs, and Recurrences in Patients with Clostridioides difficile Infection: A Real-World Data Analysis
Winnie Nelson, PharmD, MS, MBA, Laura Stong, PhD, Naomi Sachs, PhD, Alexandria Portelli, MPH, Bridget Healey, MPH, Kathleen Lang, PhD, David N. Duhald, PhD; winnie.nelson@ferring.com

C8 Real-World Assessment of Healthcare Costs for Patients with Metastatic Pancreatic Cancer Following First-Line Chemotherapy Initiation
Nina Hill, PhD, Andrea J. Bullock, MD, MPH, Christopher G. Rowan, PhD, Homa Yeganeh, MSC, E. Gabriela Chiorian, MD; nhill@halozyme.com

C13 A Flexible Open-Source Cost-Effectiveness Model for Metastatic EGFR+ Non-Small Cell Lung Cancer Treatment
Suepattra G. May, PhD, Caroline Huber, MPH, Alison Silverstein, MPH, Mark Limthicum, MPP, Jason Shafrin, PhD, Upal Basu Roy, PhD, MPH, Katie Brown, OPN-CG, Jennifer Bright, MPA; suepattra.may-slater@precisionhealtheconomics.com

C17 Adverse Events of Special Interest in Patients with Advanced Basal Cell Carcinoma Receiving Sonidegib: Long-Term 42-Month Results from the BOLT Study
Alexander Guminski, PhD, Nicholas Squittieri, MD, John Lear, MD; alexander.guminski@sydney.edu.au

C18 Practical Management of Adverse Events Using Dosing Strategies for Patients Receiving Sonidegib for Advanced Basal Cell Carcinoma
John Lear, MD, Nicholas Squittieri, MD, Alexander Guminski, PhD; john.lear@srft.nhs.uk

D8 Healthcare Resource Utilization and Costs Among Patients with Steroid-Resistant Chronic Graft-Versus-Host Disease: A Retrospective Claims Database Analysis
Jingbo Yu, PhD, Lincy Lal, PhD, PharmD, Amy Anderson, MS, Mary DuCharme, MLIS, Shreekant Paraisaraman, PhD, BPharm, Daniel Weisdorf, MD, MPP, T2; jya@incyte.com

E9 Critical Components of an Effective Medication Adherence Program: A Case Study
Jenny Glennon, PharmD, MPH, Stephen O’Malley, MS, Gulotta Gulotta, MBA; jglennon@healthdialog.com

E10 Real-World Effectiveness of Semaglutide in Early Users from a U.S. Commercially Insured and Medicare Advantage Population
Tam Dung-Tan, PhD, Jay Visaria, PhD, Paul Petraro, ScD, Bal Nepal, PhD, Vincent Willey, PharmD; tadt@novonordisk.com

E11 DUAL VIII (NCT02501161): Significantly Longer Time to Treatment Intensification with Insulin Degludec/Liraglutide Versus Insulin Glargine in a 104-Week Randomized Trial Mirroring Clinical Practice
Ryan J. Flugge, PharmD, Vanita R. Aroda, MD, Guillermo González-Galvez, MD, Martin Haluszka, MD, Robert Silver, MD, Randi Gramc, PhD, Natalie Halladin, MD, Petra Ørsy, MD, Giorgio Sesti, MD; ryj1@novonordisk.com

E22 A Model to Predict Risk of Hyperkalemia in CKD Patients Using a Large Administrative Claims Database
Paula J. Alvarez, RPh, MBA, MPH, Ajay Sharma, DO, Steven D. Woods, PharmD, Jeaneene Fogli, PhD, RD, Dingwei Dai, PhD; palvarez@relypsa.com

F1 Evaluating the Real-World Clinical Approach to the Diagnosis and Coding of Patients with Hypoactive Sexual Desire Disorder
Sharon J. Parish, MD, Amod Athavale, BPharm, MS, PhD, Rahul Ravindranath, Nadunci Hadker, Michelle Z. Lin-Watson, MPh, MBA; shp9079@med.cornell.edu

F3 Recovery from Opioid Use Disorder Post-Monthly Buprenorphine Extended-Release Treatment: 12-Month Longitudinal Outcomes
Ann Wheeler, Walter Ling, MD, Vijay Nadipelli, MS, Naoko Ronquest, PhD, Arnie Aldridge, PhD, Caitlyn Solem, PhD, Nicholas Peiper, PhD, Susan Learned, MD, PharmD, PhD, Christian Heidbreder, PhD; ann.wheeler@Indivior.com

F22 The Efficacy and Safety of Amphetamine Extended-Release Oral Suspension in Children with Attention-Deficit/Hyperactivity Disorder
Thomas R. King, MS, MPH, Ann Childress, MD, Judith Kando, PharmD, Lisa Stroess, PharmD, Antonio Pardo, MD, Barry K. Herman, MD MMM; lstrouss@tripharma.com

F23 Clinical Responses and Symptomatic Remissions Achieved with Delayed-Release and Extended-Release Methylphenidate in Children with Attention-Deficit/Hyperactivity Disorder
Ryan Gregg, PharmD, Ann Childress, MD, Andrew J. Cutler, MD, Andrea Marraffino, PhD, Norberto J. DeSousa, MA, Bev Incledon, PhD, Nicholas Peiper, PhD, Susan Learned, MD, PharmD, PhD, Sharon Wigal, PhD; ryan.gregg@ironshorepharma.com

G1 Cost of Treatment and Supportive Care for Patients with Spinal Muscular Atrophy: A Real-World Database Analysis
Er Chen, MS, Gaurav Seth, MD, MBA, Annie Tan, PhD, TuMy To, Susan Lannaccone, MSc; seth.gaurav@gene.com

G2 Clinical Experience of Spinal Muscular Atrophy Treatment: A Combination of Perspectives from a Large Survey
Er Chen, MS, Sarah Whitmire, MS, Josh Noone, PhD, Daniel Buchenberger, MS, Carol Jean Guittari, PharmD, PhD, Rosalina Mills; chen.er@gene.com
Encore Poster Titles and Presenters

G3  Validity and Reliability of the MFM32 in Children with Neuromuscular Disorders and in Individuals with Type 2 and Non-Ambulant Type 3 SMA  
Scott Moody, PharmD, Dylan Trundell, BS, MS, Stephanie Le Scouller, Hannah Staunton, BS, MS, Ksenija Gorni, MD, PhD; moody.jessie@gene.com

G4 Type 1 Spinal Muscular Atrophy Patients Treated with Onasemnogene Abeparvovec-xioi Have Lower Use of Ventilatory Support, Hospitalization, and Associated Costs Compared with Those Treated with Nusinersen  
Ramesh Arjunji, PhD, Rebecca Dean, MS, Ivar Jensen, MBA, Beckley Miller, MPH, Melissa Mener, MS, Douglas M. Sproule, MD, Douglas E. Feltner, MD, Marcus Droge, PhD, MBA, Farid Khan, MD, Omar Dabbous, MD, MPH, RArunji444@avexis.com

G5  The Value of Onasemnogene Abeparvovec-xioi Gene-Replacement Therapy for Spinal Muscular Atrophy Type 1: Improved Survival, Pulmonary and Nutritional Support, and Motor Function with Decreased Hospitalization  
Omar Dabbous, MD, MPH, Douglas M. Sproule, MD, Douglas E. Feltner, MD, Marcus Droge, PhD, MBA, Farid Khan, MD, Ramesh Arjunji, PhD; ODabbous902@avexis.com

G6  Using Rasch Analysis to Estimate Thresholds Associated with Gain/Loss of Daily Function on the Motor Function Measure  
Dylan Trundell, BS, MS, Hannah Staunton, BS, MS, Stephanie Le Scouller, Laurent Servais, MD, PhD, Ulla Werlauff, PhD, Marta Gutiérrez, Ksenija Gorni, MD, PhD, Carole Vuillerot, MD, PhD, Amy Bivens; bivens.amy@gene.com

G7  Cost Utility and Budget Impact Analyses of One-Time Gene-Replacement Therapy for Spinal Muscular Atrophy Type 1 Compared to Chronic Nusinersen Treatment  
Omar Dabbous, MD, MPH, Daniel C. Malone, RPh, PhD, Beckley Miller, MPH, Rebecca Dean, MS, Ramesh Arjunji, PhD, Douglas E. Feltner, MD, Douglas M. Sproule, MD, Ivar Jensen, MBA, Benit Maru, MD, PhD; ODabbous902@avexis.com

G8  Cost-Effectiveness and Budget Impact of Onasemnogene Abeparvovec for Spinal Muscular Atrophy Type 1: Post-Hoc Analysis of a Model Developed by ICER  
Omar Dabbous, MD, MPH, Rebecca Dean, MS, Ramesh Arjunji, PhD, Douglas M. Sproule, MD, Douglas E. Feltner, MD, Daniel C. Malone, RPh, PhD, ODabbous902@avexis.com

G18 Use of Group-Based Trajectory Modeling to Identify Adherence Clusters in Patients with Multiple Sclerosis Newly Initiating Once- or Twice-Daily Oral Disease-Modifying Drugs  
Jacqueline Nicholas, MD, MPH, Natalie C. Edwards, MSc, Roger A. Edwards, ScD, Anna Dellarole, PhD, Luigi Manca, MScEng, Danielle E. Harlow, PhD, Amy L. Phillips, PharmD; amy.phillips@emdserono.com

G19 Predictors of Non-Adherence Among Patients with Multiple Sclerosis Newly Initiating Once- or Twice-Daily Oral Disease-Modifying Drugs  
Jacqueline Nicholas, MD, MPH, Natalie C. Edwards, MSc, Roger A. Edwards, ScD, Anna Dellarole, PhD, Luigi Manca, MScEng, Danielle E. Harlow, PhD, Amy L. Phillips, PharmD, nedwards.bssc@gmail.com

G29 Impact of Eptinezumab on the Health-Related Quality of Life of Patients with Episodic or Chronic Migraine: SF-36 Analysis by Months 1 and 3 Across the Spectrum of Migraine  
Merle L. Diamond, MD, Richard B. Lipton, MD, Rusal Horblyuk, PhD, MBA, Joe Hirman, PhD, Roger Cady, MD, FAHS, Eric Kassell, PhD; richard.lipton@einstein.yu.edu

G30 Eptinezumab for Prevention of Chronic Migraine: Results of 2 Infusions in the Phase 3 PROMISE-2 Trial  
David Kudrow, MD, Richard B. Lipton, MD, Stephen D. Silberstein, MD, Roger Cady, MD, FAHS, Barbara Schaeffler, MBA, David M. Biondi, DO, FAAN, Jeff Smith, MD, FRCP, dbkudrow@earthlink.net

G31 Downward Shift in Migraine Frequency for Patients Treated with Eptinezumab for the Prevention of Migraine  
Roger Cady, MD, FAHS, David M. Biondi, DO, FAAN, Joe Hirman, PhD, Eric Kassell, PhD; rcady@alderbio.com

G32 Eptinezumab for the Prevention of Episodic Migraine Through 1 Year: Results from the Phase 3 PROMISE-1 Trial  
Ashina Messoud, MD, PhD, Timothy Smith, MD, PhD, MPH, George Chakhava, MD, Roger Cady, MD, FAHS, Barbara Schaeffler, MBA, David Biondi, DO, FAAN, Joe Hirman, PhD, Jeff Smith, MD, FRCP, ashina@daddlnet.dk

G33 Cost-Utility and Budget Impact Analyses of One-Time Gene-Replacement Therapy for Spinal Muscular Atrophy Type 1 Compared to Chronic Nusinersen Treatment  
Omar Dabbous, MD, MPH, Daniel C. Malone, RPh, PhD, Beckley Miller, MPH, Rebecca Dean, MS, Ramesh Arjunji, PhD, Douglas E. Feltner, MD, Douglas M. Sproule, MD, Ivar Jensen, MBA, Benit Maru, MD, PhD; ODabbous902@avexis.com

G34 Improved Functionality, Global Impression of Change, and Satisfaction in Patients Treated with Ubegapat for the Acute Treatment of Migraine Attacks  
Jessica Ailani, MD, Susan Hutchinson, MD, Richard B. Lipton, MD, Kerry Knievel, DO, Sang Yun Yu, BA, Michelle Finnegan, MPH, Lawrence Severt, MD, PhD, Armin Szegedi, MD, PhD, Joel M. Trugman, MD; Jessica.X.Ailani@gunet.georgetown.edu

G35 Health-Related Quality of Life Based on Response to Triptans in People with Migraine: Analysis of Real-World Data  
Richard B. Lipton, MD, Stephen D. Silberstein, MD, Sarah Baradaran, PharmD, MS, Anand R. Shewale, PhD, Sarah Cotton, MA, James Jackson, BA, Hema N. Viswanathan, PhD; richard.lipton@einstein.yu.edu
Encore Poster Titles and Presenters

G36 Real-World Treatment Utilization of Sodium Oxybate in Pediatric Patients with Narcolepsy: An Analysis of Claims Data
Chad M. Ruoff, MD, Aatif M. Husain, MD, Sheila Reiss Reddy, PhD, RPh, Ryan S. Tieu, MS, Danielle Hyman, PhD, Judi Profant, PhD, DBSM, Mo Yang, PhD, Morgan Bron, PharmD, MS, Kathleen Villa, MS; cmruoff@gmail.com

G37 Real-World Treatment Utilization of Sodium Oxybate in Adult Patients with Narcolepsy: An Analysis of Claims Data
Aatif M. Husain, MD, Chad M. Ruoff, MD, Sheila Reiss Reddy, PhD, RPh, Ryan S. Tieu, MS, Danielle Hyman, PhD, Judi Profant, PhD, DBSM, Mo Yang, PhD, Morgan Bron, PharmD, MS, Kathleen Villa, MS; aatif.husain@duke.edu

H3 Effect of Oxymetazoline on Superior Visual Field and Marginal Reflex Distance in Blepharoptosis: Results of a Phase 3 Randomized, Double-Masked, Vehicle-Controlled Study
Charles Slonim, MD, Michael Korenfeld, MD, Steven Silverstein, Robert Smyth-Medina, MD, Shane Foster, OD, Tina Devries, PhD, David Jacobs, MD, MBA, Mark Jarek, PhD, Shane Kannarr, OD; djacobs@oznolica.com

H4 Effect of OTX-101, a Novel Nanomicellar Cyclosporine A Formulation, on Conjunctival Staining in Individual Zones in Patients with Keratoconjunctivitis Sicca
Paul Karpecki, OD; Abayomi.Ogunde@sunpharma.com

H5 Long-Term Safety of OTX-101 0.09%, a Novel Nanomicellar Formulation of Cyclosporine A, and Its Efficacy in Patients with Keratoconjunctivitis Sicca
Jodi Luchs, MD, Barry Schechter, MD, John Sheppard, MD, Abayomi Ogunde, PharmD, Charles Darby, MS, Mark Bergmann, MD, Paul Karpecki, OD; Abayomi.Ogunde@sunpharma.com

H6 Effect of OTX-101, a Novel Nanomicellar Cyclosporine A Formulation on Tear Production in Patients with Aqueous Deficient Keratoconjunctivitis Sicca
Barry Schechter, MD, David Evans, MD, Shane Kannarr, OD, John Sheppard, MD, Abayomi Ogunde, PharmD, Charles Darby, MS, Jodi Luchs, MD, Paul Karpecki, OD, Bridgitt Shen Lee, OD, Melissa Toyes, MD; Abayomi.Ogunde@sunpharma.com

I12 Using Real-World Evidence to Design Value-Based Contracts for the Real World
Amanda Patrick, MS, Todd Gorsuch, MBA, Pattra Mattox, SM, Jeremy Rassen, ScD; amanda.patrick@action.com

I13 Patient-Reported “Good” Days During a Prospective Study of the Treatment of Neurogenic Orthostatic Hypotension with Droxidopa
Steven Kymes, PhD, L. Arthur Hewitt, PhD, Clément François, PhD; SKYM@lundbeck.com

J5 Reduced Asthma Exacerbations and Asthma-Related Healthcare Resource Use with Omalizumab from the Real-World PROSPERO Study
Yamina Raiput, MSc, Thomas Casale, MD, Ahsan Iqbal, MBBS, Joseph Dang, PharmD, Ming Yang, PhD; rajput.yamina@gmail.com

J6 A Predictive Model for Clinical Asthma Exacerbations Using Albuterol eMDPI (ProAir Digihaler): A 12-Week, Open-Label Study
Guilherme Safioti, MD, Lena Granovsky, PhD, Thomas Li, PhD, Michael Reich, PhD, Shahar Cohen, PhD, Yonatan Hadar, MSc, Roy Pleasants, PharmD, Henry Chrystyn, MPHarm, PhD, Tanisha Hill, PhD, Michael DePietro, MD; guilherme.safioti@tevaopharma.com

J7 Inappropriate Triple Therapy: A Budget Impact Cost Calculator to Identify Avenues for Potential Savings in Patients with COPD
Swetha R. Palli, MS, Jessica Franchino-Elder, MPH, PhD; swetha.palli@boehringer-ingelheim.com

J8 Durability of Culture Conversion in Patients Receiving Amikacin Liposome Inhalation Suspension for Treatment-Refractory Mycobacterium avium Complex Lung Disease in the CONVERT Study
David E. Griffith, MD, Rachel M. Thomson, PhD, Doreen J. Addrizzio-Harris, MD, Stephen K. Field, MD, Jhaok Van Ingen, MD, PhD, Richard J. Wallace, MD, Chris Coulter, MD, Kevin Mange, MD, James Nezamis, PhD, Kevin L. Winthrop, MD, MPH; David.Griffith@uhctc.com

J9 An Open-Label Extension Study of Amikacin Liposome Inhalation Suspension for Treatment-Refractory Lung Disease Caused by Mycobacterium avium Complex
Kevin L. Winthrop, MD, MPH, Kozo Morimoto, MD, Paola Francesca Castellotti, MD, Jai-Joon Yim, MD, Stephen Rouss, MD, Itak Van Ingen, MD, PhD, Chris Coulter, MD, Kevin Mange, MD, James Nezamis, PhD, David E. Griffith, MD; winthrop@ohsu.edu

J12 Making the Case for EGFR TKI Sequencing in EGFR-Mutated NSCLC: A GioTag Study U.S. Patient Analysis
Ijeoma Nwosu, PharmD, Balazs Halmos, MD, MS, Rasim Guclay, MD, Wenbo Tang, PhD, Angela Marten, MD, Barbara Mornings, PharmD, MBA, Bruce Feinberg, DO, Maximillian J. Hochmair, MD; ijeoma.nwosu@boehringer-ingelheim.com

K6 Plecanatide-Improved Patient Global Rating of IBS Symptoms in Adult Patients with IBS-C
Christopher Chang, MD, PhD, Kelly Chong, PhD, Howard Franklin, MD, Howard.Franklin@salix.com

K7 Positive Results from REGENERATE: A Phase 3, International, Randomized, Placebo-Controlled Study Evaluating Obeticholic Acid Treatment for NASH
Reshma Shringarpure, Zobair Younossi, MD, MPh, FACCP, FACP, AGAF, Vlad Raitziu, MD, Rohit Loomba, MD, Mary Rinella, MD, Quentin M. Anstee, MD, Zachary Goodman, MD, PHD, Pierre Bedossa, MD, PHD, Luna Zara, Leigh MacConell, Stephen Harrison, MD, Arun J. Sanyal, MD; reshma.shringarpure@interceptpharma.com

K9 Using Data Aggregation to Determine Thematic Knowledge Transfer and Lasting Performance Change in Multiple Continuing Education Activities on IBD
Whitney E. Faler, MPA, Sharon A. Tordoff, BS, Jan Perez, Tara Gross, Greg Salinas, PhD; wfaler@cmeoutfitters.com
L4  Dupilumab Improves Outcomes in Patients with Atopic Dermatitis in Clinical Practice: Results from the EaRly ReAL WorLD Patient Evaluation for Dupilumab in Atopic Dermatitis (RELIEVE-AD) Study
Bruce Strober, MD, PhD, Usha G. Mallya, BSPharm, MS, PhD, Min Yang, MD, PhD, Abhijit Gadlak, MS, PhD, Susan Boklage, PhD, Miriam C. Fenton, MPH, PhD, Christina X. Chamberlain, PhD, Debra Sierka, PharmD, Eric Q. Wu, PhD, Alexa B. Kimball, MD, MPH; susan.boklage@regeneron.com

L5  Dupilumab Improves Treatment Satisfaction and Reduces Treatment Burden in Adults with Atopic Dermatitis: Results from the EaRly ReAL WorLD Patient Evaluation for Dupilumab in Atopic Dermatitis (RELIEVE-AD) Study
Alexa B. Kimball, MD, MPH, Usha G. Mallya, BSPharm, MS, PhD, Min Yang, MD, PhD, Abhijit Gadlak, MS, PhD, Susan Boklage, PhD, Miriam C. Fenton, MPH, PhD, Christina X. Chamberlain, PhD, Debra Sierka, PharmD, Eric Q. Wu, PhD, Bruce Strober, MD, PhD; susan.boklage@regeneron.com

L15  Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 1 and reSURFACE 2
Alan M. Mendelsohn, MD, Richard G. Langley, MD, FRCPC, Jeffrey Crowley, MD, Melinda Goedheram, MSc, MD, FRCPC, Kim A. Papp, MD, PhD, FRCPC, Neil J. Korman, MD, PhD, Lynda Spelman, MBBS, FACD, Atsuyuki Igarashi, MD, PhD, Mamitaro Ohtsuki, MD, PhD, Aditya K. Gupta, MD, PhD, Paul Yamauchi, MD, PhD, Jeffrey Parno; alan.mendelsohn@sunpharma.com

L16  Tildrakizumab Efficacy by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 3-Year Data from the Phase 3 reSURFACE 1 and reSURFACE 2 Studies
Mark G. Lebwoh, MD, Nehal N. Mehta, MD, MSCE, FAHA, Alice B. Gottlieb, MD, PhD, Alan M. Mendelsohn, MD, Jeffrey Parno, MS, Stephen J. Rozzo, PhD, Alan M. Menter, MD; alan.mendelsohn@sunpharma.com

L17  Effect of Metabolic Syndrome on Efficacy and Safety in Patients with Psoriasis Treated with Etanercept or Tildrakizumab: Post Hoc Analysis of Two Phase 3 Clinical Studies (reSURFACE 1 and reSURFACE 2)
Alice B. Gottlieb, MD, PhD, Nehal N. Mehta, MD, MSCE, FAHA, Mark G. Lebwoh, MD, Alan M. Mendelsohn, MD, Jeffrey Parno, MS, Stephen J. Rozzo, PhD, Alan M. Menter, MD; alan.mendelsohn@sunpharma.com

M8  Healthcare Costs Among Patients with Ankylosing Spondylitis or Psoriatic Arthritis Who Switch or Discontinue Biologics in the United States
Esther Yi, PharmD, Dong Dai, PhD, Olivia W. Piao, MS, Josh Z. Zheng, MS, Peter Hur, PharmD, MBA, Yu Jin Park, PharmD; estheryi@novartis.com

N2  Disparities in Real-World Utilization Patterns of Potassium Binders in U.S. Veterans with Hyperkalemia
Steven D. Woods, PharmD, Elvira O. Gosmanova, MD, Csaba P. Kovesdy, MD, Jeannene Fogli, PhD, RD, Christopher G. Rowan, PhD, Jared L. Hansen, MStat, Brian C. Sauer, PhD, MS; swoods@relypsa.com

O1  Updates and Future Directions: Development of a Pharmacoeconomic Registry to Evaluate the Risks of Unintended Pregnancies Resulting from Drug Interactions with Hormonal Contraceptives
Annessa White, PharmD, MS, PhD, Meenakshi Srinivasan, PharmD, Georges Adunlin, PhD, Marc Fleming, PhD, MPH, RPh; annessa.white@unthsc.edu

U19  Impact of Specialty Pharmacist Integration on Time to Medication Access for Pimavanserin
Sabrina Livezey, PharmD, CSP, Robert W. McCormick, BS, Nisha Shah, PharmD, Leena Choi, PhD, Josh DeClercq, MS, Autumn D. Zuckerman, PharmD, BCPS, AAhwp, CSP; Rmccorm4@uthsc.edu

U20  Lessons Learned from Hurricane Maria: Continuity of Prescription Benefits Programs During Natural Disasters
Lissette Lorenzo, PharmD, Suzette Veléz-Rivera, PharmD, BCACP, BCGP, Ana M. Rivera, PharmD; ana.rivera@abarcahealth.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**

- **Patrick J. Campbell, PharmD, RPh, PhD, [E7]** Associations of Medication Synchronization: A Propensity Score-Matched Diabetes Cohort Study Evaluating Adherence, Healthcare Resource Utilization, and Expenditures
- **Brooke Hunter, MS, [R1]** Using Pharmacy Claims to Measure Opioid Misuse and Prospectively Identify At-Risk Patients
- **Isabell Kang, PharmD, [U17]** Has There Been a Change in the Payer Perspective on the Academy of Managed Care Pharmacy Format Version 4.0 Pre-Approval Dossier?
- **Frances Lynch, PhD, [F18]** Incremental Health Care Costs for Persons with Treatment-Resistant Depression in Managed Care Organizations

**GOLD**

- **Jeremy J. Whalen, PharmD, BCP, [C19]** Osimertinib First-Line Approval in Epidermal Growth Factor Receptor Mutation Positive Metastatic Non-Small Cell Lung Cancer Impact on Utilization and Total Cost of Care Among 15 Million Commercially Insured Members
- **Xinke Zhang, PhD, [C9]** Treatment Patterns and Sequencing Among Patients with Advanced Non-Small Cell Lung Cancer Who Received Systemic Chemotherapy or Immuno-Oncology Regimens in the U.S. Community Oncology Setting: A Real-World Retrospective Observational Study
- **Hiba Alzouby, PharmD Candidate, [Z1]** Impact of Shingrix (Recombinant Zoster Vaccine) Second Dose Reminder Member Calls by a Commercial Health Plan
- **Lauren Bartolome, PharmD, MS, [C11]** Budget Impact of the Introduction of Dacomitinib as a First-Line Treatment for Patients with Metastatic EGFR Mutation-Positive Non-Small Cell Lung Cancer in the U.S.
- **Steven W. Champaloux, PhD, MPH, [U15]** Proactive Pharmacist Call Program: Assessing the Impact of a Predictive Model-Driven Medicare Member Outreach on Adherence and Star Ratings
- **Steven W. Champaloux, PhD, MPH, [U7]** Medicaid Missed Refill Letter Intervention Impact on Refill Rate Versus Randomized Controls
- **Zsolt Hepp, PharmD, MS, [C27]** Real-World Burden of Illness and Unmet Need in Locally Advanced or Metastatic Urothelial Carcinoma Following Discontinuation of PD-1/PD-L1 Inhibitor Therapy: A Medicare Claims Database Analysis
- **Harsh Kuvadia, MPharm, [F14]** Economic Burden of Treatment-Resistant Depression in Privately Insured U.S. Patients with Physical Comorbidities
- **Sam Leo, PharmD, [U11]** Evaluating the Relationship Between Increased Patient Engagement and Adherence to Specialty Medications
- **Qian Li, PhD, [E2]** Use of Glucose-Lowering Treatments Among Patients with Diabetic Kidney Disease in the United States
- **Jeffrey Trocio, MPH, [C20]** Patient Preferences for CDK4/6i + Aromatase Inhibitor Treatment Attributes in Advanced/Metastatic Breast Cancer: Discrete Choice Experiment and Best-Worst Scaling Exercise
- **Maria Cecilia Vieira, MS, [E20]** Healthcare Utilization and Mortality Among Medicare Beneficiaries with Diagnosis of Wild-Type Transthyretin Amyloid Cardiomyopathy
- **Alice Wang, MA, [D1]** Burden of Heavy Menstrual Bleeding Associated with Uterine Fibroids: A Retrospective Analysis of a Large Commercially Insured Population in the U.S.
- **Setareh A. Williams, PhD, [M11]** Economic Burden of Osteoporosis-Related Fractures in Medicare Patients
Medal-Winning Abstracts

**SILVER**

**Kristin Brown-Gentry, MS, CCRP,** [F9] Comparison of New Start Antipsychotic LAI Members and Members Non-Adherent to an Oral Regimen

**Patrick P. Gleason, PharmD, MBA, MS,** [U8] Drug Super Spenders: 2016-2018 Growth in Number of Members and Total Pharmacy Plus Medical Benefit Drug Cost for Members with Extremely High Annual Drug Cost in a 17 Million-Member Commercially Insured Population

**Xingdi Hu, PhD,** [J10] An Early View of Characteristics and Treatment Patterns of Patients Initiated on Tezacaftor/IVacaftor in the United States: An Administrative Claims Data Analysis

**Qing Huang, PhD, MHS,** [C33] Real-World Evidence of Ibrutinib Use Among Patients with Chronic Lymphocytic Leukemia and/or Small Lymphocytic Lymphoma in the U.S. Veteran Health Administration Population

**Kristen Johnson, PhD, MPH,** [G17] Healthcare Resource Utilization Among Multiple Sclerosis Patients < 65 Years of Age with Commercial or Medicare Advantage Coverage: Real-World Evidence from an Administrative Claims Database

**William N. Kelly, PharmD,** [U9] Association of Pharmacist Medication Counseling with Adherence, 30-Day Hospital Readmission, and Mortality: A Systematic Review and Meta-Analysis of Randomized Trials

**Chris LaVallee, MS,** [I3] Antihypertensive Agent Utilization Among Uncontrolled Hypertension Patients with Diabetes and Chronic Kidney Disease in the United States

**Richard B. Lipton, MD,** [G22] Psychometric Evaluation of the Functional Impact of Migraine Questionnaire Within the COMPEL Trial

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**Brandon J. Patterson, PharmD, PhD,** [B1] Public Health and Economic Impact of Adjuvanted Recombinant Zoster Vaccine Adoption for a Large, Integrated Delivery Network: Utilizing Real-World Epidemiological Data in a Budget Impact Model


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**Joseph Tkacz, MS, CCRP,** [M4] Relationship Between Treatment Persistence and Healthcare Expenditure in Biologic-Naive Rheumatoid Arthritis Patients Initiating Etanercept or Adalimumab with or Without Methotrexate

**Erica Wozniak, MS, CCRP,** [I1] Impact of Valsartan Drug Recalls on Medication Adherence in Medicare Part D Patients

**Yichen Zhang, MPH,** [U39] Impact of Quality Blue on Healthcare Utilization and Costs
C9 Treatment Patterns and Sequencing Among Patients with Advanced Non-Small Cell Lung Cancer Who Received Systemic Chemotherapy or Immuno-Oncology Regimens in the U.S. Community Oncology Setting: A Real-World Retrospective Observational Study

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BACKGROUND: The emergence of immuno-oncology (IO) therapies has changed the treatment landscape for advanced non-small cell lung cancer (aNSCLC), as evidenced by favorable outcomes and toxicity profiles reported in clinical trials. However, limited information exists on treatment patterns and sequencing in the U.S. community oncology setting since IO introduction.

OBJECTIVE: To evaluate patient (pt) profiles and treatment patterns and sequencing among aNSCLC pts who initiated first-line (1L) treatment within the U.S. Oncology Network (USON).

METHODS: This was a retrospective study of adult pts with aNSCLC who initiated 1L treatment with systemic chemotherapy (chemo), an IO regimen, or targeted therapy (TT) between 3/1/15 and 8/1/18, and who were followed up until 2/1/19. Data were derived from electronic health records. Baseline characteristics and treatment patterns were assessed descriptively.

RESULTS: Among 7,746 pts who met eligibility criteria, the median age was 68 years (range, 26-90+ years); 55.0% were male and 78.9% were white at 1L initiation. Of these, 5,859 (75.6%) received chemo, 907 (11.7%) IO monotherapy, 656 (8.5%) TT, and 324 (4.2%) IO combination therapies in the 1L setting. Of 1L pts with squamous cell carcinoma (SCC), 86.8% received chemo, 12.7% IO therapy, and 0.6% TT. Of 1L pts with non-SCC, 70.8% received chemo, 17.7% IO therapy, and 11.5% TT. Following 1L treatment, 46.7% advanced to 2L and 15.9% to 3L. In the second quarter of 2015 (i.e., first complete quarter of the study period), 21% of 1L regimens contained an IO therapy (1.7% monotherapy and 0.4% combination therapy); in the second quarter of 2018 (i.e., last complete quarter of the study period), 36.0% of 1L regimens contained an IO therapy (22.9% monotherapy and 13.1% combination therapy). The most common treatment sequences were 1L chemo followed by 2L IO (n = 2,127 [27.5%]) regimen and 1L chemo followed by 2L chemo (n = 636 [8.2%]). Among pts who received 1L IO therapy (n = 1,231), 14.2% (n = 175) advanced to 2L chemo, 4.0% (n = 49) to an IO regimen, 2.4% (n = 30) to TT, and 79.4% (n = 977) did not advance to a subsequent treatment within the USON during the study period.

CONCLUSIONS: Current treatment patterns show high utilization of IO chemo for aNSCLC over the study period. Adoption of IO therapy is increasing, however, <40% of 1L pts treated in the U.S. community oncology setting received an IO regimen in the second quarter of 2018.

Future studies should investigate outcomes associated with choice of 1L regimen and continue to evaluate the need for effective and safe IO options.

SPONSORSHIP: Pfizer and EMD Serono.

C19 Osimertinib First-Line Approval in Epidermal Growth Factor Receptor Mutation-Positive Metastatic Non-Small Cell Lung Cancer Impact on Utilization and Total Cost of Care Among 15 Million Commercially Insured Members

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BACKGROUND: Osimertinib (OSI) is a tyrosine kinase inhibitor of epidermal growth factor receptor (EGFR-I). Approved in 2015 for metastatic non-small cell lung cancer (NSCLC) patients who progressed on or after initial EGFR-I therapy. In April 2018, the FDA approved OSI for first line use and the NCCN designated it as the preferred agent. With OSI having a $177,152 annual wholesale acquisition cost, 1.7-fold higher than competitor EGFR-I (cEGFR; erlotinib, gefitinib, alatinib), it’s important to understand real-world OSI uptake and impact on total cost of care (TCC) for value-based contracting and management opportunities.

OBJECTIVE: To describe OSI uptake and compare TCC among first line new start members on OSI vs. cEGFRs.

METHODS: Using integrated medical and pharmacy claims for 15 million commercially insured members with an EGFR-I claim (OSI or cEGFR) were queried from January 2017 through March 2019 (27 months). OSI quarterly member utilization trend was identified. First-line new start was defined as no previous EGFR-I use in prior 6 months and continuous enrollment (CE) required. Members first OSI claim was their index date. TCC defined as all medical and pharmacy claim allowed amounts including member share and inclusive of network discounts were summed by member for the 6 months pre EGFR-I index date and 6 months post index date. Descriptive statistics were used to compare the average member pre and post period TCC for OSI and cEGFR users.

RESULTS: Of 904 members with a claim for an EGFR-I in the 27 months, 692 had CE 6 months pre, and 433 were identified as first line new starts to EGFR-I therapy. OSI accounted for 7.1% (4 of 56) of first line use in 1Q17 as compared to 76.9% (30 of 39) in 1Q19. 251 of 433 (58%) members met the 6-month pre/post continuous enrollment criteria comprising 86 OSI and 165 cEGFR members. Mean TCC for cEGFR was $74,653 pre and $86,167 post, a 15.4% increase. For OSI, mean TCC increased from $61,825 pre to $121,586 post, a 96.7% increase. Mean TCC post period 6-month was $33,419 higher in the OSI group vs. cEGFR group.

CONCLUSIONS: In this real-world analysis of a large commercially insured population, osimertinib (OSI) first line approval was associated with a 10-fold increase in use to treat NSCLC with 3 of 4 new EGFR-I
Individuals with diabetes often have multiple comorbidities and complex medication regimens that impact medication adherence. One solution to improve adherence rates and reduce healthcare costs is medication synchronization, where complex medication refill schedules are standardized. However, additional research is needed to evaluate synchronized medication refill schedules among individuals with diabetes.

**OBJECTIVE:** To assess the relationship between medication synchronization and adherence, healthcare resource utilization, and healthcare expenditures among individuals with diabetes.

**METHODS:** This retrospective, cohort study examined differences in diabetes medication adherence, inpatient admissions, and total healthcare costs among subjects with synchronized medication refill schedules compared to propensity-score matched controls. Data from the 2015-2018 Truven MarketScan Research Databases were used to identify subjects eligible for inclusion in the Pharmacy Quality Alliance (PQA) diabetes medication (excluding insulin) adherence measure. Subjects with two or more diabetes, statin, or renin-angiotensin system antagonist drug classes were included. A conditional logistic regression model was used to assess the relationship between medication synchronization and adherence, whereas generalized linear mixed models with log link and gamma distribution (expenditures) or negative binomial distribution (utilization) assessed economic outcomes. Odds ratios (OR), rate ratios (RR), and cost ratios (CR) were estimated.

**RESULTS:** A total of 20,325 medication synchronization cases were successfully matched to controls. Commercial cases (n = 16,136) were more adherent (67.7% vs. 57.4% [OR = 1.67, 95% CI = 1.59,1.75]), had fewer hospital admissions (RR = 0.59, 95% CI = 0.53,0.67), and lower median healthcare expenditures ($3,687 vs. $7,480 [CR = 0.61, 95% CI = 0.57, 0.65]) than controls. Medicare supplemental cases (n = 4,189) were more adherent (86.5% vs. 70.4% [OR = 2.96, 95% CI = 2.62,3.35]), had fewer hospital admissions (RR = 0.72, 95% CI = 0.63,0.82), and lower median healthcare expenditures ($7,353 vs. $10,592 [CR = 0.69, 95% CI = 0.64, 0.75]) than controls.

**CONCLUSIONS:** Medication synchronization was associated with higher adherence, lower inpatient utilization, and lower healthcare costs. Medication synchronization may facilitate improved health outcomes across various populations.

**SPONSORSHIP:** Prime Therapeutics.
Using Pharmacy Claims to Measure Opioid Misuse and Prospectively Identify At-Risk Patients

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BACKGROUND: Approximately 46 people die per day in the U.S. from prescription opioid overdose according to the CDC. This national crisis warrants action, including the preemptive identification of patients at risk of opioid misuse.

OBJECTIVE: To (1) create an Opioid Misuse Index (OMI) from pharmacy claims that is designed to globally identify patients at risk of inappropriate opioid use (e.g., opioid abuse, overdose, illicit use) and (2) create a predictive model that will prospectively identify patients at risk of opioid misuse using pharmacy claims data only.

METHODS: The OMI is a summative index of 6 indicators (e.g., pharmacy shopping, prescriber shopping, MME, concurrent benzo-diazepine use), and can have a value that ranges from 0 to 6 where 6 indicates the highest level of risk. Using a sample of 14,619 Medicaid patients, regression analyses were conducted where the OMI was used to predict concurrent and future medical outcomes (i.e., opioid overdose, opioid use disorder diagnosis, excessive emergency department [ED] visits). Subsequently, 225 independent variables were created from pharmacy claims data and used to predict the OMI in a backwards stepwise linear regression analysis in a sample of 12,684 Medicaid members from several different U.S. states in order to create a predictive model that identifies members at risk of opioid misuse. The model was cross validated using an independent sample composed of 5,316 members.

RESULTS: OMI concurrent validity - The OMI significantly predicted ED visits (odds ratio = 1.60, P ≤ 0.001), opioid substance use disorder diagnosis (odds ratio = 1.82, P ≤ 0.001), and opioid overdose (odds ratio = 1.85, P ≤ 0.001) during the same measurement period. OMI predictive validity—the OMI significantly predicted ED visits (odds ratio = 1.34, P ≤ 0.001), opioid substance use disorder diagnosis (odds ratio = 1.71, P ≤ 0.001), and opioid overdose (odds ratio = 1.76, P ≤ 0.001) during a future measurement period. A regression model predicting the OMI was developed with 20 predictors, R² = 0.39, and the linear correlation between the predicted OMI and the observed OMI was 0.63.

CONCLUSIONS: Pharmacy claims data can be used to prospectively identify patients at risk of opioid misuse with a fair level of accuracy. The OMI is a theory based index of opioid misuse that demonstrates both a concurrent and prospective relationship to adverse medical events associated with opioid misuse. Additionally, the regression model developed to predict the OMI has demonstrated the ability to prospectively identify patients at risk of opioid misuse.

SPONSORSHIP: Magellan Health.

Has There Been a Change in the Payer Perspective on the AMCP Format Version 4.0 Pre-Approval Dossier?

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BACKGROUND: AMCP Format v4.0 offers guidance to manufacturers on providing product information to healthcare decision-makers (HCDMs) prior to approval by the FDA. However, the pre-approval information exchange (PIE) landscape is evolving; this topic is covered in the FDA’s final guidance published in June 2018 titled “Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities” (FDA Guidance).

OBJECTIVE: To evaluate if HCDM perspectives on the utility of pre-approval dossiers have changed from 2018 to 2019.

METHODS: An initial web-based survey (N = 44) was fielded December 2017-January 2018 to members of Xcenda’s proprietary market research panel of payer practitioners in the United States. In this follow-up analysis, a web-based survey was fielded January-February 2019 with similar questions; responses were compared in aggregate to the initial data. Descriptive and inferential statistics were used to compare differences between years.

RESULTS: In 2019 (N = 47), a majority of HCDMs (66%) represented managed care organizations, followed by pharmacy benefit managers (26%). Over half (57%) represented regional plans, and most were either pharmacy (62%) or medical directors (28%). HCDM characteristics were similar between 2018 and 2019 surveys. HCDM requests for pre-approval dossiers increased from 2018 to 2019 but remained low (8/44 [18%] vs. 12/47 [26%], respectively; P < 0.05). Notably, there was a slight increase in frequency of receiving a pre-approval dossier from a manufacturer after an unsolicited request from the HCDM (2018 vs. 2019, respectively: always/frequently/sometimes, 22/44 [50%] vs. 28/47 [60%]). Of the 12 HCDMs in 2019 who requested a pre-approval dossier, most requests were made 1-6 months prior to anticipated approval date (10/12 [83%])—consistent with 2018 survey results (8/8 [100%]). In 2019, primary reasons for requesting a pre-approval dossier were ease of information gathering (36%), expectation of additional data provided (23%), education on a novel product mechanism of action (13%), and education on disease state (11%). In 2019, for the optimal length of the pre-approval dossier, a majority (79%) preferred a shorter document (10-40 pages; 47%; < 10 pages: 32%).

CONCLUSIONS: From 2018 to 2019, there was an increase in the proportion of HCDMs who requested a preapproval dossier and an upward trend in the frequency HCDMs were receiving a preapproval dossier. Given recent FDA Guidance on PIE and the upcoming AMCP Format v4.1, it is anticipated this increasing trend will continue.

SPONSORSHIP: Xcenda.
Epidemiological Data in a Budget Impact Model

Assessing incremental clinical and economic impact of adopting novel health technology is critical for population-based decision makers (PBDMs). In October 2017, Shingrix, adjuvanted Recombinant Zoster Vaccine (RZV), was approved for herpes zoster (HZ) prevention in adults 50 years and older by the Food and Drug Administration, joining Zostavax, Zoster Vaccine Live (ZVL), as U.S.-marketed vaccines against HZ. A budget impact model was created to inform PBDMs about incremental value of RZV adoption. While a budget impact model populated using national data can inform PBDMs about the incremental value of RZV adoption overall, heterogeneity across plans highlights the need for rigorously gathered, plan-specific data to enhance the relevance of the model for PBDMs in their decision-making process.

OBJECTIVE: To utilize rigorously analyzed epidemiological inputs from a large, integrated delivery network (IDN) along with nationally averaged costs data in modeling clinical and economic outcomes associated with adoption of RZV.

METHODS: A budget impact model based on the published ZOster ecoNomic Analysis (ZONA) model was created accounting for IDN-collected population characteristics (size, age distribution) and epidemiological data (incidence of HZ and complications, HZ recurrence rate), vaccine characteristics from randomized controlled trials and observational studies (efficacy, waning, 2nd dose compliance for RZV, adverse event rate), national costs averages (vaccine, direct medical for HZ and complications avoidance and vaccine adverse events), vaccine characteristics from randomized controlled trials and observational studies (efficacy, waning, 2nd dose compliance for RZV, adverse event rate), national costs averages (vaccine, direct medical for HZ and complications avoidance and vaccine adverse events), vaccine coverage and growth, and market share assumptions. Incremental clinical (HZ and complications) and economic (per-member per-month [PMPM] costs) impact at 5-, 10-, and 15-year time horizons was assessed comparing scenarios where RZV is added to one where ZVL is solely utilized.

RESULTS: For the ~1.4 million persons ≥ 50 years of age in the health plan, in the 5, 10, and 15 years following RZV adoption, approximately 8.8 thousand (k), 33.9k, and 71.6k more HZ cases and 0.8k, 3.1k, and 7.1k more cases of post herpetic neuralgia would be avoided, respectively. Across plan membership (~4.1 million persons), estimated incremental PMPM cost would be $0.41, $0.34, and $0.26, respectively.

CONCLUSIONS: RZV adoption would avoid a greater number of HZ cases and complications at a low incremental PMPM cost. The results suggest that these health gains would increase and that the costs incurred would decrease over longer time horizons.

SPONSORSHIP: GlaxoSmithKline Biologicals SA.
CONCLUSIONS: Among almost 73,000 U.S. adult PLWH, individuals initiating STRs had significantly longer persistence on first-line therapy compared to those initiating MTRs. Among STRs, persistence was highest for BIC/FTC/TAF. Optimal selection of first-line therapy in terms of regimen type and formulation is crucial to ensuring persistence for PLWH.

SPONSORSHIP: Gilead Sciences.

B4 Adherence to Antiretroviral Therapy and Healthcare Utilization Trends over 4 Years of Follow-Up in a Commercially Insured Population of Patients with HIV

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BACKGROUND: High daily adherence to antiretroviral (ARV) medications for treating HIV is essential to keep the virus undetectable and prevent development of resistance and transmission to others.

OBJECTIVE: To compare all-cause and HIV-related healthcare resource utilization (HRU) over time by adherence to daily oral ARV regimens among commercially insured HIV patients.

METHODS: A retrospective study using Optum Clinformatics U.S.-based claims data was conducted. Patients with an HIV-1 diagnosis during 2011-2017, age ≥18 years at index (date of first complete ARV regimen) and continuous enrollment for ≥3 months before index (baseline) and ≥12 months after index (observation) were included. Adherence to ART was measured as the proportion of days covered (PDC), categorized as low (PDC<80%), moderate (80% to <90%), high (90% to <95%), or very high (PDC≥95%). HRU included outpatient (OP), emergency room (ER) and inpatient (IP) visits. Chi-square tests compared HRU between very high and low adherence groups. PDC and HRU were examined after 1-year and across 4 years, among patients with that amount of follow-up.

RESULTS: Among the 15,153 included patients, median age was 45 years, 88% were male, and 53% were in the South, with an average of 3 years of follow-up. In year 1 following index, the percentage of patients by adherence category were 41% very high, 22% high, 17% moderate and 20% low. Over 4 years of follow-up, the percentage of very high adherence declined to 22%. HIV-related ER and IP visits were higher among those with lower adherence. With 1 year of observation, 5% and 4% more patients with low adherence had an HIV-related ER or IP visit, respectively, compared to those with very high adherence; after 4 years the difference increased to 10% more patients with low adherence having ER visits (P<0.001) and 8% more having IP visits (P<0.001). Results were similar for all-cause HRU. More than 98% of patients had ≥1 OP visit per year (mean 3.8 HIV-related; 8.8 all-cause visits); this did not differ across adherence levels.

CONCLUSIONS: Adherence to ART in this population of patients with HIV showed room for improvement, particularly over time. The proportion of patients with more costly HRU (i.e., ER and IP) was significantly lower in patients with very high adherence, and the difference grew larger with additional years of observation. Maintaining high adherence to ARV daily oral therapy over time is a challenge but is critically important for optimal management of HIV patients.

SPONSORSHIP: ViiV Healthcare.

B5 Clinical and Economic Outcomes of Formulary Conversions of Antiretroviral Medications in an Integrated Health Care Delivery System

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BACKGROUND: Though new diagnoses of the human immunodeficiency virus (HIV) continue to occur, the advancement of available therapies has transformed the clinical outlook on HIV from a terminal disease to a chronic condition. Therefore, the focus of HIV management has shifted from primarily preventing disease progression to preventing new infection, improving medication adherence, managing comorbidities, and improving health outcomes as patients age. The cost of managing patients living with HIV (PLWH) also continues to increase as chronic disease management efforts improve. Managed care organizations often seek to balance mitigating the need to provide optimized, guideline-based care to PLWH with the rising cost of medications used to treat HIV.

OBJECTIVE: To evaluate (a) viral suppression rates, (b) 6-month persistence rates, and (c) change in cost per treated patient following antiretroviral medication conversions to formulary single-tablet regimens.

METHODS: An interregional pharmacy claims database was used to identify patients included in an antiretroviral formulary conversion between January 2016 and December 2018. Conversions involved transitioning patients from second-line medications to first-line options based on HIV guidelines. Patients with documented viral load tests within 6 months of conversion were reviewed. The viral suppression rate was defined as the proportion of patients who had a documented undetectable viral load (HIV RNA <20). Persistence rates were calculated as the proportion of patients who maintained a proportion of days covered (PDC) ≥ 80% within 6 months of the conversion. Patients were excluded if they did not participate in the conversion or disenrolled from the plan within the 6 months following the conversion.

RESULTS: Following the conversions, 76% of patients maintained viral load suppression. A PDC of ≥80% was achieved for 76% of patients, and the cost per treated patient decreased by 7%.

CONCLUSIONS: Antiretroviral medication conversions to formulary single tablet regimens based on HIV guidelines were well tolerated and led to a decrease in cost to treat each patient living with HIV. Clinical evidence and cost considerations should be constantly evaluated by managed care organizations in order to use financial resources to appropriately care for this population.

SPONSORSHIP: None.
Real-World Survival and Treatment Patterns of Patients with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma Who Were Eligible for First-Line Therapy

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BACKGROUND: Platinum-containing regimens for first-line (1L) treatment of recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) are standard of care, with recent emerging IO therapies considered by treatment guidelines to be potentially useful for 1L treatment in specific circumstances.

OBJECTIVE: To aid in future improvement in management of R/M HNSCC, the current knowledge needs to be updated regarding the evolving treatment landscape and effectiveness for 1L R/M HNSCC in the real world.

METHODS: U.S. patients with oral, cavity, oropharynx, hypopharynx, or larynx R/M HNSCC who received no prior systemic therapies for the disease were identified in the Flatiron Oncology electronic medical record database from January 2013 to December 2018. Patients' characteristics and treatment patterns were characterized. Median overall survival (OS) and associated 95% confidence intervals (CI) were calculated from the start of 1L therapy using Kaplan-Meier estimates.

RESULTS: A total of 902 patients with de novo metastatic disease (1LM) and 4,745 with recurrent disease (1LR) were identified. The median age was 65 and 64 years for 1LM and 1LR patients, respectively. Most patients were male (82.2% 1LM; 75.3% 1LR). The most common primary site of disease was oropharynx (50% in the 1LM group and 42% in the 1LR group). Very few patients were tested for PD-L1, but of those, 25% (7/28) were positive in the 1LM group and 17.8% (22/124) in the 1LR group. Median duration of follow-up from start of 1L was 282 days and 297 days for 1LM and 1LR, respectively. Among patients receiving at least one line of therapy (722/902 for 1LM and 3,590/4,745 for 1LR), platinum-based regimens were most commonly prescribed 1L therapies (80% and 63% for 1LM and 1LR, respectively) with median treatment duration of 140 days and 160 days for 1LM and 1LR, respectively. Two percent of 1LM patients and 11% of 1LR patients received IO therapy in 1L with median treatment duration of 95 days and 118 days, respectively. Median OS (95% CI) from start of 1L therapy was 12.9 (11.5-14.0) months for the 1LM group and 12.1 months (11.7-12.5) for 1LR patients.

CONCLUSIONS: Real-world OS of R/M HNSCC patients who received at least one line of therapy was over 1 year in both patient groups which aligns with the range of OS found in past studies. IO therapy was used in the 1L setting, including being used as chemo-IO combination therapy. With upcoming data expected for a number of IO agents this setting, it will be of interest to observe how further uptake of IO may affect OS for patients treated in this setting.

SPONSORSHIP: AstraZeneca.

Real-World Treatment Patterns of Patients with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma Who Were Eligible for Second-Line Therapy After Platinum-Based Chemotherapy


BACKGROUND: Recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) patients (pts) who have progressed or recurred on platinum-based chemotherapy have a poor prognosis as the therapeutic options in this setting have limited efficacy.

OBJECTIVE: Some immuno-oncology (IO) therapies have recently been introduced and/or approved for the treatment of HNSCC in the second-line (2L) setting, but a better understanding of the current real-world treatment patterns and effectiveness of treatments is needed.

METHODS: U.S. pts with oral, cavity, oropharynx, hypopharynx, or larynx R/M HNSCC who were eligible for 2L therapy after platinum-based chemotherapy were identified in the Flatiron Oncology electronic medical record database from January 2013 to December 2018. Patients' characteristics and treatment patterns were characterized.

RESULTS: Of the 2L eligible pts identified, 515 pts had metastatic disease (2LM) at initial diagnosis and 2074 met study criteria for recurrent disease (2LR). The median age was 65 and 64 years for 2LM and 2LR pts, respectively. Most pts were male (83.9% for 2LM and 76.0% for 2LR). The most common primary site of disease was oropharynx (52.0% for 2LM and 42.5% for 2LR). Very few pts were tested for PD-L1, but of those, 12.5% (n = 3 of 24) were positive in the 2LM group and 14.9% (n = 10 of 67) in the 2LR group. Median duration of overall follow-up from start of 2L was 234 days for 2LM and 210 days for 2LR, respectively. A total of 260 2LM and 1,151 2LR patients received at least 2L. In the 2L setting, platinum-based regimens (used by 33.1% and 32.1% of 2LM and 2LR patients, respectively), IO therapies (used by 30.8% and 33.5% of 2LM and 2LR patients, respectively), and other chemotherapies/targeted-agents (used by 36.2% and 34.4% of 2LM and 2LR patients, respectively) were essentially equally popular choices. The median treatment duration in 2L was the longest with platinum-based regimens (119 days and 111 days for 2LM and 2LR, respectively), followed by other chemotherapies/targeted-agents (104 days and 99 days for 2LM and 2LR, respectively), and IO therapies (84 days and 89 days for 2LM and 2LR, respectively).

CONCLUSIONS: IO therapy has been approved for pts after a prior platinum-containing regimen since 2016 and is gaining popularity as a choice for treating patients and IO therapies account for approximately a third of treatment choices. It will be of interest to observe how any approvals for IO therapy in the 1L setting affect treatment choices for pts in the 2L setting.

SPONSORSHIP: AstraZeneca.

Economic Burden of Systemic Therapy-Related Adverse Events in Patients with Advanced Head and Neck Cancer

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BACKGROUND: Systemic therapy (chemotherapy, targeted therapy, biologics, immunotherapy) has had an emerging role in the treatment of advanced head and neck cancer (HNC) patients. Despite increased systemic therapy use to treat advanced HNC, medical care costs associated with adverse events (AEs) are not well defined.

OBJECTIVE: To estimate average total and incremental medical care costs associated with AEs for advanced HNC patients who received first-line system therapy.

METHODS: Data on adult patients diagnosed with recurrent or de novo metastatic (stage III or IV) HNC between 2010 and 2016 were included in this retrospective cohort study (n = 229). Among patients who received first-line systemic therapy, we identified those who experienced severe principal AEs within 12 months of therapy initiation, based on inpatient or emergency room encounters for which an AE was the principal diagnosis. The Common Terminology Criteria for Adverse Events (CTCAEs) was used to categorize AEs. Descriptive statistics were used to summarize baseline patient and clinical characteristics, and AEs. Multivariable generalized linear models adjusting for demographic, clinical and treatment characteristics were used to estimate medical care costs associated with severe principal AEs in the 12 months following systemic therapy initiation. Total and by service type (ambulatory, inpatient, medication, outpatient).

RESULTS: Approximately 73% (n = 167) of advanced HNC patients received first-line systemic therapy. Among patients who received first-line systemic therapy, 42% (n = 70) had ≥ 1 severe principal AE. In adjusted analysis, average total medical care costs were significantly higher among patients with ≥ 1 severe principal AE ($106,252; 95% confidence interval [95% CI]: 93,853-120,290) compared to those without a severe principal AE ($73,653; 95% CI: 66,482-81,958), as were adjusted average costs for ambulatory ($9,837; 95% CI: 6047-16,001 vs. $4,599; 95% CI: 3090-6845, respectively) and inpatient care ($26,971; 95% CI: 11,552-62,966 vs. $1,536; 95% CI: 803-2937, respectively).

CONCLUSIONS: Our findings underscore the overall economic burden to the health care system associated with AEs among advanced HNC patients who receive systemic therapy. Total medical care costs were significantly higher for advanced HNC patients who experienced a severe principal AE. These findings highlight the magnitude of medical care costs and the need for approaches to prevent and improve management of AEs among HNC patients receiving systemic therapy, which may help contain the rising economic burden of HNC cancer.

SPONSORSHIP: AstraZeneca.

C5 Treatment Patterns, Survival Rate, and Total Costs by Line of Therapy for FDA-Approved/NCCN Category 1 Treatments for Medicare Patients with Metastatic Pancreatic Cancer

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BACKGROUND: There is currently limited real-world evidence regarding metastatic pancreatic cancer (m-PANC) FDA-approved/NCCN Category 1 outcomes for Medicare fee-for-service (FFS) patients.

OBJECTIVE: To analyze treatment patterns, total costs, and survival rates for Medicare FFS patients with m-PANC by chemotherapy regimen and line of therapy (LOT).
OBJECTIVE: To assess incremental cost-effectiveness (CE) associated with 8 sequences in advanced HCC to inform formulary decisions and clinical pathways in the U.S.

METHODS: We developed a model to estimate the lifetime costs (in 2019 US$), life years (LYs) and quality-adjusted life years (QALYs) experienced by patients with unresectable HCC comparing these 8 sequences. The model captures disease and treatment progression via 4 health states: progression-free 1L, progression-free 2L, progressed 2L, and dead. Model transition probabilities were derived from the published data from each therapy’s registration trial using a joint multistate Markov modeling framework. For nivolumab, patient-level data from CheckMate 040 were utilized. Drug acquisition costs were based on the RED BOOK online (February 2019) and adverse event costs were taken from the Healthcare Cost and Utilization Project. All costs and outcomes were discounted by 3%/year.

RESULTS: The costs, LYs, and QALYs were as follows for sequences with 1L sorafenib followed by 2L with regorafenib ($260,029 | 2.154 | 1.455), cabozantinib ($253,754 | 1.971 | 1.345), nivolumab ($245,149 | 4.629 | 2.658), and pembrolizumab ($226,232 | 4.066 | 2.404). Corresponding values were as follows for sequences with 1L lenvatinib followed by 2L with regorafenib ($267,658 | 2.312 | 1.576), cabozantinib ($261,617 | 2.135 | 1.471), nivolumab ($251,882 | 4.702 | 2.736), and pembrolizumab ($233,244 | 4.147 | 2.483). Sequences with a 2L IO agent cost less and resulted in greater LYs and QALYs gained versus sequences with a 2L TKI. Sequences with nivolumab as 2L resulted in incremental cost/LY gained < $45,000 and incremental cost/QALY gained < $80,000 versus those with 2L pembrolizumab.

CONCLUSIONS: In advanced HCC, treatment sequences with 2L IO result in both lower costs and higher LYs and QALYs compared to sequences with 2L TKIs. Sequences with 2L nivolumab result in higher LYs and QALYs and are cost-effective based on currently used thresholds compared to sequences with 2L pembrolizumab.

SPONSORSHIP: Bristol-Myers Squibb.

C7 Characteristics, Systemic Treatments, and Outcomes in Patients with Advanced Hepatocellular Carcinoma: A Systematic Literature Review
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BACKGROUND: Hepatocellular carcinoma (HCC) is often diagnosed in advanced stages when systemic therapies are recommended. The National Comprehensive Cancer Network (NCCN) recommends 2 agents (sorafenib, lenvatinib) in the first-line (1L) setting and 5 agents (regorafenib, cabozantinib, ramucirumab, pembrolizumab, nivolumab) in the second-line (2L) setting.

OBJECTIVE: To describe the characteristics, treatments, and clinical outcomes of patients with advanced HCC enrolled in intervention trials administering systemic therapies.

METHODS: A systematic literature review was conducted to identify trials (any phase) reporting efficacy of systemic therapies in patients with advanced HCC from the United States, China, Japan,
or South Korea in Embase/MEDLINE articles from 2008-2018 and ClinicalTrials.gov entries. Patient, treatment, efficacy, and safety data were extracted and synthesized, and stratified means based on trial arm sample size were calculated and stratified by line of therapy.

RESULTS: From 3,722 total citations, 118 unique trials (1L: 45, 2L: 73) describing 13,534 patients were included. Most trials were phase 2 (49%) or phase 3 (14%). Most trials were single-arm or dose-escalation studies (75%), or compared 2 active arms (13%), active arm vs. placebo (10%), or active arm vs. best supportive care (2%). Barcelona Clinic Liver Cancer (BCLC) was the most frequently used staging system (47%); most patients in both 1L and 2L cohorts were BCLC C (81%). Evidence of advanced disease included extrahepatic spread (1L: 58%, 2L: 66%); vascular invasion (1L: 33%, 2L: 28%), and portal vein thrombosis (1L: 34%, 2L: 18%). Patients had undergone previous resection (1L: 29%, 2L: 40%), ablation (1L: 13%, 2L: 19%), and other loco-regional treatments (1L: 42%, 2L: 63%). Similar results for active therapy arms were observed for 1L and 2L cohorts in overall response rates (1L: 9%, 2L: 8%), disease control rates (1L: 57%, 2L, 55%), median progression-free survival (mPFS; 1L: 4.2 mo, 2L: 3.5 mo), and overall survival (mOS; 1L: 10.0 mo, 2L: 9.6 mo). The mPFS/mOS of NCCN-recommended therapies trended longer vs. other active therapies (1L: 4.3/10.4 mo vs. 4.0/9.0 mo, 2L: 3.9/10.7 mo vs. 3.3/8.9 mo). Among all active therapy arms, patients had treatment-emergent adverse events (TEAE) that led to discontinuation (1L: 26%, 2L: 18%) or experienced Grade 3+ TEAE (1L: 60%, 2L: 55%).

CONCLUSIONS: Despite recent FDA approvals, advanced HCC patients continue to have poor outcomes. There is an unmet need for more efficacious and tolerable systemic therapies for advanced HCC.

SPONSORSHIP: AstraZeneca.

Treatment Patterns and Sequencing Among Patients with Advanced Non-Small Cell Lung Cancer Who Received Systemic Chemotherapy or Immuno-Oncology Regimens in the U.S. Community Oncology Setting: A Real-World Retrospective Observational Study

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BACKGROUND: The emergence of immuno-oncology (IO) therapies has changed the treatment landscape for advanced non-small cell lung cancer (aNSCLC), as evidenced by favorable outcomes and toxicity profiles reported in clinical trials. However, limited information exists on treatment patterns and sequencing in the U.S. community oncology setting since IO introduction.

OBJECTIVE: To evaluate patient (pt) profiles and treatment patterns and sequencing among aNSCLC pts who initiated first-line (1L) treatment within the U.S. Oncology Network (USON).

METHODS: This was a retrospective study of adult pts with aNSCLC who initiated 1L treatment with systemic chemotherapy (chemo), an IO regimen, or targeted therapy (TT) between 3/1/15 and 8/1/18, and who were followed up until 2/1/19. Data were derived from electronic health records. Baseline characteristics and treatment patterns were assessed descriptively.

RESULTS: Among 7,746 pts who met eligibility criteria, the median age was 68 years (range, 26-90+ years); 55.0% were male and 78.9% were white at 1L initiation. Of these, 5,859 (75.6%) received chemo, 907 (11.7%) IO monotherapy, 656 (8.5%) TT, and 324 (4.2%) IO combination therapies in the 1L setting. Of 1L pts with squamous cell carcinoma (SCC), 86.8% received chemo, 12.7% IO therapy, and 0.6% TT. Of 1L pts with non-SCC, 70.8% received chemo, 17.7% IO therapy, and 11.5% TT. Following 1L treatment, 46.7% advanced to 2L and 15.9% to 3L. In the second quarter of 2015 (i.e., first complete quarter of the study period), 2.1% of 1L regimens contained an IO therapy (1.7% monotherapy and 0.4% combination therapy), in the second quarter of 2018 (i.e., last complete quarter of the study period), 36.0% of 1L regimens contained an IO therapy (22.9% monotherapy and 13.1% combination therapy). The most common treatment sequences were 1L chemo followed by 2L IO (n = 2,127 [27.5%]) regimen and 1L chemo followed by 2L chemo (n = 636 [8.2%]). Among pts who received 1L IO therapy (n = 1,231), 14.2% (n = 175) advanced to 2L chemo, 4.0% (n = 49) to an IO regimen, 2.4% (n = 30) to TT, and 79.4% (n = 977) did not advance to a subsequent treatment within the USON during the study period.

CONCLUSIONS: Current treatment patterns show high utilization of 1L chemo for aNSCLC over the study period. Adoption of IO therapy is increasing, however, <40% of 1L pts treated in the U.S. community oncology setting received an IO regimen in the second quarter of 2018. Future studies should investigate outcomes associated with choice of 1L regimen and continue to evaluate the need for effective and safe IO options.

SPONSORSHIP: Pfizer and EMD Serono.

Economic Burden in Patients with Anaplastic Lymphoma Kinase-Positive Non-Small Cell Lung Cancer Receiving First-Line Anaplastic Lymphoma Kinase Inhibitors

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BACKGROUND: Non-small cell lung cancer (NSCLC) makes up 84% of lung and bronchus cancer cases; among these, 2-8% of cases are anaplastic lymphoma kinase-positive (ALK+). The current standard of care for ALK+ NSCLC involves treatment with ALK inhibitors.

OBJECTIVE: To describe the real-world economic burden of patients with ALK+ NSCLC treated with first-line ALK inhibitors.

METHODS: This retrospective study used the MarketScan Commercial and Medicare Supplemental (MarketScan) Claims databases to identify adults with a lung cancer diagnosis code (≥ 1 inpatient claim or ≥ 2 outpatient claims of ≥ 30 days but ≤ 1 year apart) and use of a first-line ALK inhibitor ( Alecibib, ceritinib, crizotinib) from January 2011 to June 2018. Patients were followed for at least 6 months and up to 12 months after the index date (defined as the date of first claim with a first-line ALK inhibitor). Healthcare costs (2018 USD) and utilization rates were evaluated on a per-patient-per-month (PPPM) basis from the treatment start with a first-line ALK inhibitor to the end of follow-up.

RESULTS: A total of 578 patients (mean age: 56.8 years) with NSCLC received a first-line ALK inhibitor (45 alectinib, 8 ceritinib, 525 crizotinib). PPPM total healthcare cost for these patients was $19,940. Non-pharmacy medical costs accounted for 43% of total costs. Healthcare resources utilized most frequently were office and outpatient hospital visits (1.85 per month for each). Mean inpatient hospital stay per months was 1.13 days with a mean cost of $2,789. Among non-inpatient costs, the top cost drivers were pemetrexed injection (7.2%), brain stem magnetic resonance imaging with or without dye (4.6%) and denosumab injection (4.0%).

CONCLUSIONS: The economic burden in patients with ALK+NSCLC treated with first-line ALK inhibitors is high, emphasizing the need for novel, effective and tolerated therapies to reduce the overall healthcare costs.

SPONSORSHIP: Millennium Pharmaceuticals.

C11 Budget Impact of the Introduction of Dacomitinib as a First-Line Treatment for Patients with Metastatic EGFR Mutation-Positive Non-Small Cell Lung Cancer in the U.S.

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BACKGROUND: Lung cancer is the second most commonly diagnosed form of cancer in the U.S. and the leading cause of cancer-related death. Non-small cell lung cancer (NSCLC) accounts for 80%-85% of lung cancer cases. In the U.S., epidermal growth factor receptor (EGFR) mutations are present in 14%-23% of patients with NSCLC. In 2018, dacomitinib was approved by the FDA for first-line treatment of patients with metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

OBJECTIVE: To assess the budget impact of the introduction of dacomitinib as a first-line treatment for patients with metastatic EGFR mutation-positive NSCLC from a U.S. third-party payer perspective.

METHODS: A model was developed to estimate the 5-year budget impact associated with introducing dacomitinib as a first-line treatment for patients with metastatic EGFR mutation-positive NSCLC in a hypothetical U.S. plan with 1 million members. The model combined epidemiological data, clinical trial data on treatment duration, market share estimates, drug treatment costs, and disease management and adverse event costs for the 4 approved comparators (gefitinib, erlotinib, afatinib, and osimertinib) and dacomitinib over a time horizon of up to 5 years. The incremental total budget impact and per-member-per-month (PMPM) cost was calculated to compare the scenario with vs. without dacomitinib. Scenario analyses were conducted to explore the impact of potential model drivers.

RESULTS: In the base case, 12 people out of 1 million were estimated to receive active first-line treatment each year for metastatic EGFR mutation-positive NSCLC. The overall budget impact in the base case was a total increase of $606,422 over a 5-year time horizon ($13.96 million in the reference scenario without dacomitinib vs. $14.56 million in the projected scenario with dacomitinib), representing a 4.35% budget increase with the introduction of dacomitinib as a first-line treatment for patients with metastatic EGFR mutation-positive NSCLC. The expected budget impact per member per month (PMPM) in the U.S. was $0.01. In scenario analyses, drug costs, treatment duration and market share variations had the greatest impact on the budget estimates.

CONCLUSIONS: The addition of dacomitinib to a U.S. plan formulary for first-line treatment for patients with metastatic EGFR mutation-positive NSCLC is expected to have a minimal incremental impact.

SPONSORSHIP: Pfizer.

C15 How Should the Validity of Survival Extrapolations Following Cancer Treatments Be Established? Findings from a Rare Cancer Case Study

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BACKGROUND: Recently, immuno-oncology (IO) treatments have been shown to provide substantial survival advantages vs. traditional cancer therapies, yet they are associated with a higher acquisition cost. Quantifying the value of IO treatments is contingent on an appropriate prediction of clinical benefit, which often relies on extrapolation of survival data beyond the period of follow-up in the pivotal clinical trial. A multitude of survival extrapolation approaches are documented within published literature, so the choice of method is frequently debated. The most appropriate methods may be revealed over time through the validation of initial projections.

OBJECTIVE: To understand what survival extrapolation methods have been previously used and how the accuracy of these methods has been tested within the context of a rare cancer case study (avelumab for metastatic Merkel cell carcinoma [mMCC]).

METHODS: We reviewed published health technology assessment reports and other published literature to identify extrapolation methods used for avelumab in mMCC. We synthesized commentary provided by study authors, reviewers, and payers regarding the appropriateness of survival extrapolation methods and how they were validated. We also ascertained the accuracy of projections.

RESULTS: Extrapolation methods were defended based on their flexibility to address the complex pattern of survival expected with IO treatments. Two studies validated earlier extrapolation methods by comparing with later data cuts with longer patient follow-up. Alternative methods of partitioning patients (e.g., by response) were shown to be accurate within 1% of the observed data yet provided substantially different long-term estimates. Flexible spline-based models, which were validated using clinician opinion in addition to statistical fit criteria, provided a better fit to the data vs. traditional parametric approaches (24-month survival estimated within 2% vs. 4%).

CONCLUSIONS: A range of extrapolation methods have been used for IO treatments. Novel approaches adopting a ‘flexible’ method of extrapolation provided a good fit to early and later data, as shown by validation. Appropriate survival extrapolation should be based on a logical selection of methods, which includes assessing statistical fit, exploring subpopulations with high predictive impact, carefully considering clinical expert opinion, and performing interim validation as data matures and provides longer patient follow-up.

SPONSORSHIP: Merck KGaA and Pfizer.
BACKGROUND: Osimertinib (OSI) is a tyrosine kinase inhibitor of epidermal growth factor receptor (EGFR-I). Approved in 2015 for metastatic non-small cell lung cancer (NSCLC) patients who progressed on or after initial EGFR-I therapy. In April 2018, the FDA approved OSI for first line use and the NCCN designated it as the preferred agent. With OSI having a $177,152 annual wholesale acquisition cost, 1.7-fold higher than competitor EGFR-I (cEGFR; erlotinib, gefitinib, afatinib), it’s important to understand real-world OSI uptake and impact on total cost of care (TCC) for value-based contracting and management opportunities.

OBJECTIVE: To describe OSI uptake and compare TCC among first line new start members on OSI vs. cEGFRs.

METHODS: Using integrated medical and pharmacy claims for 15 million commercially insured members with an EGFR-I claim (OSI or cEGFR) were queried from January 2017 through March 2019 (27 months). OSI quarterly member utilization trend was identified. First-line new start was defined as no previous EGFR-I use in prior 6 months and continuous enrollment (CE) required. Members first OSI claim was their index date. TCC defined as all medical and pharmacy claim allowed amounts including member share and inclusive of network discounts were summed by member for the 6 months pre EGFR-I index date and 6 months post index date. Descriptive statistics were used to compare the average member pre and post period TCC for OSI and cEGFR users.

RESULTS: Of 904 members with a claim for an EGFR-I in the 27 months, 692 had CE 6 months pre, and 433 were identified as first line new starts to EGFR-I therapy. OSI accounted for 7.1% (4 of 56) of first line use in 1Q17 as compared to 76.9% (30 of 39) in 1Q19. 251 of 433 (58%) members met the 6-month pre/post continuous enrollment criteria comprising 86 OSI and 165 cEGFR members. Mean TCC for OSI was $74,653 pre and $86,167 post, a 15.4% increase. For OSI, mean TCC increased from $61,825 pre to $121,586 post, a 96.7% increase. Mean TCC post period 6-month was $35,419 higher in the OSI group vs. cEGFR group.

CONCLUSIONS: In this real-world analysis of a large commercially insured population, osimertinib (OSI) first line approval was associated with a 10-fold increase in use to treat NSCLC with 3 of 4 new EGFR-I therapy starts are now with OSI. However, OSI costs are ~$70,000 more annually than cEGFRs and our real world TCC 6-month post initiation findings confirm higher costs at $35,419, equating to over $3 million in additional costs for 86 OSI treated members. These findings provide foundational understanding on OSI TCC for value-based contracting and managed care pharmacy opportunities.

SPONSORSHIP: Prime Therapeutics.
HER2-negative advanced or metastatic breast cancer (mBC). Palbociclib, the first in the class, was approved in 2015, and ribociclib and abemaciclib were approved in 2017.

**OBJECTIVE:** To investigate preferences for CDK4/6i + aromatase inhibitor (AI) treatment attributes among U.S. patients with mBC.

**METHODS:** Patients with mBC (N = 304) were recruited to complete a web-based survey. Using a discrete choice experiment (DCE), patients were presented with a series of choice tasks, including two hypothetical treatment profiles comprised of combinations of levels reflecting different attributes. Attributes included risk of dose reduction due to adverse events (AEs), risk of diarrhea, risk of abdominal pain, need for ECG monitoring, risk of Grade 3/4 neutropenia, regimen, and dosing schedule. Bayesian hierarchical estimation was used to obtain preference weights (range: min -1.16, max 0.99) for each attribute level. A best-worst scaling (BWS) exercise was used to assess relative prioritization of a larger set of 16 treatment attributes.

**RESULTS:** DCE: Patients rated lower risk of diarrhea and Grade 3/4 neutropenia similarly (23% and 24%, respectively) and highest among attributes tested in relative importance for treatment choice. Lowering risk of diarrhea from 81% to 35% was 2.2 times more influential to treatment choice than lowering risk of Grade 3/4 neutropenia from 66% to 60% (weights: 1.58 vs. 0.71). Lowering risk of Grade 3/4 neutropenia from 22% to 60% was 4.2 times more important to treatment choice than lowering risk of dose reduction due to AEs from 43% to 36% (weights: 1.13 vs. 0.27). Lower risk of diarrhea and Grade 3/4 neutropenia were each 2.5 times more important than lower risk of dose reduction due to AEs (25% or 24% vs. 10%). BSW: Lower risk of heart dysfunction and Grade 3/4 neutropenia and real-world efficacy were rated as the top three most important attributes.

**CONCLUSIONS:** DCE results suggested that patients value lower risk of diarrhea and Grade 3/4 neutropenia similarly and perceive them as more important than other attributes tested to their treatment choice. In the BWS exercise, lower risk of heart dysfunction and Grade 3/4 neutropenia and real-world efficacy, were rated as the most important attributes.

**SPONSORSHIP:** Pfizer.

**C22** Longitudinal Evaluation of Characteristics, Treatment Patterns, and Healthcare Resource Utilization Among Patients Using Granulocyte Colony Stimulating Factors: A Study by the Biologics and Biosimilars Collective Intelligence Consortium

**Objective:** To evaluate characteristics and product use patterns in patients treated with GCSFs observed in insurance claims. This analysis was to prepare for a large-scale, real-world, observational GCSF comparative effectiveness research (CER) study using the Biologics & Biosimilars Collective Intelligence Consortium (BBCIC) distributed research network (DRN).

**METHODS:** The budget impact of A+F in PM women with PIK3CA mutated HR+/HER2- ABC from a hypothetical U.S. commercial health plan perspective with one million members was evaluated using an economic model developed in Microsoft Excel. The model compares breast cancer-related healthcare costs over a 3-year period for patients receiving first or second-line therapy for ABC under two scenarios: a Reference Scenario in which A+F is assumed to be unavailable and a New Scenario in which it is assumed to be available. Treatments potentially displaced by A+F include CDK4/6 inhibitors plus aromatase inhibitors (AIs), CDK4/6 inhibitors plus fulvestrant, AIs, fulvestrant, tamoxifen, everolimus plus exemestane, and chemotherapies. The numbers of patients eligible for treatment with A+F were based on published sources. Treatment mix under the reference and new scenarios were based on market research data. Dosages were based on prescribing information. Estimates of duration of treatment for A+F and F were from the SOLAR-1 trial, those for other treatments were based on indirect treatment comparisons using published trial reports. PIK3CA mutation testing, medications, administration and dispensing, and follow-up and monitoring costs were from published sources.

**RESULTS:** In a hypothetical population of one million commercially insured members, 104 patients were estimated to become eligible for treatment with A+F over a 3-year period; a total of 27 patients were projected to receive such treatment. Cumulative costs of ABC-related care for eligible patients were estimated to be $7.0 million in the Reference Scenario and $7.4 million in the New Scenario. Total budget impact of A+F over 3 years was an increase of $475 thousand overall and $0.013 on a per-member-per-month basis.

**Conclusions:** For U.S. commercial health plans, the budget impact of A+F treatment for ABC is likely to be relatively modest and within the range of published estimates for oncology therapies. These results may assist payers in making coverage decisions regarding the use of A+F in ABC.

**SPONSORSHIP:** Novartis.

**Background:** Breast cancer is the second leading cause of cancer deaths among women in the U.S. Alpelisib is a frequently FDA-approved therapy targeting postmenopausal women (PM) with PIK3CA mutated HR+/HER2- advanced breast cancer (ABC). There is a need to evaluate its budget impact on U.S. commercial payers.

**Objective:** To evaluate the budget impact of alpelisib plus fulvestrant (A+F) in PM women with PIK3CA mutated HR+/HER2- ABC from a U.S. commercial payer perspective.
METHODS: Adults treated with any GCSF from 1/1/2012 to 6/30/2018 were included. A distributed query using FDA Sentinel analytic tools was developed to capture characteristics of patients receiving GCSF treatment or prophylaxis for febrile neutropenia. Data were aggregated from five research partners in the BBCIC DRN.

RESULTS: Over 36 million eligible health plan members representing over 81 million person-years of data were evaluated. 29,992 filgrastim, 4,686 tbo-filgrastim, and 4,743 filgrastim-sndz incident users were identified. Patients were similar across groups in age (59.9 years for filgrastim, 60.4 for tbo-filgrastim, 59.8 for filgrastim-sndz) and sex, (females accounted for 58.3% filgrastim, 58.6% tbo-filgrastim, and 61.3% filgrastim-sndz). Total use of all filgrastim products remained consistent at about 6,900 users annually, however, use of filgrastim decreased to less than 45% of all incident users in 2017 in favor of increased use of filgrastim-sndz (35.7%) and tbo-filgrastim (19.5%). Utilization of filgrastim decreased from 6,261 users in 2014 to 2,980 in 2017, while tbo-filgrastim utilization increased from 644 users in 2014 to 1,298 in 2017, and filgrastim-sndz utilization increased from 40 users in 2015 to 2,378 in 2017. Of filgrastim-sndz incident users, 556 (11.4%) had a recorded history of filgrastim use, while 254 (0.85%) of incident filgrastim users had a history of filgrastim-sndz use.

CONCLUSIONS: This systematic, longitudinal surveillance on GCSF utilization patterns in the U.S. showed that new users of biosimilars increased over time while the overall number of new users remained flat. Switching to a biosimilar from the reference product was observed in some patients, though the reason for switching is not available in claims data. This analysis suggests availability of adequate sample size and similar patient populations to conduct a CER study in GCSFs in the BBCIC DRN.

SPONSORSHIP: Biologics and Biosimilars Collective Intelligence Consortium.

C24 Team HPV: Cancer Free! Implementing a Multimodal Approach to Increase HPV Vaccination Rates in the Ambulatory Setting—Phase I

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BACKGROUND: Nearly 80 million Americans are infected with the Human Papillomavirus (HPV). HPV is thought to be responsible for more than 90% of anal and cervical cancers, 70% of oropharyngeal cancers, 70% of vaginal and vulvar cancers, and 60% of penile cancers. HPV vaccination provides safe, effective, and lasting protection against the HPV infections that most commonly cause cancer. The CDC’s Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination at age 11 or 12. HPV vaccination has decreased uptake due to parents’ perception and lack of education provided about the vaccine.

OBJECTIVE: Our scope: 11 and 12 year old boys and girls seen for a primary care well child visit (designated sites and physicians) documented in EPIC during the measurement period. At baseline, 32.5% of children received the HPV vaccine. Our goal: increase HPV vaccination from 32.5% to 40% by 2/18/19.

METHODS: A review of commercial insurance claims data revealed low HPV immunization rates in patients 13 and younger. Reviewing literature studies identified beliefs and reasons for low HPV vaccination. Studies also show a strong provider recommendation is proven to increase vaccination rates. Individual provider immunization rates were measured to increase awareness, accountability, and track best practices. Physician and staff education was provided discussing HPV
Healthcare Resource Use and Costs Associated with Metastatic Castration-Sensitive Prostate Cancer in Medicare Advantage and Commercially Insured Patients in the United States

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BACKGROUND: Despite recent changes in the metastatic castration sensitive prostate cancer (mCSPC) treatment landscape, real-world studies evaluating healthcare resource use (HRU) and economic outcomes of mCSPC patients remain scarce.

OBJECTIVE: To assess HRU and total health plan paid (HPP) costs in U.S. Medicare Advantage (MA) and commercially-insured (COM) mCSPC patients.

METHODS: Men with ≥2 claims for prostate cancer (PC), ≥1 claim for metastasis, ≥1 castration sensitivity (CS) indicator (CS diagnosis code [dx]; castration and no prostate-specific antigen [PSA] rise; or hormone/castration naive for ≥18 months before index [date of 1st metastasis dx on or after 1st PC dx]) were identified in Optum Clininformatics Extended DataMart (01/01/2014-06/30/2018). Patients were excluded if they had any pre-index castration-resistance (CR) indicator (CR dx; castration with PSA rise; or a claim for any drug solely recommended for metastatic CRPC [mCRPC]). Progression to mCRPC was identified if patients had (1) any post-index CR indicator including a claim for any drug solely recommended for mCRPC or (2) initiation of a drug approved for both mCSPC and mCRPC (abiraterone/docetaxel) but only if initiation occurred ≥12 months after post-index androgen deprivation therapy (ADT) initiation or ≥12 months post-index for those without evidence of ADT to avoid including patients who received the two therapies for mCSPC as being defined as mCRPC.

RESULTS: Of 3,395 patients who progressed to mCRPC (MA: 15%; COM: 13%), the mean [SD] PPPY total HPP cost was $151,587 [$260,444; $87,718] for MA and $162,384 [$208,552; $85,611] for COM before and after CR. In the 483 (14%) patients who progressed to mCRPC (MA: 15%; COM: 13%), the mean [SD; median] PPPY total HPP cost was $151,587 [$260,444; $87,718] for MA and $162,384 [$208,552; $85,611] for COM before and after CR. In the 485 (14%) patients who progressed to mCRPC (MA: 15%; COM: 13%), the mean [SD; median] PPPY total HPP cost was $151,587 [$260,444; $87,718] for MA and $162,384 [$208,552; $85,611] for COM before and after CR.

CONCLUSIONS: Patients with mCSPC covered by MA or COM plans incurred significant HRU and costs both before and after CR. These results provide new and important insights for population health decision-makers about the overall disease burden of U.S. patients with mCSPC.

SPONSORSHIP: Janssen Scientific Affairs.
(66%) patients had a subsequent medical oncologist visit. Median time from first urologist visit to medical oncologist visit was longer for M0 (114 d) than M1 (87 d) patients and median time to medical oncologist visit was 17% shorter for M1 compared to M0 patients (HR: 1.17 [1.00-1.36]). Patients who saw a medical oncologist any time after first urologist visit were more likely to receive chemotherapy compared to those who did not (HR: 2.71 [2.13, 3.47]).

**CONCLUSIONS:** More than half of advanced UC patients initially see a urologist and follow up with a medical oncologist. Metastatic patients follow up with medical oncologists sooner than non-metastatic patients. The findings align with treatment expected in advanced bladder cancer patients.

**SPONSORSHIP:** AstraZeneca.

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**C27 Real-World Burden of Illness and Unmet Need in Locally Advanced or Metastatic Urothelial Carcinoma Following Discontinuation of PD-1/PD-L1 Inhibitor Therapy: A Medicare Claims Database Analysis**

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**BACKGROUND:** Several programmed cell death (PD)-1/PD-ligand-1 inhibitors (PD-1/PD-L1i) are approved for first and second line treatment of locally advanced or metastatic urothelial carcinoma (La/mUC); however, only 13%-21% respond based on clinical trials. Data describing real-world treatment patterns and healthcare resource utilization (HRU) in La/mUC patients (pts) post-PD-1/PD-L1i discontinuation are limited.

**OBJECTIVE:** To evaluate treatment patterns, HRU, and costs among Medicare Fee-for-Service (FFS) beneficiaries with La/mUC who discontinue PD-1/PD-L1i.

**METHODS:** The 100% sample of Medicare FFS claims (Parts A/B/D) was used to identify pts aged ≥ 65 y with ≥ 1 inpatient or ≥ 2 outpatient diagnosis claims for bladder cancer from 2015-2017 who initiated and subsequently discontinued PD-1/PD-L1i (index=discontinuation date). To identify the La/mUC population, pts must have received systemic therapy and no surgery or other therapies indicative of earlier stage disease. At least 12 months prior and 3 months post-index continuous Medicare enrollment was required. Pts were followed until enrollment, death, or data cut off.

**RESULTS:** Among 28,063 pts included in the La/mUC cohort, 6.2% (n = 1,726), 8.8% (n = 2,469), and 1.6% (n = 457) received PD-1/PD-L1i as 1st, 2nd or 3rd line of therapy (LoT). Of these, 791 (17%) discontinued or switched PD-1/PD-L1i and met other inclusion criteria; the majority of other pts were lost to follow-up or died. Discontinued pts were mostly male (73%) with median age 76 y and multiple comorbidities (Charlson Comorbidity Index 10.66). Following discontinuation, 3% (n = 26) received a different PD-1/PD-L1i, 46% (n = 361) chemotherapy, and 51% (n = 404) no further systemic treatment. HRU was high during follow-up: 97% (n = 770) of discontinued pts had ≥ 1 outpatient visit and 52% (n = 408) ≥ 1 hospitalization (mean length of stay 11 days); 33.5% (n = 265) advanced to hospice care. Total all-cause healthcare costs per-person-per-month were $7,153 pre-index and $7,745 (adjusted) post-index; cost of systemic therapy was higher pre- vs. post-index ($2,978 vs. $1,195) but other costs were higher post-index: outpatient ($1,437 pre vs. $2,064 post), hospitalization ($1,120 vs. $2,200), and skilled nursing facility ($106 vs. $384). Costs did not differ by PD-1/PD-L1i LoT.

**CONCLUSIONS:** Over half of La/mUC pts who discontinued PD-1/ PD-L1i received no further treatment. Pts who discontinued PD-1/PD-L1i had intensive HRU during follow-up regardless of whether post PD1/ PD-L1i treatment was administered, demonstrating a need for effective therapies that reduce disease burden for this population.

**SPONSORSHIP:** Seattle Genetics and Astellas.

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**C28 Budget Impact of Introducing Avelumab as a Treatment for Genitourinary Cancers, Including First-Line Treatment for Advanced Renal Cell Carcinoma and Second-Line Treatment for Locally Advanced Metastatic Urothelial Cancer in the United States**

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**BACKGROUND:** Avelumab (Ave), a fully human monoclonal antibody directed against the PD-L1 molecule, in combination with axitinib (Ave+AXI) showed significantly longer progression-free survival and a promising overall response rate compared with sunitinib for the first-line (1L) treatment (Tx) of advanced renal cell carcinoma (aRCC). In addition, Ave has shown durable responses in the second-line (2L) setting in patients with metastatic urothelial cancer (mUC) who had disease progression during or following platinum-containing chemotherapy.

**OBJECTIVE:** To estimate the budget impact of adding Ave Tx for genitourinary (GU) cancers, consisting of Ave + AXI as 1L Tx for aRCC and Ave as 2L Tx for mUC, to a commercial health plan in the U.S.

**METHODS:** An economic model was developed to estimate the budget impact of adding Ave to a commercial health plan of 1,000,000 members over 3 years. Number of eligible patients, Tx duration (for estimating drug, administration, and adverse event [AE] costs), and risks of AEs were sourced from published epidemiological data, clinical trials, and U.S. package inserts. Drug costs (2019 $US) were based on wholesale acquisition cost. Costs considered in the analysis included drug, administration, monitoring, and AE management costs. Tx in the current market mix (i.e., without Ave) for mUC included atezolizumab, nivolumab, pembrolizumab, and chemotherapy; and for aRCC included nivolumab + ipilimumab, pazopanib, sunitinib, cabozantinib, AXI, high-dose interleukin 2, and temsirolimus. The projected uptake of Ave in the revised market mix in years 1-3 was 1.7%, 1.2%, and 1.0%, respectively, for mUC and 3.4%, 7.3%, and 8.4%, respectively, for aRCC.

**RESULTS:** Over 3 years, 230 patients with aRCC and 37 patients with mUC were estimated to be eligible for Ave Introduction of Ave + AXI in aRCC and Ave in mUC was estimated to increase the total budget for GU cancers by 4.98% over 3 years. Total cost per member per month (PMPM) increased by $0.03 in year 1, $0.06 in year 2, and $0.08 in year 3. Weighted average total cost per eligible patient per month (PPPM) prior to and after the introduction of Ave + AXI (or Ave) was $12,302 and $13,496, respectively.
CONCLUSIONS: Ave can be an affordable and beneficial treatment option for aRCC in the 1L setting (when used in combination with AXI) and mUC in 2L setting. The adoption of Ave in indicated GU cancers will have a modest budget impact over U.S. commercial health plans.

SPONSORSHIP: EMD Serono and Pfizer.

C29 Budget Impact of Entrectinib in NTRK-Positive Solid Tumors in the United States
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BACKGROUND: Entrectinib is an experimental cancer therapy being investigated for use in ROS1 + NSCLC and NTRK + solid tumors.

OBJECTIVE: To estimate the potential budget impact of adding entrectinib to formulary for NTRK+ patients across all solid tumors in a hypothetical one million-member plan.

METHODS: A budget impact model was developed from a U.S. health plan perspective and a 3-year time horizon. The base case scenario estimated the number of patients eligible for treatment and the per member per month (PMPM) cost in a hypothetical plan of all ages. The population eligible for treatment was estimated based on incidence rates, expected treatments in each line of therapy (LOT) for all relevant solid tumors, projected NTRK testing rates over time, and NTRK positivity rates. Comparators in the model included larotrectinib and a standard of care (SOC) arm comprised of select treatments weighted by the distribution of estimated eligible population across tumor types. Costs included drug (wholesale acquisition costs or average sales price), administration and biomarker testing costs. Scenario analyses included estimating eligible patients across all LOTs versus select LOTs in the base case, PMPM in 1-million member commercial versus Medicare aged populations, and the impact of increased biomarker testing. One-way sensitivity analyses were conducted on key inputs.

RESULTS: In a million-member plan, the base case model estimated 2 patients eligible for treatment in the 1st year, with up to 3 patients by year 3 due to the projected increase in testing. When including all LOTs, the estimated number of eligible patients rose to 4 patients in the 1st year and up to 6 patients in the 3rd year. The model projected total cost savings in years 1-3 of $1,300, $8,300 and $10,900, respectively, which equates to an overall PMPM across the first 3 years of -$0.001. The estimated number of patients in years 1 to 3 in a Medicare aged population ranged from 9 to 11, while a commercial population ranged from 1 to 2. The estimated PMPM in both of these populations was less than -$0.001. In the scenario where testing rates increased by 25% with the launch of entrectinib, this resulted in a net increase of $228,700 and a PMPM of $0.01. One-way sensitivity analyses demonstrated the results to be robust with PMPM ranging from $0.00 to >$-0.01.

CONCLUSIONS: Adding entrectinib to formulary for NTRK+ solid tumors is expected to have minimal budget impact, including scenarios in which testing rates increases.

SPONSORSHIP: Genentech.
Comparison of Healthcare Resource Utilization and Total Direct Costs for Chronic Lymphocytic Leukemia Patients Treated with Ibrutinib or Chemoimmunotherapy

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Background: Ibrutinib (ibr), a first-in-class, once-daily inhibitor of BTK, is the only approved BTK inhibitor for chronic lymphocytic leukemia (CLL). Chemoimmunotherapy (CIT) was the previous standard of care for CLL. This study assessed real-world healthcare resource utilization (HRU) and total direct cost of care (medical and pharmacy) in patients with CLL treated with ibr vs CIT.

Objective: To compare all-cause HRU and total costs between single-agent ibr and CIT in first-line (1L) and second-line (2L) patients with CLL in the U.S.

Methods: Adult patients with newly diagnosed (index) CLL were identified using IBM MarketScan Commercial Database starting from the earliest ibr approval date for CLL of 2/12/2014 to 12/31/2017. Patients had 12 months of continuous eligibility before index date and no pre-index evidence of other primary malignancies, antineoplastic agents, or hematopoietic stem-cell transplantation. Baseline demographic and clinical characteristics, differences in mean per patient per month (PPPM) all-cause HRU, and mean monthly cost differences were compared for ibr and CIT patients in 1L and 2L. Adjusted analyses (for baseline characteristics) were also conducted.

Results: In ibr-treated (1L: n = 107; 2L: n = 44) and CIT-treated (1L: n = 326; 2L: n = 18) patients, mean follow-up times were 653 and 622 days, respectively. Both ibr and CIT cohorts had comparable baseline characteristics across treatment lines. Ibrutinib-treated 1L patients had less than half the number of outpatient service visits compared with CIT-treated 1L patients (3.5 vs. 7.5 PPPM, P < 0.001) due to fewer other outpatient services including antineoplastic drug-administration-related visits (2.8 vs. 6.9 PPPM, P < 0.001), resulting in a net monthly outpatient cost decrease of $32,978 (P < 0.001) compared to CIT patients. Similarly, net outpatient costs were significantly lower for ibr compared with CIT in 2L (-$47,019, P = 0.024). Despite higher pharmacy costs (1L: +$12,208; 2L: +$10,787), ibr patients had lower overall net monthly total direct cost (1L: -$34,726, P = 0.092) compared with CIT patients. Adjusted analyses and CLL-specific HRU/costs were similar (lower for ibr) across treatment lines.

Conclusions: Ibr was associated with lower HRU and total direct costs compared to CIT in patients with 1L CLL. Lower medical costs fully offset higher ibr pharmacy costs, mainly driven by outpatient cost differentials resulting in net total direct cost reduction compared with CIT. 2L, adjusted analyses, and CLL-specific outcomes trended similarly.

Sponsorship: Pharmacyclics.

Real-World Evidence of Ibrutinib Use Among Patients with Chronic Lymphocytic Leukemia and/or Small Lymphocytic Lymphoma in the U.S. Veterans Health Administration Population

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Background: Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) is the most common adult leukemia, accounting for ~37% of all leukemias in the United States. Limited real-world evidence is available on the outcomes of ibrutinib use among previously untreated patients in the U.S. Veterans Health Administration (VHA) population diagnosed with CLL/SLL.

Objective: To evaluate time to next treatment (TTNT), healthcare resource utilization (HRU) and costs among patients with CLL/SLL, who initiated first-line (1L) single-agent ibrutinib vs. chemoimmunotherapy (CIT).

Methods: Adults with ≥2 claims for CLL/SLL and ≥1 claim for ibrutinib or CIT (index date = first prescription [Rx] claim date) after CLL/SLL diagnosis from the VHA population (01APR2013-31MAR2018) were included. Continuous enrollment (CE) for ≥12 months pre- and ≥30 days post-index was required. The 1L therapy included agents prescribed within 30 days of the index date through the earliest of addition or subtraction of any agent to the index regimen, initiation of a non-index regimen, or resumption of index regimen after >90-day gap or death/CE end/study end. Kaplan-Meier (KM) and Cox proportional hazards models were used to estimate TTNT (index date to 2L initiation), the generalized linear models were used to determine all-cause per patient per month (PPPM) HRU and costs (during 1L) for propensity score-matched (PSM) ibrutinib and CIT cohorts.

Results: Among the eligible CLL/SLL patients, 787 initiated single-agent ibrutinib, and 1,039 initiated 1L CIT. Most common CIT regimens included bendamustine + rituximab (597), fludarabine + cyclophosphamide + rituximab (150), and chlorambucil + obinutuzumab (94). After PSM, 614 patients were included in each cohort and were well balanced based on baseline characteristics. Ibrutinib patients had significantly longer TTNT (from KM curve: at 36 months post-index, 65.4% of ibrutinib patients did not initiate a new treatment compared to 45.9% CIT patients; log-rank P < 0.001) and less likely to initiate a 2L (hazard ratio = 0.52; 95% confidence interval [CI] = 0.42, 0.65; P < 0.001) vs. CIT patients. Ibrutinib patients had significantly fewer outpatient visits (rate ratio [RR] = 0.38, 95% CI = 0.28, 0.52; P ≤ 0.05) and outpatient visits PPPM (RR = 0.72, 95% CI = 0.68, 0.77; P ≤ 0.05), and a significant monthly medical cost savings ($7,308, 95% CI = -$9,892, -$4,895; P ≤ 0.05) compared with CIT.

Conclusions: Our findings demonstrate that 1L treatment with ibrutinib was associated with longer TTNT and lower HRU and medical costs compared to CIT.

Sponsorship: Janssen Scientific Affairs.
Hospitalization cost associated with neurologic consciousness (n = 525), and aphasia (n = 500). (n = 635), delirium (n = 560), mental status changes/depressed level of activity, diplegia, cerebral edema, aphasia, peripheral neuropathy, and cerebral edema (all between 7 and 9 days). The highest inpatient cost was for agitation/restlessness (mean $70,891, median $18,155), and cerebral edema (mean $48,457, median $26,437). Seizure, abnormal motor activity and delirium had the longest LOS (median 27 days, range 20-30) followed by delirium (mean $50,534, median $30,726) and encephalopathy (mean $48,457, median $26,437). Seizure, abnormal motor activity, diplegia, cerebral edema, aphasia, peripheral neuropathy, somnolence, and disturbance in attention were associated with mean costs of $10,459 to $40,377 (median $10,168 to $17,367). Neurologic conditions of interest that occurred in ≥50% of hospitalizations were: encephalopathy (n = 3,575), followed by headache (n = 1,465), cerebral edema (n = 1,460), confusional state/dysorientation (n = 690), syncope (n = 635), delirium (n = 560), mental status changes/depressed level of consciousness (n = 525), and aphasia (n = 500).

CONCLUSIONS: Hospitalization cost associated with neurologic conditions vary and may be substantial. Studies using patient-level databases are warranted to confirm the study results. The NIS does not contain treatment information. Therefore the relationship between treatments and neurologic SAES could not be confirmed.

SPONSORSHIP: Novartis Pharmaceuticals.

Patient-Reported Outcomes in Patients with HER2-Advanced Breast Cancer and a Germline BRCA1/2 Mutation Receiving Talazoparib Versus Physician’s Choice Chemotherapy: A Focus on EMBRACA Age Subgroups

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BACKGROUND: FLT3 mutations are common in acute myeloid leukemia (AML) and are associated with poor prognosis. Limited effective therapy options exist for patients with relapsed/refractory (R/R) FLT3 mutation-positive (FLT3mut+) AML. Gilteritinib, a FLT3 inhibitor, was approved by the FDA in November 2018 for the treatment of R/R FLT3mut+ AML.

OBJECTIVE: To assess the budget impact of including gilteritinib in a U.S. health plan for treating R/R FLT3mut+ AML patients.

METHODS: A model was developed to estimate the 3-year budget impact associated with the introduction of gilteritinib for adult patients with R/R FLT3mut+ AML in a hypothetical U.S. plan with 1 million members. The total health care costs were estimated under two scenarios: before and after gilteritinib entry. The number of patients with R/R FLT3mut+ AML was estimated using epidemiologic data. In addition to gilteritinib, the model considered 11 commonly used regimens for treatment of R/R FLT3mut+ AML, including 3 less intensive regimens (e.g., mitoxantrone, etoposide, and cytarabine combination), midostaurin, venetoclax combination, sorafenib and azacitidine combination, and best supportive care. The market shares of these treatments before and after gilteritinib entry were estimated from market research data, which reflects the anticipated market uptake of gilteritinib and other newers agents. The model considered the costs of treatment and its administration, hospitalization, monitoring, adverse events, blood and platelet transfusions, subsequent stem cell transplantation, medical services, and FLT3 testing. Drug costs were obtained from Redbook. Unit costs were from the CMS Fee Schedule and literature. The incremental total budget impact and per-member-per-month (PMPM) cost (2018 USD) were calculated, comparing the scenarios before vs. after gilteritinib entry. One-way sensitivity analysis was performed.

RESULTS: The model estimated 21 R/R FLT3mut+ AML patients in a 1-million-member health plan. The market share of gilteritinib was predicted to increase from 30% in year 1 to 45% in year 3 following entry. The estimated annual increase in the total budget was $637,953, $1,035,687, and $1,043,930 from year 1 to year 3, respectively. The corresponding incremental PMPM was $0.053, $0.086, and $0.087, respectively. The model results remained robust in sensitivity analyses.

CONCLUSIONS: Adding gilteritinib to the formulary for the treatment of adult patients with R/R FLT3mut+ AML had a small budget impact on the U.S. payer.

SPONSORSHIP: Astellas.
chemotherapy (PCT) were observed in both HER2- germline BRCA1/2 mutation (gBRCAm) advanced breast cancer (ABC) age subgroups: patients (pts) < 50 yr and ≥ 50 yr old.

**OBJECTIVE:** These post hoc analyses evaluated patient-reported outcomes (PRO).

**METHODS:** PRO was assessed at baseline (day 1), at start of each treatment cycle (every 3 weeks), and end of treatment, using the EORTC QLQ-C30 and breast cancer module QLQ-BR23. Higher scores indicate better functioning/global health status (GHS/QoL) or worse symptom severity. PRO analyses, performed separately in < 50 yr and ≥ 50 yr age subgroups, for GHS/QoL, functional and symptom scales include: Overall mean change from baseline (per longitudinal repeated measures mixed-effects model) and time to definitive clinically meaningful deterioration (TTD) (per survival analysis methods). Between-arm comparisons of TTD were made using stratified log-rank test and Cox proportional hazards model.

**RESULTS:** Baseline scores were similar between arms. A statistically significant estimated overall change from baseline in GHS/QoL favored TALA vs PCT for both < 50 yr (6.2 [95% CI: (0.9, 11.5)] P = 0.023) and ≥ 50 yr (9.1 [95% CI: (3.3, 15.0)] P = 0.002) age subgroups. A statistically significant estimated overall change from baseline in patient reported pain symptoms favored TALA vs PCT for both < 50 yr (-11.5 [95% CI: (-19.1, -3.8)] P = 0.003) and ≥ 50 yr (-12.7 [95% CI: (-20.2, -5.3)] P < 0.001) age subgroups. A statistically significant delay in TTD favoring TALA was observed in GHS/QoL for both < 50 yr [median: 24.3 vs 10.3 mos, HR = 0.45 (95% CI: 0.25, 0.80); P = 0.006] and ≥ 50 yr [median: 21.1 vs 6.0 mos, HR = 0.36 (95% CI: 0.21, 0.62); P < 0.001] age subgroups. A statistically significant delay in TTD favoring TALA was observed in patient reported pain symptoms for both < 50 yr [median: 22.7 vs 5.8 mos, HR = 0.32 (95% CI: 0.18, 0.56); P < 0.001] and ≥ 50 yr [median: 21.8 vs 10.3 mos, HR = 0.37 (95% CI: 0.20, 0.69); P = 0.001] age subgroups. When comparing between arms, none of the analyses in either the < 50 yr and ≥ 50 yr age subgroups yielded statistically significant PRO results favoring the PCT.

**CONCLUSIONS:** In pts with HER2- ABC, TALA (vs PCT) resulted in significantly better change from baseline and significantly delayed TTD in GHS/QoL and patient reported pain symptoms in both < 50 yr and ≥ 50 yr age subgroups; none of the analyses significantly favored the PCT. These results further support the positive risk–benefit profile of TALA vs PCT in pts < 50 yr and ≥ 50 yr old with HER2- ABC and gBRCAm.

**SPONSORSHIP:** Pfizer.

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**Burden of Heavy Menstrual Bleeding Associated with Uterine Fibroids: A Retrospective Analysis of a Large Commercially Insured Population in the U.S.**

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**BACKGROUND:** Heavy menstrual bleeding (HMB) is one of the most common and bothersome symptoms among women with symptomatic uterine fibroids (UFs). While previous research has examined the economic burden associated with HMB or UF, there is limited published data on the financial burden associated with both UF and HMB.

**OBJECTIVE:** To characterize the financial burden on caregivers of PwP who experience OFF periods compared to those who do not.

**METHODS:** Data were analyzed from a survey, “Financial and Social Impact of Parkinson’s Disease” (September 17, 2018–October 8, 2018), developed by The Michael J. Fox Foundation for Parkinson’s Research and the Parkinson’s Foundation. One survey per household was completed voluntarily online by the PwP, care partner, family member, or close friend of the PwP. Data from respondents who reported experiencing OFF periods in the past 12 months were compared to data from those who reported no OFF periods.

**RESULTS:** 4,548 respondents completed the survey. 65% of respondents reported PwP experiencing OFF periods, 27% reported not experiencing OFF, and 8% reported they didn’t know. Average disease duration for patients reporting OFF was 8.2 years vs 5.6 years for those not experiencing OFF. 69% of PwP with OFF had a primary caregiver vs 54% of PwP reporting no OFF. 24% PwP with OFF had an additional secondary caregiver vs 12% of those without OFF. Primary and secondary caregivers spent a combined 38 hours/week caring for PwPs with OFF vs. 28 hours for PwPs with no OFF. 33% of primary and 69% of secondary caregivers to PwP were otherwise employed. 27% of all caregivers caring for PwPs with OFF said that PD played a major role in their decision to stop working vs 17% of those caring for PwPs with no OFF. 42% of all caregivers of PwPs with OFF responded that they had reduced or changed their working hours, had lost opportunities, or were unable to keep a job for reasons related to PD vs 30% for caregivers of PwPs with no OFF. Caregivers for PwPs with OFF periods reported an average annual loss of employment income of $22,221 compared to $8,711 for caregivers of PwPs with no OFF.

**CONCLUSIONS:** Caregivers of PwPs experiencing OFF periods reported that their financial burden had increased, and they were spending more hours in a typical week giving care compared to caregivers of PwPs without OFF periods. These findings suggest that greater consideration of the financial burden on caregivers needs to be given when organizing and planning for PD care in healthcare systems.

**SPONSORSHIP:** Acorda Therapeutics.
were grouped into four cohorts based upon diagnosis: (a) HMB only (ICD-9-CM 626.2 or 627.0, or ICD-10-CM N92.0, N92.1 or N92.4), (b) UF only (ICD-9 218.x or ICD-10 D25.x), (c) UF and HMB, and (d) controls. Baseline patient characteristics and treatment type (medication, surgical/procedure, or no treatment) in the 12 months post initial diagnosis were examined descriptively for each cohort. Multivariable analyses controlling for age, region, insurance type, total baseline healthcare costs, and the Charlson Comorbidity Index were utilized to compare all-cause total healthcare costs (inpatient and outpatient visits, surgeries, ER visits and pharmacy) during the 12 months post diagnosis between the combined UF and HMB group versus each of the other cohorts.

RESULTS: The study population included 1,149,007 women diagnosed with UF and/or HMB, and 2,244,368 controls. Among women diagnosed with UF, 54.1% were also diagnosed with HMB; and of those who are diagnosed with HMB, 31.3% were also diagnosed with UF. During the 12 months post diagnosis, 33.4% of women diagnosed with both UF and HMB received no treatment, 25.3% were treated with a surgery or procedure without medication use, 15.5% were treated with medications only, and 25.7% were treated both medications and a surgery or procedure. In the same time period, mean [SD] all-cause total healthcare costs in the combined UF and HMB cohort ($17,505 [$27,642]) were significantly higher compared to costs for women with UF only ($14,803 [$32,097]), HMB only ($10,522 [$24,912]), or controls ($5,880 [$19,708]; all P < 0.05).

CONCLUSIONS: Among women diagnosed with both UF and HMB, mean all-cause total healthcare costs were significantly higher than costs for women with UF only, HMB only, and controls.

SPONSORSHIP: AbbVie.

Elagolix Reduces Productivity Losses in Uterine Fibroids Patients with Heavy Menstrual Bleeding: Evidence from Pivotal Trials

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BACKGROUND: Uterine fibroids (UF), or leiomyomas, are one of the most common benign tumors in women of reproductive age. Heavy menstrual bleeding (HMB) is one of the most common and bothersome symptoms among women with symptomatic UF. Previous research reported substantial impact of symptomatic UF on work productivity among pre-menopausal women. The impact of elagolix, an oral gonadotropin-releasing hormone antagonist, on work productivity loss trials was studied in two pivotal in women with UF associated with HMB.

OBJECTIVE: To examine the impact of elagolix, an oral gonadotropin-releasing hormone antagonist, on workplace productivity in symptomatic UF patients with HMB.

METHODS: Women aged 18 to 51 with HMB (>80 mL menstrual blood loss per cycle) associated with UF were enrolled in two replicate 6-month phase III placebo-controlled randomized clinical trials (Elaris UF-1, Elaris UF-2). Women were randomized in 1:1:2 ratio to placebo, elagolix 300 mg twice daily (BID) and elagolix 300 mg BID in combination with 1 mg estradiol (E2/0.5 mg norethindrone acetate (NETA) daily add-back therapy (E2/NETA). Symptom-related workplace productivity hours lost to absenteeism (percent work time missed) and presenteeism (percent impairment while working) were measured at baseline and month 6 using the Questionnaire for Work Productivity and Activity Impairment associated with UF (WPAI-UF). Changes from baseline were compared between both elagolix arms and placebo with analysis of covariance, controlling for baseline absenteeism and presenteeism, respectively.

RESULTS: In Elaris UF-1, 102, 104, 206 patients were randomized to placebo, elagolix BID and elagolix BID + E2/NETA, respectively. Mean age at baseline was 42 years. At month 6, larger reductions in least-squared (LS) mean percent work time lost due to absenteeism were observed for elagolix 300 mg BID and elagolix 300 mg BID + E2/NETA (LS means: -8.6, and -6.9 hours, respectively) compared to placebo (LS means: -4.9 hours). Reductions in LS mean percent work time lost due to presenteeism were greater for elagolix 300 mg BID and elagolix 300 mg BID + E2/NETA (LS Means: -41.7, and -34.5 hours, respectively) than placebo (LS means: -19.0 hours); P value was < 0.01 in both elagolix 300 mg BID and elagolix 300 mg BID + E2/NETA arms. Similar results were observed in Elaris UF-2.

CONCLUSIONS: Elagolix with add back reduces UF-related work productivity loss in women with HMB associated with UF.

SPONSORSHIP: AbbVie.


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BACKGROUND: As a field, hematology/oncology (hem/onc) is continually evolving; therapeutic advances often involve novel therapeutic strategies or completely new disease aspects (e.g., precision medicine). Additionally, hem/onc clinical guidelines often differ substantially from real-world clinical practice, which may also vary by geographic location. Cost is also a substantial consideration. Given the nuances in this therapeutic area, oncology-trained team members who possess the expertise necessary to navigate this dynamic field are poised to make significant contributions to understanding novel oncology products.

OBJECTIVE: To describe the role and value of oncology-trained pharmacists in communicating the clinical and economic value of hem/onc products and identifying gaps in market access strategy.

METHODS: A team of oncology board-certified and residency-trained pharmacists consult with pharmaceutical manufacturers to develop market access strategies for novel therapies with distinctive barriers to patient access. A team of oncology board-certified and residency-trained pharmacists consult with pharmaceutical manufacturers to develop market access strategies for novel therapies with distinctive barriers to access, both in the U.S. and European Union (EU). Herein we present 2 cases of novel oncology products with multiple barriers to patient access.

RESULTS: The first case involved a high cost cellular and gene therapy product for an oncologic indication with early phase data seeking market access after Food and Drug Administration (FDA) approval. This was a first-in-class product for the indication with no previously FDA-approved therapies, thus a specialized approach incorporating real-world clinical practice and guideline recommendations was used to convey the unmet need of the disease state to ensure successful market access.
patient access. The second case involved a biomarker-based therapy studied in a unique clinical trial design seeking market access for a rare cancer. One of the multiple barriers to access associated with this product was the need to identify a novel biomarker-defined patient population spreading across a multitude of histologic subtypes of cancer. Both of these case studies demonstrate complex market access issues that often arise in the oncology space, including clinical value, cost, and identification of the appropriate patient population. The market access strategy for each case will be presented.

CONCLUSIONS: The insights provided by our oncology-trained pharmacist team has allowed for the development of a market access strategy that overcomes barriers to access and facilitates an understanding of the value of these novel oncology products among U.S. payers and/or health technology assessments (HTAs).

SPONSORSHIP: Xcenda.

D5 Enrollment Patterns Among New Jersey Medicaid Patients with Sickle Cell Disease

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BACKGROUND: Sickle cell disease (SCD) is a genetic disease characterized by hemolysis and anemia. SCD is debilitating, and many patients suffer from multiple downstream complications and end-organ damage such as stroke, kidney dysfunction, and pulmonary hypertension. The substantial morbidity of SCD makes maintaining employment challenging; consequently, a high proportion of SCD patients are insured through Medicaid. Medicaid enrollment and SCD prevalence are high in New Jersey (NJ) relative to other states.

OBJECTIVE: To better understand the burden of SCD on Medicaid, this study aims to evaluate the enrollment patterns of patients with SCD insured through NJ Medicaid.

METHODS: We identified patients with SCD (≥3 nondiagnostic SCD claims on different days within 5 years) enrolled in Medicaid between 1/1/2008 and 12/31/2017 in the MarketScan Medicaid Multi-State Database. Patient age distribution, proportion of pediatric patients returning to the same state Medicaid program in adulthood, and duration of enrollment (DOE) were summarized descriptively. Analyses were stratified by de-identified state and age subgroups. An enrollment gap >60 days was considered as discontinuation. Total enrollment (TE) includes re-enrollment after discontinuation.

RESULTS: A total of 23,122 patients with SCD on Medicaid were identified across 15 states, with 5 states contributing 91.0% of patients. In 2017, 55.6% (state-level range 50.8-61.7%) of these patients were adults. Of patients aged 6-11 years upon first SCD diagnosis, 75.8% (50.6-100.0%) remained on the same-state Medicaid program after turning 18, and 90.5% (87.1-96.1%) aged 12-17 years remained on same-state Medicaid. The median duration of TE was 5.4 (4.7-7.7) years, whereby 71.6% of patients had TE ≥3 years, 52.9% had TE ≥5 years, and 28.2% had TE ≥8 years. The median duration of continuous enrollment (CE) was 3.7 (3.3-5.8) years, whereby 59.6% of patients had CE ≥3 years, 41.6% had CE ≥5 years, and 22.5% had CE ≥8 years. Transition-age patients (18-30 years) had the shortest median DOE (TE, 4.9 years; CE, 3.0 years) among all age groups. The majority of patients (59.7%) were continuously enrolled through the end of the study period.

CONCLUSIONS: More than half of patients with SCD on Medicaid in this analysis were adults, and most pediatric patients returned to the same state Medicaid in adulthood. With less than 10 years’ follow up, more than half of SCD patients stayed with the same-state Medicaid plan for more than 5 years, with almost one-third staying for more than 8 years. Medicaid policy decisions regarding SCD management should adopt a long-term perspective to consider the cumulative burden and treatment needs of patients with SCD.

SPONSORSHIP: Global Blood Therapeutics.
D7 Cost-Effectiveness Model of Antihemophilic Factor (Recombinant) Versus Emicizumab Treatment of Patients with Severe Hemophilia A Without Inhibitors

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BACKGROUND: Recombinant factor VIII (FVIII) replacement therapy, including Advate (antihemophilic factor [recombinant] rAHF), Baxalta U.S., a Takeda company, Lexington, MA) is the standard of care for patients with hemophilia A without inhibitors. The treatment landscape is evolving, with non-factor therapy such as Hemlibra (emicizumab; Genentech; South San Francisco, CA) becoming available.

OBJECTIVE: Compare cost-effectiveness of rAHF vs. non-factor therapy emicizumab for treatment of severe hemophilia A without inhibitors using a model developed from the U.S. healthcare system perspective.

METHODS: The Markovian model was based on 5 mutually exclusive health states: with/without target joints (TJs), with/without arthropathy, dead. Each health state was associated with costs and utilities summed over time, and used to calculate incremental cost-effectiveness ratios (ICERs) for pairwise comparisons. Health states remained constant/changed, depending on bleeds and recovery probability. Model parameters were populated with data from published literature and clinical trials, including patient baseline characteristics, prior on-demand or prophylactic treatment, annualized bleeding rate (all or joint bleeds), probability of developing/resolving TJs or arthropathy, mortality, number infusions per bleed, medical check-ups, hospitalization.

RESULTS: For patients with prior on-demand treatment, rAHF prophylaxis was estimated to be less costly and more effective (total $13,314,045; quality-adjusted life years [QALYs] 15.86) vs. emicizumab prophylaxis ($15,491,994; 15.76). In a separate scenario, the treatment monotherapy subgroup to create mono therapy subgroups: Metformin ER, Metformin IR, and Brand. The dependent variables were (1) Two-year PDC; (2) Treatment gap of ≥ 90 days; (3) Six-month HbA1c; (4) New cardiovascular (CV) complication; and (5) Two-year cumulative pharmacy and medical claims (TCC).

CONCLUSIONS: This cost-effectiveness analysis suggests rAHF prophylaxis is a cost-effective long-term intervention for hemophilia A patients without inhibitors vs. non-factor prophylaxis with emicizumab.

SPONSORSHIP: Shire U.S. Inc., a Takeda company.

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

E1 Glucose Control, Therapy Persistence, and Total Cost of Care in a Commercially Insured Cohort of Treatment-Naive Type 2 Diabetics According to Prescribed Monotherapy Class: A Two-Year Historic Cohort Study

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BACKGROUND: Expert guidelines recommend metformin monotherapy as first-line oral medication for newly diagnosed patients with Type 2 DM. Branded agents (DPP4i, SGLT2, GLP1) are sometimes prescribed first-line for uncomplicated cases, counter to guidelines.

OBJECTIVE: To determine whether higher costs of branded agents are offset by improvements to adherence, HbA1c, cardiovascular outcomes, and incurred medical costs.

METHODS: Two-year, retrospective cohort study using commercial claims. Subjects were ≥ 18 y, with medical and pharmacy benefit for ≥ 12 m prior to first antidiabetic pharmacy claim. We excluded subjects with baseline diabetes complications, or who lacked baseline HbA1c. We used the first 90 d of antidiabetic claim history to create mono therapy subgroups: Metformin ER, Metformin IR, and Brand. The dependent variables were (1) Two-year PDC; (2) Treatment gap of ≥ 90 d; (3) Six-month HbA1c; (4) New cardiovascular (CV) complication; and (5) Two-year cumulative pharmacy and medical claims (TCC).

CONCLUSIONS: In a commercially insured cohort of treatment-naive patients with Type 2 diabetes, prescription of branded formulations as first-line therapy provided no evident clinical advantage over guideline-recommended metformin, but doubled TCC via pharmacy expenditure. Absent contraindication, patients with newly diagnosed, uncomplicated diabetes should be initiated on metformin monotherapy.

SPONSORSHIP: None.

E2 Use of Glucose-Lowering Treatments Among Patients with Diabetic Kidney Disease in the United States

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BACKGROUND: Expert guidelines recommend metformin monotherapy as first-line oral medication for newly diagnosed patients with Type 2 DM. Branded agents (DPP4i, SGLT2, GLP1) are sometimes prescribed first-line for uncomplicated cases, counter to guidelines.

OBJECTIVE: To determine whether higher costs of branded agents are offset by improvements to adherence, HbA1c, cardiovascular outcomes, and incurred medical costs.

METHODS: Two-year, retrospective cohort study using commercial claims. Subjects were ≥ 18 y, with medical and pharmacy benefit for ≥ 12 m prior to first antidiabetic pharmacy claim. We excluded subjects with baseline diabetes complications, or who lacked baseline HbA1c. We used the first 90 d of antidiabetic claim history to create mono therapy subgroups: Metformin ER, Metformin IR, and Brand. The dependent variables were (1) Two-year PDC; (2) Treatment gap of ≥ 90 d; (3) Six-month HbA1c; (4) New cardiovascular (CV) complication; and (5) Two-year cumulative pharmacy and medical claims (TCC).

CONCLUSIONS: In a commercially insured cohort of treatment-naive patients with Type 2 diabetes, prescription of branded formulations as first-line therapy provided no evident clinical advantage over guideline-recommended metformin, but doubled TCC via pharmacy expenditure. Absent contraindication, patients with newly diagnosed, uncomplicated diabetes should be initiated on metformin monotherapy.

SPONSORSHIP: None.
OBJECTIVE: To examine the recent use of GLDs in patients with DKD, stratified by severity of renal impairment, in the U.S.

METHODS: From MarketScan national-level database with linked claims and electronic medical records, adult patients (≥ 18 years old) with type 2 diabetes, who had estimated glomerular filtration rate (eGFR) value between 15 and 89 mL/min/1.73 m² during 7/1/2013-12/31/2015, were selected. A randomly picked eGFR value defined index date and index eGFR cohort (75-89, 60-74, 45-59, 30-44, and 15-29). Use of different GLD and treatment regimens during 12 months after the index date was examined across eGFR cohorts and assessed by a trend test. Analysis was also conducted by subgroups based on baseline HbA1c (< 7% and ≥ 7%).

RESULTS: In the study sample (N = 26,485), 40%, 28%, 19%, 9%, and 2% of patients were in eGFR cohorts of 75-89, 60-74, 45-59, 30-44, and 15-29, respectively. The eGFR cohorts (from eGFR 75-89 to 15-29) had mean ages of 65, 69, 73, 76 and 77 years old, respectively. The sample contained 50% males and 11% African-Americans. 55% of patients with eGFR 75-89 used metformin, which decreased to 12% for those with eGFR 15-29 (P < 0.05). Insulin usage increased noticeably with decreasing eGFR (from 21% to 40%), including insulin without glucagon-like peptide 1 receptor agonists (GLP-1RAs) or oral GLDs (from 7% to 23%), all P < 0.05. Increased use with lower eGFR was also observed for sulfonylureas (from 26% to 33%), dipeptidyl peptidase-4 inhibitors (DPP-4is, from 14% to 17%), and thiazolidinediones (from 5.6% to 6.3%, all P < 0.05). The use of GLP-1RAs and sodium-glucose co-transporter-2 inhibitors (SGLT-2is) were both 5% or less across cohorts. Similar trends across eGFR cohorts were observed in HbA1c subgroups. Among patients with baseline HbA1c ≥ 7% (N = 7,592), a large proportion of patients only used oral GLDs even with eGFR < 45 (36% for eGFR 30-44 and 22% for eGFR 15-29).

CONCLUSIONS: Treatment of DKD in U.S. may not be optimal (e.g., low usage of safe and effective GLDs, such as GLP-1RAs, among patients with eGFR < 45) and in most cases not consistent with most guidelines (e.g., use of metformin among those with eGFR < 30). Efforts are needed to improve the knowledge of how different GLDs impact outcomes in patients with DKD.

SPONSORSHIP: Novo Nordisk.

E4 Association Between the Process of Diabetes Care and Healthcare Expenditures in Patients with Diabetes
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BACKGROUND: Suboptimal compliance with American Diabetes Association (ADA) guideline recommendations for diabetes care may result in severe complications and increasing healthcare costs. We examined quality of diabetes care in terms of compliance versus non-compliance with the ADA guideline recommendations and healthcare expenditures in patients with diabetes in the United States.

OBJECTIVE: To determine the economic impact of compliance with ADA diabetes care guidelines.

METHODS: Adult patients with diabetes were identified from the 2015 Medical Expenditure Panel Survey (MEPS) data, a nationally representative survey of the civilian noninstitutionalized population in the United States. The Diabetes Care Survey (DCS) was used to categorize patients with diabetes as compliant or non-compliant with ADA guideline recommendations for diabetes care based on frequencies of (1) HbA1c check, (2) foot examination, (3) dilated eye-examination, (4) blood cholesterol, (5) flu vaccination, (6) blood-pressure check, and (7) dental check-up. The economic outcomes included total annual healthcare, inpatient-hospitalization, outpatient-visit emergency-room visit, and medication expenditures. Survey sampling weights and a two-part model were used to estimate the economic outcomes between the 2 groups (ADA compliance vs. non-compliance).
RESULTS: A total of 2,755 adult patients with diabetes were identified, of which 15.3% (n = 421) met the ADA guideline recommendations for diabetes care. The weighted means (standard errors) of total annual healthcare, inpatient-hospitalization, and emergency-room visit, and medication expenditures between patients with ADA-compliance vs. ADA-non-compliance were $13,585 ($460) vs. $15,025 ($251), P < 0.001; $3,203 ($165) vs. $4,128 ($115), P < 0.001; $901 ($39) vs. $984 ($28), P = 0.089; $275 ($9) vs. $326 ($5.50), P < 0.001; $5,217 ($155) vs. $5,462 ($91), P = 0.183, respectively.

CONCLUSIONS: Compliance to processes of diabetes care have been shown to reduce microvascular and macrovascular complications. Our study findings show that compliance with ADA guideline recommendations for diabetes care also results in significant reduction in total annual healthcare, inpatient-hospitalization and emergency room expenditures in patients with diabetes.

SPONSORSHIP: None.

E5 Real-World Data from the First Commercial U.S. Long-Term Implantable Continuous Glucose-Monitoring System
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Senseonics

BACKGROUND: The Eversense Continuous Glucose Monitoring (CGM) System, with a 90-day implanted sensor based on fluorescent technology, was approved by the FDA in June 2018 for commercial use in patients age ≥ 18 years with diabetes after 3 pivotal trials demonstrated its accuracy (MARD 8.9%) and safety.

OBJECTIVE: To evaluate glucometric data from the first 205 patients completing a full 90-day sensor wear period to demonstrate real-world experience with the first long-term implantable sensor.

METHODS: De-identified sensor glucose (SG) data from 8/1/18 to 5/11/19 was analyzed using the Eversense Diabetes Management System (DMS) in patients who had completed a 90-day sensor wear period. The SG mean, standard deviation (SD), coefficient of variation (%CV), glucose measurement index (GMI; a mathematical estimate of the HbA1c), and percent and time in minutes at various SG ranges were computed. Sensor accuracy was assessed using paired SG and SMBG measurements for calibrations performed 2 times/day. The sensor reinsertion rate at the end of the 120 days past the initial sensor insertion date was calculated. The median wear time of the transmitter was calculated for patients who had data beyond 30 days after sensor insertion.

RESULTS: Of the 205 patients, 110 were male, 94 were female and 1 was unreported. With regards to diabetes type, 129 identified as type 1, 18 as type 2, and 58 were unreported. Fifty patients reported as CGM naive, 112 had prior CGM experience, and 43 were unreported. The mean (SD) SG, SD, %CV and GMI were 161.8 mg/dL (57.4 mg/dL), 0.35 (0.06), and 7.18% (0.80). Percent time in the ranges < 54 mg/dL was 1.2% (18.0 min/day), 54 ≤ 70 mg/dL was 2.9% (41.8 min/day), 70-180 mg/dL was 62.3% (897.7 mins/day or ~15 hours/day), > 180-250 mg/dL was 21.9% (315.8 min/day), and > 250 mg/dL (severe hyperglycemia) was 11.6% (166.7 min/day). The MARD (SD; 27,708 SG-SMBG paired points) was 11.2% (11.3%). The sensor reinsertion rate was 76.9%. Median transmitter wear time was 83.6% in those subjects who had at least 30 days of data (92% of subjects).

CONCLUSIONS: Real-world data from the first 205 patients in the U.S. who completed a 90-day sensor wear period showed promising glycemetic results. These data suggest that the implanted Eversense CGM system is a valuable tool for management of diabetes.

SPONSORSHIP: Senseonics.

E6 The Association Between Adherence to Insulin Therapy and Healthcare Costs for Adults with Type 2 Diabetes: Evidence from a U.S. Retrospective Claims Database
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BACKGROUND: Research has shown that many patients with type 2 diabetes (T2D) are not adherent to their medication regimen.

OBJECTIVE: To examine the association between adherence to insulin therapy and all-cause healthcare costs for patients with T2D.

METHODS: The study utilized the IQVIA PhrMetrics Plus adjudicated claims database from January 1, 2012 through September 30, 2017. Patients were included if they were identified with T2D and initiated therapy on basal insulin (BI) or basal-bolus (BB) combination at any time from January 1, 2013 through October 1, 2016. Patients younger than age 18, who used an insulin pump, identified as pregnant, or did not have continuous insurance coverage from 1-year prior to initiation on insulin therapy through 1-year post initiation were excluded. Descriptive statistics compared patient characteristics and costs between patients who were adherent or non-adherent to their insulin therapy in the 1-year post-period, where adherence was defined as having proportion of days covered (PDC) of at least 80%. Adjusted costs were examined separately for adherent and non-adherent patients using generalized linear models (GLM with gamma error distribution and log link) controlling for patient characteristics, and prior general health and comorbidities, resource utilization, medication use, and type of insulin. Two predicted values of covariate-adjusted costs were computed for each individual (factual and counterfactual) and a one-sample t-test was applied to paired predictions to compare costs between adherent and non-adherent patients. Costs were adjusted to 2017 dollars.

RESULTS: There were 13,296 patients included in the BI cohort (5,502 adherent; 7,794 non-adherent) and 10,069 in the BB cohort (2,006 adherent; 8,063 non-adherent). Adherent patients had significantly lower all-cause total unadjusted costs following initiation on BI ($29,322 vs. $31,888, P = 0.0134) and BB combination ($36,229 vs. $40,147, P = 0.0078). Drug costs comprised 39-45% of costs among adherent patients and 23-26% of costs among non-adherent patients. Multivariable analyses revealed that adherent patients had significantly lower all-cause total costs than non-adherent patients in both the BI cohort ($30,127 vs. $37,049, P = 0.0004) and the BB cohort ($36,603 vs. $44,702, P < 0.0001).

CONCLUSIONS: In patients with T2D who initiated basal insulin or basal-bolus combination therapy, adherence was associated with significantly lower all-cause total medical costs, despite significantly higher drug costs. These results illustrate the economic benefits associated with adherence to insulin therapy.

SPONSORSHIP: Eli Lilly.
Individuals with diabetes often have multiple comorbidities and complex medication regimens that impact medication adherence. One solution to improve adherence rates and reduce healthcare costs is medication synchronization, where complex medication refill schedules are standardized. However, additional research is needed to evaluate synchronized medication refill schedules among individuals with diabetes.

**BACKGROUND:** Individuals with diabetes often have multiple comorbidities and complex medication regimens that impact medication adherence. One solution to improve adherence rates and reduce healthcare costs is medication synchronization, where complex medication refill schedules are standardized. However, additional research is needed to evaluate synchronized medication refill schedules among individuals with diabetes.

**OBJECTIVE:** To examine the relationship between patients' engagement with a DRM and adherence to oral diabetes drugs (OAD).

**METHODS:** A retrospective, propensity score matched cohort study was conducted using de-identified administrative claims data from a large pharmacy benefit manager. Commercially insured patients aged 18 or older and having ≥ 2 30-day adjusted OAD claims comprised the target sample. Patients enrolled in insurance plans that implemented DRM, who had ≥ 1 BG check (ever engaged) between April 1, 2015 and March 31, 2018 (exposure) were matched to patients enrolled in insurance plans that did not implement DRM (non-exposure). After a 1:2 matching on baseline demographics, disease burden proxy, total pharmacy out-of-pocket costs, prior adherence and insulin use, non-exposure group patients were assigned the same first BG check date as their matched DRM patient. Medication adherence measured as proportion of days covered (PDC) in the 365 days following first BG check was examined as a continuous and binary outcome measure (PDC ≥ 80% or adherent vs. < 80% or non-adherent). Multivariable linear and logistic regression were conducted to examine differential magnitude in adherence and likelihood of being adherent, respectively.

**RESULTS:** The final sample consisted of 6,002 exposure and 12,004 non-exposure group patients. DRM patients who were ever engaged had 4.5% higher adherence rate (P < 0.001) and 42% higher odds of being adherent (P < 0.001) in the period after engagement compared to non-exposure patients. Sensitivity analyses showed patients engaged continuously (≥ 1 BG check per week) for 3, 6 and 12 months had 5.1%, 5.2% and 6.4% higher adherence rates, respectively (P < 0.001), and 52%, 64% and 98% higher odds of being adherent, respectively (P < 0.001), compared to non-exposure patients.

**CONCLUSIONS:** The study findings offer evidence that DRM engagement is associated with higher odds of medication adherence. DRM solutions that provide access to glucose test results, personalized coaching, educational resources and lower testing supply cost can also influence adherence. Our findings have important implications for payers and patients related to improved health outcomes due to higher medication adherence.

**SPONSORSHIP:** Express Scripts.
even in vulnerable populations, but relapse is all too familiar after study completion.

**OBJECTIVE:** To test the hypothesis that unexpected escalating rewards, personalized to individual preferences, can lead to greater physical activity as compared with static, expected incentives that are delivered through the same means. We tested the additional hypothesis that intelligent patient reported outcomes (iPROs) derived in response to our AI rewards engine from time-stamped Fitbit inputs can corroborate self-reported activity levels.

**METHODS:** We performed an observational study on 30 consenting participants over a period of 45 days. Individuals were recruited via Facebook with a base reward of an Amazon cash gift card for $10 per week in exchange for commitment to link Fitbit to trUStr. These unexpected rewards (in the form of the above gift cards) in amounts of $2, $5, $15 and $50 were issued randomly, along with chatbot generated supportive text messages that offered words of encouragement towards individualized healthy behavioral change. Given the “panel” nature of this data set, “difference in difference” random effects models were developed to isolate the pre- and post-intervention effects of multivalued rewards on time-corroborated and continuously measured physical activity patterns.

**RESULTS:** Difference in difference models reveal that $2, $5 and $50 rewards did not have any significant treatment effect; however, the $15 reward led to a significant increase of 4.54% (P = 0.004, 1.45% to 7.64%) steps per day. Low- ($2 or $5) and high-value ($50) rewards did not induce behavioral change, whereas an unexpected $15 reward induced significantly increased physical activity. With a 91% retention rate, we further found that each subject generated 234 text message exchanges with our platform per month, on the average, displaying a very high engagement rate with our text chatbot.

**CONCLUSIONS:** Text messaging and chatbot interactions can add value to wearable data that in turn can corroborate iPROs. Unexpected rewards, when timed and calibrated to each individual’s unique circumstances, can increase the value of wearables and other autonomously collected information.

**SPONSORSHIP:** trUStr.

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**E19 Impact of BMI, Type, and Number of Comorbid Conditions on Health-Related Quality of Life Outcomes**

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**BACKGROUND:** Several studies have observed an association between increasing Body Mass Index (BMI) with reduced health-related quality of life (HRQOL). Elevated BMI is also associated with multiple chronic conditions including diabetes and cardiovascular disease. Nevertheless, patients with overweight or obesity may also suffer from comorbidities not directly related to the pathophysiology of high BMI measures such as mental-health related illness.

**OBJECTIVE:** To determine the impact of BMI and different types of chronic conditions on HRQOL outcomes.

**METHODS:** Adult patients were identified from Medical Expenditure Panel Survey (MEPS) 2013-2015 data and classified into 6 weight categories: Underweight (BMI: < 18.5), Normal weight (BMI: 18.5 to 24.9), Overweight (BMI: 25 to 29.9), Class 1 obesity (BMI: 30.0 to 34.9), Class 2 obesity (BMI: 35.0 to 39.9), and Class 3 obesity (BMI: ≥ 40). Twenty chronic conditions were considered and categorized as obesity-related (concordant) or -unrelated (discordant) conditions. HRQOL outcomes were measured using Short Form-6 Dimensions (SF-6D) scores directly derived from responses for the generic health-status Short Form-12 (SF-12) in the MEPS datasets. Multivariate regression was used to examine associations between type and number of comorbid conditions and BMI categories on SF-6D scores.

**RESULTS:** A sample of 58,981 subjects aged 18 or older were identified. Of which, 1.6%, 31%, 34.1%, and 33.3% were classified as underweight, normal weight, overweight, and obese, respectively. Among patients with obesity, 25.3% had Class 2 obesity (BMI: ≥ 35) and 16.6% had Class 3 obesity (BMI: ≥ 40). SF-6D scores were significantly decreased across all obesity classes, with the largest reduction in Class 3 obesity (0.025; P < 0.001). Additionally, individuals with obesity having one or more discordant or discordant comorbidities further reduced SF-6D scores—between 0.025 and 0.092 (both P values < 0.001), and between 0.076 and 0.194 (both P values < 0.001), respectively.

**CONCLUSIONS:** Individuals with obesity had a significant reduction in SF-6D scores compared to those with normal BMI. Importantly, discordant comorbid conditions resulted in greater reduction in HRQOL outcomes compared to discordant comorbidity in patients with obesity.

**SPONSORSHIP:** None.

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**E20 Healthcare Utilization and Mortality Among Medicare Beneficiaries with Diagnosis of Wild-Type Transthyretin Amyloid Cardiomyopathy**

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**BACKGROUND:** Transthyretin amyloid cardiomyopathy (ATTR-CM) is caused by the deposition of amyloid fibrils in the myocardium with typical clinical presentation as heart failure (HF). There is little data on prevalence, healthcare utilization (HCU) and outcomes in this rare disease. Research increasingly relies on administrative claim data using the International Classification of Diseases (ICD) codes to understand disease and population health management. There have been no specific codes to identify ATTR-CM until the Tenth Revision code (ICD-10) introduced in October 2017 to identify ATTR-CM wild type ATTRwt. The adoption of the code is likely to help facilitate research on ATTRwt.

**OBJECTIVE:** To describe demographic and clinical characteristics of Medicare patients classified as ATTRwt by the new ICD code and quantify HCU and mortality.

**METHODS:** A retrospective cohort study was conducted using Medicare fee-for-service claims available from January 2010 until October 2018. Eligible patients were adults (> 65 yrs) diagnosed with ATTRwt (ICD-10 E85.82). The index date was defined as the date of the first diagnosis of ATTRwt or amyloidosis (277.3x or E85.xx), whichever happened...
Among the 726 ATTRwt patients identified, mean age was 77.6 ± 6.8; 85% were male; 80% were White. During the pre-index period, most patients (55%) had a Charlson Comorbidity Index (CCI) above 2; 98% had outpatient visits and 39% had hospitalizations. During the follow-up period, 10% of the patients died; 53% had ≥1 all-cause hospitalization and 49% had ≥1 cardiovascular-related hospitalization with a mean length of stay of 6 days for both types of hospitalization. About 15% of the patients were re-hospitalized within 30 days of discharge, 46% visited the ER (24% for CV-related conditions); and 98% had ≥1 outpatient visit (89% for cardiology).

CONCLUSIONS: Patient with diagnosis of ATTRwt were predominately older white males with several comorbidities and frequent health resource utilization. The adoption of the new ICD code for ATTRwt will facilitate learning on prevalence, diagnosis and health care utilization in this rare disease.

SPONSORSHIP: Pfizer.

E24 Epidemiology of Hereditary Transthyretin Amyloidosis: A Real-World Analysis of a U.S. Commercially Insured Population

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BACKGROUND: Hereditary transthyretin (hATTR) amyloidosis is a rare genetic, progressive, and fatal disease caused by build-up of misfolded transthyretin protein (amyloid) in organs and tissues. The recent incidence of hATTR amyloidosis in the U.S. is not well documented. Additionally, rates are most likely underestimated due to a lack of awareness and diagnostic uncertainty.

OBJECTIVE: To generate a recent U.S. estimate of diagnosed incidence of hATTR amyloidosis, focusing on patients with hATTR-associated polyneuropathy and/or mixed phenotype.

METHODS: We identified patients ≥18 years diagnosed with hATTR amyloidosis in IBM MarketScan Commercial and Medicare Supplemental data, using a claims-based algorithm due to lack of specific medical coding. Diagnosis required ≥1 medical claim with a relevant diagnosis code for amyloidosis (ICD-10-CM: E85.0-4, E85.89, E85.9; excludes light chain and wild type) in the calendar year (CY) of 2016 and ≥1 occurrence of qualifying criteria for hATTR any time during study (2013-2017): ≥15 days diflunisal use without >30-day gap, liver transplant, or claim with code E85.1 or E852.2. All disease-free enrollees (continuously enrolled and without a diagnosis code of hATTR amyloidosis) were included. Annual diagnosed incidence was calculated as the number of new cases of hATTR patients divided by total at-risk patient years from January 1 to diagnosis (cases) or enrollment end (non-cases) in CY 2016 and reported per million person years (PMPY). Enrollment was continuous during at-risk period.

RESULTS: Annual diagnosed incidence of hATTR in 2016 was 9.0 patients PMPY. Incident cases were concentrated in older age groups (65+ years: 23.3, 55-64 years: 14.6, 35-54 years: 5.8, 18-34 years: 2.2 PMPY) and slightly more common among females than males (9.6 vs. 9.0).
CONCLUSIONS: The epidemiology of hATTR amyloidosis is not well understood or quantified. This study reveals a small but meaningful number of new patients diagnosed with hATTR in the U.S. in 2016. Consistent with previous studies, new cases are predominately of advanced age. Future estimation of prevalence is planned.

SPONSORSHIP: Akcea Therapeutics.

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

F2 Short-Acting Opioid Duration Edit Substantially Reduces Large Days Supply for Commercially Insured Opioid-Naive Members Compared to a Control Group Without an Edit

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BACKGROUND: CDC opioid prescribing guidelines note “...more than seven days will rarely be needed.” To improve safe opioid use, some insurers have applied a duration limit edit (DLE) at the point of sale. To our knowledge, there is no data assessing impact of a DLE on reducing opioid supply compared to a concurrent control group with no edit in place. Only pre-post studies with no control have been published. A control group is important as opioid large supply prescribing may be decreasing due to the CDC guidelines.

OBJECTIVE: To examine the impact of a short-acting opioid DLE among opioid naive users compared to a group without the DLE.

METHODS: In October 2017, a 2 million commercial life plan (i.e., intervention group) applied a DLE on naive short acting opioid users, exempting members with cancer or in hospice. The DLE queries 180 days of historical pharmacy claims data to determine if a member is opioid naive. For opioid naive members, insurance coverage is limited to 7-day supply or less. To examine the DLE impact, monthly pharmacy claims data were queried from January 2017 to December 2018 among the intervention plan compared to a control group of 4 other commercial plans with 1.6 million lives with no opioid DLE. The percent of naive opioid members with a short acting opioid claim with more than a 7-day supply was determined each month and the difference between intervention and control groups was compared pre- and post-edit using a generalized estimating equation (GEE).

RESULTS: In January 2017, the intervention plan had 18,578 (9 per 1,000) members naive to short acting opioids and 18,637 (9 per 1,000) in December 2018. The monthly proportion of opioid naive members receiving more than 7 days short-acting opioid supply decreased by 46 percent, from 26% September 2017 down to 14% in December 2018, with a peak effect of 3% in January 2018 due to edit modifications. The control group had 16,699 (10 per 1,000) members naive to short acting opioids in Jan 2017 and 14,901 (9 per 1,000) in December 2018. Opioid naive members with more than a 7-day opioid supply decreased from 17% in Jan 2017 to 11% in December 2018, a 6% change. The GEE found a statistically significant difference, $P < 0.01$, between the intervention and control groups, accounting for a 15-percentage point decrease after the edit in members receiving more than a 7-day opioid supply.

CONCLUSIONS: A pharmacy benefit duration limit edit was associated with a statistically significant improvement in ensuring opioid supplies were within CDC prescribing guidelines compared to a control group with no edit in place.

SPONSORSHIP: Prime Therapeutics.

F6 Switching from Oral Risperidone/Paliperidone to Once-Monthly Paliperidone Palmitate: Real-World Outcomes for Patients with Schizophrenia

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BACKGROUND: Non-adherence to antipsychotics (APs) is common for patients with schizophrenia and is associated with higher costs. Switching patients from oral risperidone or paliperidone (risp/pali) to once-monthly paliperidone palmitate (PP1M), a long-acting injectable, will reduce frequency of drug administration, which may improve adherence and disease management.

OBJECTIVE: To compare patient characteristics, adherence to APs, healthcare resource utilization (HRU), and costs pre- and post-PP1M transition among commercially-insured patients in the United States previously treated with oral risp/pali.

METHODS: Adults with ≥ 1 PP1M claim, ≥ 2 schizophrenia diagnoses during continuous insurance eligibility, and ≥ 30 days of oral risp/pali treatment in the 60 days prior to first PP1M claim were selected from the IQVIA PharMetrics Plus database (01/2012-07/2018). Generalized estimating equation models adjusted for repeated measurements were used to compare patient characteristics, adherence to APs, HRU, and costs during the 6 months pre- versus post-PP1M transition.

RESULTS: Among 427 patients transitioning to PP1M following oral risp/pali treatment, mean age was 41.1 years and 37.9% were females. Post-PP1M transition, patients were less likely to have a claim with a diagnosis for substance-related or addictive disorders (odds ratio [OR] = 0.73, $P = 0.003$), depression (OR = 0.70, $P < 0.001$), bipolar and related disorders (OR = 0.59, $P < 0.001$), and anxiety disorders (OR = 0.78, $P = 0.034$), respectively, versus pre-PP1M transition. They were also > 2 times more likely to have a proportion of days covered by APs ≥ 80% (OR = 2.62, $P < 0.001$). Post-PP1M, patients were less likely to have an all-cause emergency room (ER) visit (OR = 0.70, $P < 0.001$) or inpatient (IP) admission (OR = 0.53, $P < 0.001$). All-cause total costs were numerically, but not significantly, higher post- versus pre-PP1M transition (mean monthly cost difference [MMCD] = $-528, P = 0.260$). Pharmacy costs increased post-PP1M (MMCD = $960, P < 0.001$), but were offset by decreasing medical costs (MMCD = $-732, P < 0.001$) driven by lower IP costs (MMCD = $-695, P < 0.001$) and ER costs (MMCD = $-63, P < 0.001$).

CONCLUSIONS: Transitioning to PP1M following treatment with oral risp/pali was associated with a reduction in comorbidities, an
improvement in adherence to APs, and a reduction in ER visits and IP admissions. Increasing pharmacy costs were offset by decreasing medical costs. Overall, total costs were numerically but not significantly higher. These findings suggest that transitioning to PPIM may improve disease management while remaining cost neutral.

CONCLUSIONS: Non-adherence to oral antipsychotics (OAPs) is a common cause of relapse. In 2018, Florida Medicaid released medication guidelines recommending long-acting injectable (LAI) antipsychotic treatment in patients with schizophrenia after failure of two courses of OAP monotherapy.

METHODS: Multi-state Medicaid data (01/2010-03/2018) were used to identify LAI-naive patients with ≥2 diagnoses for schizophrenia during continuous Medicaid eligibility, ≥1 OAP claim in 2010 or after, and ≥2 schizophrenia-related treatment failures (defined as having an inpatient or emergency room visit with a diagnosis of schizophrenia). AP use prior to the first relapse, between relapses, and following the second relapse was assessed to identify guideline-concordant antipsychotic treatment. Guideline-concordance was defined as patients who, sequentially, received OAP in monotherapy, incurred a first relapse, switched to ≥1 new OAP agent in monotherapy, incurred a second relapse, and then initiated an LAI after the second relapse.

RESULTS: Among 166,352 patients with ≥2 schizophrenia diagnoses, 94,737 (56.9%) had ≥1 OAP claim on or after January 1 2010. Among those with an OAP claim, 46,329 (48.9%) had ≥1 relapse following the OAP claim, among whom 30,497 (65.8%) had ≥1 subsequent relapse. Among 22,014 patients naive to LAIs prior to the second relapse, 5,085 (23.1%) initiated ≥1 new OAP between the first and second relapse, 8,558 (38.9%) continued receiving an OAP previously taken, and 8,371 (38.0%) did not have any antipsychotic treatment. Among the 5,085 patients switching OAP after the first relapse, 3,648 (71.7%) patients used OAP in monotherapy for both treatment courses. Among them, 111 patients received LAI in accordance with Florida guidelines, which represents 0.5% of patients with ≥2 relapses.

CONCLUSIONS: These findings showed that less than a quarter of Medicaid patients with schizophrenia switched OAP after their first relapse and less than one percent of patients with multiple relapses received guideline-based medication management. Further research is warranted to assess the impact of guideline-based treatment on clinical and economic outcomes.

SPONSORSHIP: Janssen Scientific Affairs.
BACKGROUND: Schizophrenia (SCZ) is a behavioral health disorder characterized by disruptions in thought processes and perceptions. The course of SCZ varies amongst individuals, and can be both persistent and severe. Adherence can be a key predictor of success among SCZ patients. Non-adherence to antipsychotics has been linked to relapse, and increased costs. Long-acting injectable (LAI) antipsychotics are used to reduce non-adherence and the likelihood of relapse. The use of antipsychotic LAIs have been limited due to risk of side effects, and their increased cost compared to oral alternatives. A retrospective cross-sectional study was conducted to compare the change in adherence and medical cost of LAI new starts with those that were non-adherent to an oral regimen.

OBJECTIVE: To compare the change in adherence and medical cost between new starts to a LAI antipsychotic regimen and non-adherent members prescribed an oral regimen

METHODS: The eligible sample consisted of members from a managed Medicaid population that were continuously enrolled for 2 years with ≥ 2 antipsychotic medications filled each year, and between the ages of 18 and 65. Adherence to antipsychotics was calculated using the URAC’s proportion of days covered (PDC) methodology. The new starts (NS-LAI) were members with no claims for a LAI during the baseline year and 2 or more LAIs the following year. The oral only subset (OR) had no LAI claims and were non-adherent (PDC < 80%) during both years. Baseline characteristics were compared. Change in medical cost and adherence were compared using an adjusted Difference-in-Difference (D-I-D) analysis. A significance threshold of 0.05 was employed.

RESULTS: The eligible sample consisted of 631 members (NS-LAI n = 90 OR n = 541). The OR subset was significantly older, predominately female (age P = 0.01 gender P < 0.01) with no difference in comorbid burden. Adherence improved by 17% in the NS-LAI subset (avg baseline PDC-72%, avg year 2 PDC-84%), whereas adherence declined by 5% within the OR subset (avg baseline PDC-51%, avg year 2 PDC-49%); D-I-D, P < 0.01. Baseline medical cost was higher in the NS-LAI subset compared to OR members. Medical cost decreased by 7% in the NS-LAI and increased by 0.2% in the OR subset. This rate of change did not achieve statistical significance.

CONCLUSIONS: When compared to members that were non-adherent to an oral regimen, NS-LAI experienced improved adherence and declined medical cost; however, the rate of change lacked significance. Additional research will need to be conducted to determine if the LAI new starts maintain adherence and if medical cost continues this downward trend.

SPONSORSHIP: None.

F11 Frequent Treatment Changes in the Course of Antidepressant Therapy: Real-World Evidence of Unmet Needs in the Pharmacotherapy of Major Depressive Disorder

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BACKGROUND: Major depressive disorder (MDD) is the largest contributor to disability worldwide and has a lifetime prevalence rate of 16.6% in the U.S. American Psychological Association (APA) guidelines recommend antidepressant (AD) medication as an initial treatment choice with a goal of achieving remission and a full return to the baseline level of function. However, studies have highlighted shortcomings of the current AD treatment options, including delayed efficacy, low remission rates, and significant side effects that may result in poor patient outcomes, low adherence, and the need for multiple treatment strategy changes.

OBJECTIVE: To examine existing clinical practice for the pharmacological treatment of MDD by examining antidepressant prescription patterns in a large, real-world patient population.

F10 Opioid Abuse and Suicidality in Postpartum Depression: An Analysis of U.S. Electronic Health Records

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BACKGROUND: In the U.S., postpartum depression (PPD) is the most common complication of childbirth, affecting 11.5% of new mothers every year. It is estimated that 1 in 300 privately insured women become persistent opioid users following an opioid prescription after cesarean delivery, and > 1 in 10 Medicaid-enrolled women fill an opioid prescription after vaginal delivery. Taken together, mental health conditions and substance use disorders contribute to 12.9% and 8.2% of pregnancy-related deaths, respectively; 6.5% of such deaths being suicides.

OBJECTIVE: To assess the association between PPD, suicide attempts/ideation, and opioid abuse in a large, real-world patient population.

METHODS: A U.S. electronic health records database (Cerner Health Facts) was retrospectively analyzed. Female patients aged 15-50 years with ≥ 12 months of prior health history were examined. A combination of diagnosis codes for depression, mood, adjustment, and anxiety disorders, interventional procedure codes, and antidepressant prescriptions was used to identify PPD. The analysis included women with and without PPD and a live birth between 2010-2017. Identification of PPD was limited to the third week through 12 months post-delivery, to exclude patients with “baby blues” during the first two weeks after birth. The analysis included deliveries with Commercial (31%), Medicaid (40%), or other payers (9%), excluding deliveries with an unknown, multiple, or Medicare payers. Suicide attempts/ideation and de novo opioid abuse (excluding opioid abuse prior to birth) were identified using relevant diagnosis codes.

RESULTS: The analysis identified 5,852 patients with PPD and 183,521 patients without PPD. More than half of the PPD patients (54%) were identified during an emergency department or inpatient visit. The proportion of postpartum suicide attempts/ideation was >100-fold higher among patients with PPD (8.49%) compared to women without PPD (0.07%; P < 0.001). Furthermore, the proportion of women with postpartum opioid abuse was four-fold higher in PPD (0.8%) versus non-PPD women (0.2%; P < 0.001). Among PPD patients, most suicide attempts/ideation cases (68%) were first recognized at the time of the PPD identification visit.

CONCLUSIONS: Women with PPD had significantly higher suicide attempts/ideation and postpartum opioid abuse compared to women without PPD symptoms, underscoring the importance of early detection and treatment to prevent adverse outcomes to the mother affecting both the child and family.

SPONSORSHIP: Sage Therapeutics.
METHODS: A U.S. claims database from 2013 to 2017 (Truven Health MarketScan) was retrospectively analyzed. Adults (≥ 18 years old) with an ICD-9/10 diagnosis for depression and ≥ 1 pharmacy claim for an AD on or after their first diagnosis were examined. Patients with bipolar disorder or schizophrenia were excluded, as were those who received antidepressants or lithium prior to, or atypical antipsychotics or perphenazine on, the date of initiation of MDD treatment. Only patients who received antidepressant monotherapy as their first-line MDD treatment were included.

RESULTS: The algorithm identified 218,933 patients with MDD receiving AD monotherapy as their first-line MDD treatment. During the first year of treatment, only 10% of patients persisted with their first-line therapy. Treatment changes were observed within 90 days for 55% of patients, with a large proportion (41% of total) discontinuing pharmacotherapy and a smaller proportion (14% of total) switching, augmenting or combining their course of ADs, independent of the class of AD prescribed. Discontinuation of a first AD course occurred at a median of 75 days versus a median time to medication switch of 48 days. By one year after index, 57% of patients discontinued AD usage.

CONCLUSIONS: This study expands on previous literature documenting the limitations of existing AD treatments. Most patients discontinued their first-line therapy, and those patients who remained on ADs frequently switched medications within the first year of treatment. These data highlight the need for additional pharmacological options for the treatment of patients with MDD.

SPONSORSHIP: Sage Therapeutics.

F12 High Comorbidity Burden, Healthcare Resource Utilization, and Costs in a Claims Database Analysis of Major Depressive Disorder
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BACKGROUND: The lifetime prevalence of major depressive disorder (MDD) in the U.S. is 16.6%, and the yearly cost associated with treatment of U.S. patients with MDD exceeds $200 million, including MDD treatment and comorbidities. Comorbidities commonly associated with MDD include comorbid psychiatric conditions, sleep disorders, neurological disorders, and cardiovascular disease.

OBJECTIVE: To examine the comorbidity burden, concomitant medication usage, healthcare resource utilization, and costs across a matched population of patients with MDD versus without MDD.

METHODS: This retrospective study examined a U.S. claims database (Truven Health MarketScan) from 2013-2016. Adult patients (≥ 18 years old) with an ICD-9/10 diagnosis for depression and ≥ 1 pharmacy claim for an antidepressant on or after their first diagnosis were included. Exclusion criteria included bipolar disorder, schizophrenia, or use of an antidepressant or lithium prior to, or atypical antipsychotics or perphenazine at initiation of, MDD treatment. Propensity score matching (based on demographic and clinical characteristics) generated MDD and control patient cohorts. Initiation of the first antidepressant medication defined index visits.

RESULTS: Propensity score matching resulted in inclusion of 426,524 patients (213,262 with MDD, 213,262 without MDD). Comorbidities were more prevalent among patients with MDD. The most common comorbidities in patients with MDD were anxiety disorders (34.1% at index, 37.6% at 6 months post index) and chronic non-back pain (27.3% at index, 27.6% at 6 months post index). Concomitant medication use was higher among patients with MDD than control patients. Patients with MDD had significantly higher (P<0.0001) healthcare resource utilization and costs versus the control. On average, patients with MDD had 26.5 days with a medical visit per patient per year versus 16.9 days for patients without MDD (P<0.0001). Total annual average healthcare costs were $16,806 for patients with MDD compared with $11,015 for control patients (P<0.0001). Patients with MDD also had significantly more short-term disability days (141.8 days vs. 99.9 days) and absent days (15.9 days vs. 12.5 days) versus the control (P<0.0001).

CONCLUSIONS: The results suggest a higher comorbidity rate in patients with MDD that may support the observed increases in healthcare resource utilization and cost. This underscores the need for improved management of patients with MDD to reduce the burden of the disease.

SPONSORSHIP: Sage Therapeutics.
including weight gain (58.5%), excessive sedation (54.2%), and physical awkwardness or tremors (33.1%). Greater adherence to SGAs was associated with lower quarterly mental health-related medical costs ($192 to $686 reduction per patient per 1-unit increase in medication possession ratio). Results of SGA adherence and total health-related medical costs were similar across SGA monotherapies.

CONCLUSIONS: Suboptimal treatment patterns with oral SGAs are common and are associated with higher medical costs. Despite the range of pharmacologic medications available for BD, significant unmet need remains among patients. Addressing barriers to treatment adherence, including reducing side effects, may improve clinical and economic outcomes among BD patients.

SPONSORSHIP: Janssen Scientific Affairs.

F14 Economic Burden of Treatment-Resistant Depression in Privately Insured U.S. Patients with Physical Comorbidities

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BACKGROUND: Little is known about the incremental economic burden of treatment-resistant depression (TRD) in patients with physical comorbidities.

OBJECTIVE: To assess healthcare resource utilization (HRU) and costs, work loss days and related costs of TRD patients with physical comorbidities compared to non-TRD major depressive disorder (MDD) and non-MDD controls with the same comorbidities.

METHODS: Adults < 65 years old with MDD and antidepressant (AD) use were identified in the OptumHealth Care Solutions, Inc. database (07/2009-03/2017). MDD patients with a 3rd AD agent (index) after 2 AD regimens at adequate dose and duration were defined as TRD. A random index date was used for non-TRD MDD and non-MDD control cohorts using the IBM MarketScan Commercial database. Newly diagnosed adult MDD patients with a new antidepressant prescription from January 1, 2009 to December 31, 2017 were identified using the IBM MarketScan Commercial database. Patients with diagnoses of bipolar disorder, neurocognitive disorders, pregnancy or childbirth were excluded. After ensuring 12 months of continuous enrollment, follow up ended at lapse in continuous enrollment or the study end date. Clinical EOIs, including antidepressant treatment changes, diagnosis of moderate to severe MDD, MDD-related hospitalizations, suicide attempts or ideation, severe mental health diagnosis (e.g., psychosis), MDD-related ER visits, and receipt of brain stimulation therapy (e.g., electroconvulsive therapy) were captured during follow up. Mean PPPY all-cause healthcare costs were described, including cost in the 90 days before and after the clinical EOI.

RESULTS: Of 455,082 MDD patients identified, mean PPPY costs were $10,074 (outpatient medical 59%; inpatient 21%; outpatient pharmacy 20%). The most common clinical EOIs were treatment changes (at least 1 therapy; 90.1%, n = 410,159), moderate/severe MDD diagnosis (23.5%, n = 107,039), and MDD-related ER visit (6.1%, n = 27,960). Clinical EOIs with highest mean PPPY cost were brain stimulation therapy receipt ($49,121), severe mental health disorder ($23,096), and MDD-related hospitalization ($15,941). For most types of EOIs, average costs for up to 90 days following an EOI were substantially higher than those preceding it, indicating that the clinical EOI was a likely cost driver.

CONCLUSIONS: The cost of MDD is substantial, further amplified by certain clinical EOIs including receipt of brain stimulation therapy,
Prevalence and Mental Health Resource Utilization of Major Depressive Disorder with Suicidal Ideation and the Overlaps with Treatment-Resistant Depression Using the National Survey on Drug Use and Health

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BACKGROUND: Subsets of patients with major depressive disorder (MDD) include those with treatment-resistant depression (TRD; i.e., inadequate response to pharmacotherapy) and those with major depressive disorder with suicidal ideation (MDD+SI). Because of the high burden of these two populations, it is important to understand the prevalence, overlap and mental health resource utilization (MHRU) of these groups.

OBJECTIVE: To estimate past-year prevalence and MHRU of MDD+SI, TRD, and TRD+SI using 2017 National Survey on Drug Use and Health (NSDUH) adult data.

METHODS: Cross-sectional study of the following 3 cohorts: MDD+SI: respondents reported past-year major depressive episode and past-year serious suicidal ideation or attempt (SI); TRD: reported past-year medication-treated major depressive episode and responded, ‘Not at all’ or ‘A little’ to ‘How much has prescription medication for mood helped in the past 12 months’; and TRD+SI: MDD+SI respondents categorized as TRD. Illness prevalence, overall and by sociodemographic factors, were estimated and extrapolated to the U.S. adult population. Reported MHRU (% services received) for each study cohort was compared to that of corresponding reference groups, as follows: MDD+SI vs. MDD without SI; TRD+SI vs. MDD+SI without TRD, and vs. TRD without SI; and all 3 study cohorts vs. a global reference group (adults without MDD or SI).

RESULTS: As defined above, among 247.2M adults, 2.2% (5.5M) had MDD+SI, 0.7% (1.6M) TRD, 0.3% (0.8M) TRD+SI. Among 17.6M adults with MDD, 31.2% had MDD+SI; 9.2% TRD; 4.3% TRD+SI. Prevalence of MDD+SI was higher among 18-25 vs. 50-64-year-olds (5.7% vs. 1.6%), women vs. men (2.7% vs. 1.8%), unemployed vs. fully employed (4.1% vs. 1.9%) and Medicaid vs. commercially insured (3.8% vs. 2.0%). Similar patterns were identified in TRD and TRD+SI cohorts. MHRU was higher for MDD+SI vs. MDD without SI, and vs. the global reference group: inpatient, 10.4% vs. 2.2% and 0.6%; outpatient, 46.8% vs. 33.5% and 4.7%; prescription, 57.7% vs. 45.0% and 8.6%; and any MH treatment, 65.8% vs. 53.1% and 10.8%. MHRU was higher for TRD+SI vs. TRD without SI, vs. MDD+SI without TRD, and vs. the global reference group: inpatient, 17.6% vs. 6.9%, 9.3% and 0.6%; outpatient, 64.3% vs. 48.2%, 44.0% and 4.7%; prescription, 90.6% vs. 8.6%; and any MH treatment, 93.3% vs. 10.8%.

CONCLUSIONS: This is the first study to assess the prevalence and MHRU of the overlap of MDD and TRD, with or without SI, and show the incremental burden of TRD+SI, TRD and MDD+SI. Our findings underscore the need for optimized treatment interventions to improve patient care.

SPONSORSHIP: Janssen Scientific Affairs.

Assessment of Specific Barriers and Drivers on Provider Adoption and Appropriate Use of Digital Medication Adherence Platforms

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BACKGROUND: Accurately assessing medication adherence in serious mental illness (SMI) is challenging. A new digital medicine technology combining an ingestible event monitoring (IEM) sensor with an oral antipsychotic to track ingestion, may be beneficial. However, psychiatric care providers may be reluctant to introduce this technology in practice.

OBJECTIVE: To identify barriers and drivers to adopt an IEM adherence platform.

METHODS: An online survey of practicing psychiatric providers currently treating patients with SMI was conducted to assess drivers and barriers to technology adoption and issues concerning medication adherence. Response options included rank order preferences and Likert scales. Factor analysis was performed on 11 items representing potential positive and negative assumptions about IEM sensor adoption.

RESULTS: A total of 112 providers (32% female, 75% physicians, mean age 48.1 yrs.) participated. Over 90% agreed adherence is important, visits allow sufficient time to monitor adherence (83.5%), and tailoring treatment to level of adherence would be beneficial (92.9%). Respondents reported challenges in monitoring and managing adherence: some felt there was no right or wrong method for tracking adherence (27%), while some reported that self-report and collateral report (25% and 27%) were preferred. Most (60%) reported that accurate adherence data would save time. The majority of respondents currently assess adherence by asking the patient directly (95.5%), assessing symptomatology (61.6%) or asking collaterals (63.4%). Most (84.5%) reported using some form of digital medicine technology with patients in the past. However, they reported that computerization of medicine primarily benefits providers and payors, not patients. When asked about an IEM sensor specifically, 71.1% felt it would increase patient engagement, and is in the patient’s best interest (73.2%). Factor analysis revealed 4 underlying barriers/drivers of IEM technology adoption. Preliminary analyses indicate women were more likely to be affected by technology barriers as were those providers who have had their licenses the longest.

CONCLUSIONS: Psychiatric providers are concerned about medication adherence, perceive current monitoring tools as problematic, and are open to using digital medicine technologies to improve accuracy of adherence assessment. Barriers to adoption of an IEM sensor platform
include knowledge gaps and logistic concerns that are more likely to affect female and older providers.

**SPONSORSHIP:** Otsuka Pharmaceutical Development & Commercialization.

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**F18 Incremental Health Care Costs for Persons with Treatment-Resistant Depression in Managed Care Organizations**

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**BACKGROUND:** 16.2 million adults in the U.S. had at least one major depressive disorder (MDD) episode in 2016, among which 30% experience treatment-resistant depression (TRD) that doesn’t respond to evidence-based care. MDD is costly with a large share of cost attributable to TRD. Most previous research uses pharmacy claims and defined TRD using failure of two or more consecutive and different antidepressants at an adequate dose and duration but does not account for ongoing depression symptoms. Widespread use of screening tools for depression (i.e., 9-item Patient Health Questionnaire—PHQ9), provides an opportunity to better understand the burden of TRD. Greater understanding of costs to managed care organizations (MCO) associated with TRD could help to evaluate alternative treatments.

**OBJECTIVE:** To explore the health care costs associated with TRD and compare these to persons with MDD only (no TRD) and to those with no depression (control). It also explores use of PHQ9 data to improve understanding of costs.

**METHODS:** This analysis is part of a larger case control study using data from electronic medical records (EMR) and administrative systems of Kaiser Permanente Northwest (KPNW) and includes all KPNW members aged ≥18 with a diagnosis of MDD. We compare medical and mental health care costs of persons with TRD to persons with MDD and controls. We also explore whether clinical symptoms from the PHQ-9 can refine understanding of health care costs. We evaluate how groups differ by using generalized linear modeling.

**RESULTS:** Preliminary analyses included up to 33,138 persons with TRD, 41,128 persons with MDD only and 473,173 controls. In all comparisons, groups were similar on age and gender due to matching. Considering all study subjects identified, 72% of TRD were female; 65% of MDD and 51% of controls. Mean ages were 49 years (SD 16), 42 (SD 17) and 45 (SD 18) for TRD, MDD only and control, respectively. Compared to control, annual total costs were 82% higher (2017 USD) in persons with TRD an incremental cost of $5,447 ($P < 0.0001). Compared to MDD only, annual total costs for persons with TRD were 77% higher, with an incremental cost of $5,230 ($P < 0.0001). Compared to control, MDD only had annual costs 20% higher, with an incremental cost of $844 ($P < 0.0001). A person’s first documented PHQ-9 score in the EMR was positively associated with total annual costs ($β = 36.9, $P = 0.0006).

**CONCLUSIONS:** Widespread use of depression screening in MCO could aid in understanding the cost of caring for persons with TRD. This information could also help to evaluate new treatments for TRD on both clinical outcomes and costs.

**SPONSORSHIP:** Janssen Scientific Affairs.

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**F19 Economic Burden of Privately Insured Patients Diagnosed with Major Depressive Disorder and Suicide Ideation or Suicide Attempt in the United States**

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**BACKGROUND:** Suicide ideation (SI) and suicide attempt (SA) may occur in patients with major depressive disorder (MDD). The economic burden of those with MDD and SI or SA (SI/SA) is not well understood.

**OBJECTIVE:** To assess healthcare resource utilization (HRU) and costs of patients with MDD and SI/SA in a commercially insured population.

**METHODS:** Adults (18-64 years) diagnosed with MDD and SI/SA (1st SI/SA event defined the index date) and non-MDD controls (no MDD or SI/SA diagnoses, randomly generated index date) were identified in the Optum Health Care Solutions database of privately insured patients (10/2014-03/2017). Patients with < 12 months of health plan enrollment pre-index and/or a diagnosis of schizophrenia, bipolar disorder/mania, or dementia were excluded. Patients with MDD and SI/SA and non-MDD controls were matched 1:1 using propensity score models including demographics and the Quan-Charbon comorbidity index. Per-patient-per-month (PPPM) HRU and costs were described and compared up to 1 and 12 months post-index (index included) using Poisson and ordinary least square regression models adjusted for baseline costs; $P$ values for cost models were obtained using bootstrap procedures.

**RESULTS:** A total of 2,061 patients with MDD and SI/SA (mean age 34 years, 56.1% female, mean follow-up 7.8 months) were identified; 78.2% were classified as having SI and 21.8% as having SA. Half (49.9%) of the index events were classified as an emergency department (ED) visit, 43.8% as an inpatient stay and 4.3% as an outpatient visit. Patients with MDD and SI/SA versus controls at 1 and over 12 months post-index had 0.90 vs. 0.01 and 0.32 vs. 0.01 inpatient admissions PPPM, 4.63 vs. 0.04 and 1.55 vs. 0.04 inpatient days PPPM, 0.76 vs. 0.04 and 0.34 vs. 0.03 ED visits PPPM, 2.71 vs. 0.57 and 2.12 vs. 0.50 outpatient visits PPPM, respectively (all $P<0.01$). Higher HRU in those with MDD and SI/SA translated into higher costs. Total costs in patients with MDD and SI/SA versus controls were $8,931 vs. $409 PPPM (adjusted difference $8,138) at 1 month, and $3,829 vs. $403 PPPM (adjusted difference $3,098) over 12 months. Total HRU costs comprised 17.6% versus 16.0% of the total incremental costs associated with MDD and SI/SA.

**CONCLUSIONS:** Patients with MDD and SI/SA had higher HRU and costs compared to non-MDD controls. Inpatient and ED costs drove the incremental costs of MDD and SI/SA.

**SPONSORSHIP:** Janssen Scientific Affairs.
BACKGROUND: The estimated prevalence of comorbid major depressive disorder (MDD) is 11% in patients with diabetes and 15% in those with cardiovascular disease (CVD). Comorbid MDD continues to be a significant source of economic burden to the healthcare system.

OBJECTIVE: To assess the incremental clinical and economic burdens of comorbid MDD in patients with type 2 diabetes or CVD.

METHODS: This real-world, retrospective, administrative claims study analyzed commercially insured adults with type 2 diabetes or CVD diagnosed on at least 2 separate claims within 12 months of each other (between January 1, 2011, and September 30, 2018). CVD included congestive heart failure, peripheral vascular disease, coronary heart disease, and cerebrovascular disease. The study compared patients with and without MDD who had either type 2 diabetes or CVD. Study assessments included all-cause healthcare resource utilization (proportion of patients with hospitalization, emergency department [ED] visits, and outpatient visits) and cost.

RESULTS: Patients were propensity score matched for demographics and baseline characteristics, resulting in similar baseline characteristics for the respective subcohorts. After matching, 22,892 patients with type 2 diabetes (11,446 each with and without MDD) and 28,298 patients with CVD (14,149 each with and without MDD) were included. At follow-up, diabetic patients with MDD had significantly higher rates of hospitalization (26.1% vs. 17.4%, P<0.0001) and ED visits (55.3% vs. 43.0%, P<0.0001) than patients without MDD. The total cost for diabetic patients with MDD at follow-up was significantly higher than for those without MDD ($16,511 vs. $11,551, P<0.0001). Similarly, CVD patients with MDD had significantly higher rates of hospitalization (45.4% vs. 34.1%, P<0.0001) and ED visits (66.5% vs. 55.4%, P<0.0001) than patients without MDD at follow-up. Total cost at follow-up for CVD patients with MDD was significantly higher than for those without MDD ($25,546 vs. $18,041, P<0.0001).

CONCLUSIONS: Patients with either type 2 diabetes or CVD and comorbid MDD have higher total all-cause healthcare utilization and cost than similar patients without MDD. Study findings reinforce the need for appropriate management of MDD in patients with these comorbidities, which in turn may result in cost reductions for payers.

SPONSORSHIP: Takeda Pharmaceuticals U.S.A. and Lundbeck.

G9 Impact of OFF Periods on Aspects of Employment for People with Parkinson's Disease

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Acorda Therapeutics

BACKGROUND: Parkinson’s disease (PD) can have a financial burden on patients and their families. To better understand the burden, The Michael J. Fox Foundation for Parkinson’s Research (MJFF) and the Parkinson’s Foundation deployed the Financial and Social Impact of Parkinson’s Disease Survey to assess the financial burden of PD.
OBJECTIVE: To characterize the impact of OFF periods on aspects of employment for people with PD who have OFF periods (re-emergence of Parkinson's symptoms) compared to those who do not experience OFF periods.

METHODS: Survey results presented here are data gathered from September 17, 2018 to October 8, 2018. One survey per person with PD (PwP) was completed voluntarily online by the PwP, care partner, family member, or close friend of the PwP. Data on respondents who reported experiencing OFF periods in the past 12 months were compared to data from those who did not report experiencing OFF periods. Analyses include the percentage of missed work days and the percentage of days with reported low productivity due to PD.

RESULTS: From a total of 1,602 Fox Insights survey respondents, 70% were PwPs and 20% were their care partner, family member, or close friend. Among all respondents, 35% (n = 881) reported the PwP as having OFF periods, 27% (n = 434) reported no OFF periods, and 18% (n = 287) did not know or did not respond. 20% (n = 176) of respondents experiencing OFF periods reported working full- or part-time compared to 21% (n = 90) of respondents without OFF periods. 72% of PwPs with OFF periods had some days with reduced work productivity vs. 43% of those without OFF periods. 48% of PwPs with OFF periods averaged at least 10 days with low productivity a month, vs. 29% of PwPs without OFF periods. 34% of PwPs with OFF periods missed at least 3 working days/month on average because of PD, compared to 21% of PwP with no OFF periods. Additional analyses will be presented in the poster.

CONCLUSIONS: In this analysis of the MJFF and the Parkinson's Foundation Financial and Social Impact of Parkinson's Disease Survey, missing work days and numbers of work days with low productivity were reported more frequently for PwPs experiencing OFF compared to PwPs not experiencing OFF. More effective management of OFF periods and other PD symptoms may alleviate this burden on people with PD.

SPONSORSHIP: Teva Pharmaceuticals.

G11 Cost-Effectiveness Analysis of Opicapone and Entacapone in Parkinson's Disease: An Incremental OFF-Time Model in the United States

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BACKGROUND: Opicapone is a highly selective once-daily catechol-O-methyltransferase (COMT) inhibitor under development in the United States as an adjunct to levodopa in patients with Parkinson's disease (PD). COMT inhibitors prolong the clinical actions of levodopa, and the efficacy of opicapone in reducing OFF-time was demonstrated in two multinational Phase 3 trials (BIPARK-1 [NCT01568073], BIPARK-2 [NCT01227655]). In a previous cost-effectiveness model of entacapone, an older FDA-approved COMT inhibitor, patients with PD transitioned between health states with defined cutoffs based on the percentage of OFF-time. In contrast, our model applied an incremental approach to evaluate the impact of reducing absolute OFF-times on costs and quality-adjusted life years (QALYs).

OBJECTIVE: To evaluate the cost-effectiveness of opicapone and entacapone as adjunctive therapy to carbidopa/levodopa for the treatment of PD.

METHODS: A Markov model was developed to estimate the cost-effectiveness of PD treatment with entacapone as compared to opicapone over a lifetime horizon (25 years) in a patient population with a starting age of 64 years. Clinical inputs included efficacy results from the active-controlled and non-inferiority trial between opicapone and entacapone (BIPARK-1), other published literature, and assumptions...
RESULTS: Patients treated with opicapone had lower PD medical and overall costs compared to entacapone. Treatment with opicapone or entacapone resulted in equal life years (11.0); however, opicapone treatment resulted in slightly increased QALYs (7.09 vs. 7.02) and decreased total OFF-time (26,569 vs. 27,756 hours). Probabilistic sensitivity analysis estimated that at a willingness-to-pay threshold of $50,000/QALY, opicapone has a 61% chance of being cost-effective over entacapone.

CONCLUSIONS: Over a lifetime horizon, opicapone was associated with increased QALYs. However, the non-inferiority design of BIPARK-1 led to a degree of higher uncertainty in this Markov model, which should be considered when interpreting the results presented here.

SPONSORSHIP: Neurocrine Biosciences.

G13 Advancing the Development and Execution of Outcomes-Based Risk-Sharing Agreements in the U.S.

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BACKGROUND: Opportunities and barriers exist for the development and implementation of outcomes-based risk-sharing agreements (OBRSAs) for pharmaceuticals.

OBJECTIVE: To describe key learnings from a multi-year initiative designed to inform OBRSAs methodology, design, and engagement approaches.

METHODS: A learning laboratory was conducted by a pharmaceutical manufacturer and an information and technology-enabled health services business. Actuarial modeling and a retrospective observational study informed an OBRSAs simulation model, which estimated financial value under specific guarantee, target population, clinical outcomes, formulary and contracting conditions, from the perspectives of payers and pharmaceutical manufacturers. An assessment was also conducted to ascertain how health care policies, regulations, and related contextual factors shape the OBRSAs environment. The initiative focused on two therapeutic areas: prodromal Alzheimer’s disease, a chronic, progressive condition predominately managed in an outpatient setting, and Clostridium difficile infection, which causes symptoms ranging from severe diarrhea to life-threatening inflammation of the colon, and is treated in inpatient and outpatient settings.

RESULTS: The use of real-world data and working in partnership provided learning opportunities beyond those obtained from traditional transactional engagements. The insights illuminated differences in working cultures, terminology, methods, and value drivers, and provided an operational platform to derive OBRSAs across therapeutic areas. Examples of key learnings included the need to align on: (1) terminology and key concepts, (2) definitions of value and financial risk, (3) relevant costs, measurement methods, and quantification of financial risk, (4) integration of actuarial and health economic and outcomes research (HEOR) principles and methods, (5) time horizon and acceptability of clinical and financial outcomes, and (6) feasibility of policy constraints and/or opportunities. Consistent with the lack of standards for the implementation and adjudication OBRSAs contracts, there are also no standards for designing models to simulate and test.
the implications of different contract designs, nor are there common, simple output measures to define the model outcomes.

**CONCLUSIONS:** The experience demonstrated that development and execution of OBRAs should be viewed as a vehicle for partnership, rather than financial transactions alone. Such partnerships require alignment on the values pursued, acknowledgment of respective benefits and risks, and mutual commitment on the OBRAs methods and responsibilities.

**SPONSORSHIP:** Merck and Co.

**G16 Cost Burden of Relapses in Patients with Multiple Sclerosis**

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**BACKGROUND:** Relapsing multiple sclerosis (RMS) is characterized by episodes of neurological dysfunction followed by periods of varying recovery. Recurrent relapses throughout the course of the disease can be severe and can lead to substantial cost burden.

**OBJECTIVE:** To characterize the direct medical healthcare costs associated with relapses in MS patients, and to understand how this differs by the level of relapse severity.

**METHODS:** A retrospective cohort study using MarketScan Commercial Claims and Encounters and the Medicare Supplemental and Coordination of Benefits Database included patients aged ≥18 years with ≥1 diagnosis of MS and 12-months continuous enrollment (CE) pre- and post-MS diagnosis. Patients were identified from 01/01/2013-03/31/2017. The total annual costs (all-cause and MS related) were examined over 12 months post index period, stratified by severity of relapse defined as: (a) severe relapse (SR): claim for MS-related hospitalization; (b) mild/moderate relapse (MMR): claim for outpatient or ER visit with MS as primary diagnosis followed by a corticosteroid medication within 7 days; or (c) no-relapse (NR): no relapse in the identification period. For patients with a relapse, the index date was defined as the date of the most severe relapse during the identification period. For patients without relapse, it was defined as the date of the second MS diagnosis. Multivariable generalized linear models were conducted, controlling for baseline age, gender, region, and insurance type.

**RESULTS:** Out of 8,775 patients in the final cohort, 505 (6%), 1,929 (22%), and 6,341 (72%) patients were included in SR, MMR and NR groups, respectively. Overall, patients were mostly female (76%), mean age was 50 years and 25% were on a DMT. Patients with MMR incurred a higher incremental all-cause cost of $19,369 vs. patients with no relapse. Similarly, SR incurred $46,485 more costs vs. patients with NR (all-cause cost: SR: $87,979 vs. MMR: $60,863 vs. NR: $41,494). Similarly, patients with SR and MMR had higher MS related costs vs. those with no relapse (MS-related cost: SR: $69,586 vs. MMR: $43,233 vs. NR: $24,730). Similar trend for increase in cost by relapse severity was observed in the adjusted analysis.

**CONCLUSIONS:** The total annual cost of relapse is high among MS patients, and increases with the severity of the relapse. Treatment with an effective DMT could reduce the severity of relapses, and thereby reducing the cost of care of MS patients.

**SPONSORSHIP:** Novartis Pharmaceuticals.
BACKGROUND: Acute inpatient hospitalizations and readmissions have not been well described for patients with severe forms of refractory epilepsy including Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), and tuberous sclerosis complex (TSC).

OBJECTIVE: To characterize inpatient hospital admission diagnosis, intensive care unit (ICU) use, length of stay (LOS), and readmissions for patients with probable LGS, DS, TSC, and other refractory epilepsies in U.S. commercial and Medicaid plans.

METHODS: Patients were identified in the 2010-2015 MarketScan Commercial and Medicaid databases if they had (1) ≥1 diagnosis code for TSC or (2) ≥1 antiepileptic drug and ≥1 diagnosis code for refractory epilepsy. Patients with an acute inpatient hospitalization (≥1 day LOS) were selected if their first hospitalization was preceded by 180 days of continuous enrollment and claims evidence of epilepsy or TSC. Patients were also required to have ≥12 months continuous enrollment after the discharge date of their index hospitalization unless they had claims evidence of in-hospital death. Using a previously developed algorithm, identified patients were further stratified into 4 hierarchical cohorts: TSC, DS, LGS or other refractory epilepsies. The primary admit diagnosis was used to classify hospitalizations as related to epilepsy, bacterial or aspiration pneumonia, injury, or other. Readmissions were measured over the 12-month post-discharge period.

RESULTS: A total of 11,621 commercial patients (2,520 LGS, 174 DS, 474 TSC, 8,453 other) and 13,150 Medicaid patients (4,613 LGS, 303 DS, 454 TSC, and 7,780 other) were identified with an acute inpatient hospitalization in 46-58% of LGS, 63-70% of DS, 26% of TSC, and 37-51% of other refractory epilepsy patients, by health plan type. Pneumonia-related hospitalizations were injury-related. The presence of a migraine-related event was defined as 1 inpatient visit or 2 outpatient visits with a migraine diagnosis. Multivariable regression and geographic information systems (GIS) analyses controlling for demographics, medications, comorbidities, regions, and resource utilization.

RESULTS: From 2013-2017, 24,835 migraine-related claims were observed in the Oklahoma Medicaid population, with 90.5% occurring in females. Among females, 7.3% aged 40-49 experienced a migraine-related event, with 66.4% of events involving white race, and 51.7% in metropolitan areas. The most common comorbidities among females with a migraine event were hypertension (30.0%), COPD (24.4%), asthma (19.3%), type 2 diabetes mellitus (11.9%), and hyperlipidemia (10.9%). Among patients with migraine-related claims, 49.9% of females were prescribed a triptan medication, with other medications including opioids (80.8%), antidepressants (66.3%), NSAIDs (64.6%), and systemic corticosteroids (58.0%). Among those involving opioid use, 71.0% had >1 prescription opioid claim for that year. The multivariable GIS regression indicated that county-level clustering was statistically significant, yet explained a small amount of variation in migraine prevalence (Intraclass correlation =0.01, P<0.05).

CONCLUSIONS: High rates of opioid use among migraine patients present an important opportunity for intervention. Identifying factors and potential clustering of high prescribing associated with treatment patterns and outcomes is an important component of developing sound implementation strategies.

SPONSORSHIP: Amgen.
weeks) in adults with CM. For this psychometric evaluation, patient-reported outcome data from COMPEL were prospectively collected over 48 weeks, and data from day 1 and week 48 were used. Factor structure, reliability, validity, and ability to detect change were evaluated.

**RESULTS:** 713 patients with CM provided baseline data and 506 provided data at the 48-week follow-up. Analysis of item-level results and clinical guidance of the 24 items led to the removal of 4 FIMQ items.

**CONCLUSIONS:** The FIMQ demonstrates good internal consistency across the 3 subdomains (0.84 to 0.95). The FIMQ significantly differentiated across some MIDAS disability levels at baseline and across all MIDAS disability levels at week 48 supporting known groups validity. Concurrent validity was supported based on correlations with selected domains of the Migraine-Specific Quality of Life questionnaire v2.1 (range -0.69 to -0.82) and the 6-item Headache Impact Test (HIT-6, range 0.56 to 0.70). Anchor-based analyses with HIT-6 and distribution-based results indicated that the FIMQ detected within-patient treatment change over 48 weeks. The scores of the final 20 items were standardized on a scale from zero to 100, with higher scores indicating greater levels of impairment.

**SPONSORSHIP:** Allergan plc.

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**G24 Ten-Year Cost-Effectiveness Analyses of Fremanezumab Compared to No Treatment as a Preventive Treatment in Chronic and Episodic Migraine for Patients with Inadequate Response to Prior Preventive Treatments**

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**BACKGROUND:** Fremanezumab, a fully humanized monoclonal antibody (lgG2Δα) that selectively targets calcitonin gene-related peptide, is approved for preventive treatment of migraine in adults.

**OBJECTIVE:** To evaluate cost-effectiveness of fremanezumab compared to no treatment for the prevention of chronic (CM) and episodic migraine (EM) in patients who had responded inadequately to 2 to 4 classes of prior preventive treatments.

**METHODS:** A semi-Markov cost-effectiveness model (CEM) was developed with a 4-week cycle and 10-year analysis time horizon. Costs and benefits were discounted at 3.0% annual rates. Treatment efficacies were incorporated as reductions in mean migraine days (MDs)/28 days versus placebo. Patient cohorts were distributed among MD categories (0-28 MDs/28 days) based on mean MD levels. The CEM estimated costs (fremanezumab acquisition costs, MD-related costs [direct and indirect]) and health-related quality of life (MD- and treatment status-based utilities) for fremanezumab and no-treatment arms. Only background mortality was modeled. Outcome measures were costs, reduction in MDs, and quality-adjusted life-years (QALYs). Analyses were performed on a combined CM (67%)/EM (33%) population. Incremental cost-effectiveness ratios (ICERs) were reported as cost/QALY gained between fremanezumab and no treatment.

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**G23 Higher Healthcare Resource Utilization and Costs Among Patients with Potentially Insufficient Response to Triptans**

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**BACKGROUND:** Triptans are the most commonly prescribed class of medication for the acute treatment of migraine attacks; however, real-world observational studies have demonstrated low persistence. Data related to healthcare resource utilization and cost among patients with migraines inadequately managed by triptans are limited.

**OBJECTIVE:** To characterize healthcare resource utilization and cost among new users of triptans in a commercially insured U.S. population over a 24-month period.

**METHODS:** The analysis included adults with ≥1 triptan claim between January 1, 2013 and December 31, 2013 (first claim assigned as index date) and ≥12 months of pre-index 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. Migraine-related inpatient, outpatient, and emergency department (ED) visit frequencies, as well as all-cause total cost, migraine-related total cost, and migraine-related medical cost, were examined. Triptan users who refilled only triptan prescriptions (index and non-index) were considered optimized; new users who did not refill their index triptan but used non-triptan acute treatments, or new users who continued using a triptan but supplemented it with non-triptan acute treatments for migraine, were considered not optimized (i.e., potential triptan insufficient responders [TIRs]). Triptan users who did not refill their index triptan or any other acute medication for migraine were excluded.

**RESULTS:** Of the 7,473 new triptan users included in the analysis, 3,102 (41.5%) were potential TIR patients. Over the 24-month period, potential TIR patients had more migraine-related physician visits, inpatient visits, and ED visits (all P < 0.05), as well as higher all-cause total costs, migraine-related total costs, and migraine-related medical costs (all P < 0.05), than patients who continued to use only triptans.

In addition, adjusted total (medical and pharmacy) migraine-related costs were $2,905 higher in months 0-12 post-index and $2,615 higher in months 13-24 post-index for potential TIR patients than for those with potentially sufficient response to triptans.

**CONCLUSIONS:** Patients with potentially insufficient response to triptans have higher healthcare resource utilization and higher migraine-related total costs than those with potentially sufficient response to triptans. These findings indicate an unmet need for effective acute treatments for migraine attacks.

**SPONSORSHIP:** Allergan plc.
CONCLUSIONS: Based on current pricing and RCT results, fremanezumab treatment resulted in a cost/QALY ICER of $31,998, with average incremental costs of $10,285/patient. Where placebo effects were included, fremanezumab treatment resulted in a cost/QALY ICER of $48,925, with average incremental costs of $7,650/patient, incremental QALYs of 0.156, and an 83.6-day reduction in MDs.

RESULTS: In base-case, 10-year analysis time horizon, fremanezumab treatment dominates no treatment (less costly, more effective): average cost savings, $3,492/patient; incremental QALYs, 0.22; and reduction in MDs, 161.5 MDs. Excluding indirect costs, fremanezumab treatment resulted in a cost/QALY ICER of $13,606, with average incremental costs of $2,998/patient. When placebo effects were included, fremanezumab treatment dominates no treatment (less costly, more effective): average cost savings, $13,905/patient; incremental QALYs, 0.412; and reduction in MDs, 353.9 MDs.

CONCLUSIONS: Based on current pricing and RCT results, fremanezumab treatment is cost-effective versus no treatment, especially if treatment is halted at 12 weeks for non-responders, as defined in the analysis.

SPONSORSHIP: Teva Pharmaceuticals.

**G26** Ten-Year Cost-Effectiveness Analyses of Fremanezumab Compared to Erenumab as Preventive Treatment in Episodic Migraine for Patients with Inadequate Response to Prior Preventive Treatments

**BACKGROUND:** Fremanezumab, a fully humanized monoclonal antibody (IgG2Δa) that selectively targets calcitonin gene-related peptide, is approved for the preventive treatment of episodic migraine in adults.

**OBJECTIVE:** To evaluate the cost-effectiveness of fremanezumab versus erenumab for the prevention of episodic migraine (EM) in patients who had responded inadequately to 2 to 4 classes of prior preventive treatments.

**METHODS:** A semi-Markov cost-effectiveness model (CEM) was developed with a 4-week cycle and 10-year analysis time horizon. Costs and benefits were discounted at 3.0% annual rates. Treatment efficacies were incorporated as reductions in mean migraine days (MDs)/28 days versus placebo. Patient cohorts were distributed among MD categories (0-28 MDs/28 days) based on mean MD levels. The CEM estimated costs (fremanezumab acquisition and MD-related costs [direct and indirect]) and health-related-quality-of-life (MD- and treatment status-based utilities) for fremanezumab and no-treatment arms. Only background mortality was modeled. Outcome measures were costs, reduction in MDs, and quality-adjusted life-years (QALYs). Analyses were performed on a combined CM-EM population (67% CM, 33% EM). CM/EM patients not achieving a 30%/50% reduction in MDs/28 days at 12 weeks, respectively, i.e., non-responders, stopped fremanezumab treatment. The incremental cost-effectiveness ratio (ICER) was reported as cost/QALY gained between fremanezumab and no treatment. Fremanezumab MDs/28-day reductions versus placebo and 12-week non-response rates were sourced from a Network Meta-Analysis (NMA). The analysis assumed the same discontinuation rate for fremanezumab and erenumab.

**RESULTS:** In the base-case, 10-year analysis time horizon, fremanezumab treatment dominates erenumab (less costly, more effective), with an average incremental cost savings of $1,795/patient, incremental QALYs of 0.037/patient, and a reduction in MDs of 33.3 MDs/patient. Excluding indirect costs, fremanezumab still dominates erenumab with an average incremental cost savings of $936.96/patient.
**BACKGROUND:** Partial onset seizures (POS) are a common form of epilepsy treated with anti-epilepsy drugs (AEDs). Most AEDs act by attenuating calcium and/or sodium channels or enhancing inhibitory signals. Perampanel, a novel extended half-life AED, uniquely inhibits the excitatory AMPA glutamate receptor and clinical trials have shown it is an efficacious treatment for epilepsy. It is approved in POS and as adjunct in primary generalized tonic clonic (PGTC) seizures for patients ≥ 12 years old. Recently, it gained approval in POS for pediatric patients 4-11 years old.

**OBJECTIVE:** To estimate the one-year budget impact of utilizing perampanel in pediatric patients with POS from a U.S. commercial payer perspective.

**METHODS:** A Microsoft Excel-based model was developed to assess the costs to commercial payers of treating children 4-11 years old with perampanel. Using a hypothetical plan of 1 million members, the model compared a baseline year without perampanel market share, versus a comparator year with 2.5% perampanel market share.

- Model inputs, including drug costs, eligible patients, market share of included products and healthcare utilization rates and costs, were based on pricing guides, published literature, and analyses of commercial claims data.
- Increased perampanel market share was shifted from alternative brand only competitors (i.e., brivaracetam, eslicarbazepine and lacosamide).
- Model outcomes included total annual plan costs, per-member per-month (PMPM) costs and cost per treated patient (PTP).

**RESULTS:**

- Among an initial plan of 1 million members, we estimated that 163 patients aged 4-11 were treated for pediatric POS.
- Perampanel’s daily acquisition cost was estimated to be $29.90, with branded competitors ranging from $29.94 to $35.67. In the scenario where 2.5% of the pediatric population received perampanel, the annual plan cost decreased by $10,880 ($0.00 PMPM). Annual cost PTP for perampanel was $18,212, compared with PTP costs of $20,241, $17,090 and $21,467 for branded competitors.

**CONCLUSIONS:** Utilizing perampanel within a population of pediatric patients 4-11 years old with POS can have a negligible impact on costs while providing clinicians an effective treatment alternative. These findings can be used to inform formulary decision making. Additional analyses should be conducted to compare these findings to real-world healthcare resource utilization.

**SPONSORSHIP:** Eisai.
BACKGROUND: Three self-injectable calcitonin gene-related peptides (CGRPs) biologic monoclonal antibody medications for migraine prophylaxis were recently approved, erenumab-aooe (eren) May 2018, fremanezumab-vfrm (frem) and galcanezumab-gnlm (galc) September 2018. With generic oral migraine prophylaxis agents and provider injected botulinum toxin available, it is important for stakeholders to understand real-world CGRP uptake. It is anticipated acute migraine medication use, such as opioids, triptans, and ergotamines, would decline after chronic migraine prophylaxis therapy initiation. Sparse real-world data is available to assess CGRP uptake or change in acute migraine medication use after CGRP initiation.

OBJECTIVE: To describe CGRP uptake and associated changes to acute migraine medication use in a large national commercially-insured population.

METHODS: Integrated medical and pharmacy claims data among 15 million commercially insured members were queried from May 2018 through Mar 2019 to identify monthly rate of members initiating CGRP’s. Members’ first CGRP pharmacy claim was their index date. Members continuous enrolled 6 months prior (pre-period) and 6 months after (post-period) CGRP index date were evaluated for changes in acute migraine medication use from the pre-index to post-index period. Acute migraine medication use, in pre/post period, was defined as one or more claims in the categories of opioids, triptans, or ergotamines.

RESULTS: 5,680 commercially insured members had at least one CGRP pharmacy claim from May 2018 to March 2019. Members newly initiating a CGRP increased steadily from 6 in May 2018 to 1,032 in March 2019. Eren increased steadily from 6 in May 2018 to 610 in November 2018, then leveled off. Fre increased from 10 in September 2018 to 111 in January 2019, falling to 94 in March 2019. Galc increased steadily from 31 in October 2018 to 326 in March 2019. Of the 632 members new to CGRP meeting continuous enrollment criteria, presence of an opioid claim decreased 4.6% from pre (41.1%) to post (39.2%) period; triptans had a 9.8% reduction (64.4 % to 58.1%) and ergotamines a 22.2% reduction (4.3% to 3.3%).

CONCLUSIONS: Although CGRP utilization prevalence is 7 per 100,000 as of March 2019, uptake increased rapidly since launch. The minimal decrease in acute migraine medication use, defined as no claims in the 6 months, after CGRP initiation is not surprising as chronic migraines are difficult to treat, greater reductions are expected among those persisting on CGRPs over 6 months. These findings are important as CGRP clinical program management and value-based contacts are developed to manage this drug class.

SPONSORSHIP: Ameet.

G41 Predictors of Preventive Therapy Non-Persistence Among Patients with Migraine

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BACKGROUND: Migraine management is characterized by poor persistence with preventive medications. Understanding characteristics associated with treatment pattern changes may help improve preventive therapy persistence.

OBJECTIVE: To describe rates and predictors of non-persistence with preventive migraine medications among commercially-insured migraine patients.

METHODS: We conducted a retrospective study evaluating adult patients with migraine initiating preventive migraine medication between 01/01/2012-09/30/2016 (first treatment = index date) in the IBM MarketScan Research Databases. Patients were required to be continuously enrolled for at least 12 months pre- and post-index. Treatment patterns were evaluated by generic drug, by drug category, and for all drugs combined, and included measures of persistence, switching, discontinuation, and augmentation. We used logistic regression models to identify predictors of non-persistence and non-persistence due to discontinuation without restart. Models were adjusted for preventive drug category, demographics, pre-index comorbidities, and use of pre-index acute migraine medications.

RESULTS: A total of 95,646 patients initiated preventive migraine medications (antidepressants: 36%; anticonvulsants: 32%; antihypertensives: 24%; botulinum toxins: 2%, other: 7%). Across the measures, persistence at 12-months was low (20-28%), and the most common reason for non-persistence was discontinuation without restart (44-50%). Risk factors for non-persistence were male sex, select pre-index conditions (chronic pain, constipation, non-migraine headache, menopause or menopause-related symptoms, and nausea/vomiting), and pre-index use of NSAIDs and strong opioids. Patients receiving antidepressants, antihypertensives or botulinum toxins at index were less likely to be non-persistent than patients treated with anticonvulsants. Among non-persistent patients, greater comorbid burden was associated with a lower odds of non-persistence due to discontinuation without restart-less healthy patients were more likely to restart or switch to a new medication.

CONCLUSIONS: Persistence on preventive migraine medications was low across all categories examined. Migraine patients with chronic pain, prior use of NSAIDs and strong opioids had higher odds of non-persistence. Determining the causes of non-persistence among these patients may improve migraine therapy persistence, and potentially, quality of life.

SPONSORSHIP: Prime Therapeutics.
BACKGROUND: Dry eye disease (DED) is a multifactorial disease of the ocular surface, characterized by loss of homeostasis of the tear film. DED is a common and chronic condition, and incurs significant economic burden for both patients and healthcare systems. Cyclosporine ophthalmic solution 0.09% is a calcineurin inhibitor immunosuppressant indicated and approved to increase tear production in patients with DED.

OBJECTIVE: To assess the budget impact of introducing cyclosporine ophthalmic solution 0.09% for the treatment of patients with DED from the perspective of a hypothetical U.S. health plan.

METHODS: A budget impact model was developed to estimate the costs before and after the adoption of cyclosporine ophthalmic solution 0.09% by a health plan with 1,000,000 members over a 5-year time horizon. The patient population included adult patients diagnosed with DED who were receiving a branded prescription medication. The comparators were U.S. FDA approved treatments for DED: cyclosporine ophthalmic emulsion 0.05%, cyclosporine ophthalmic emulsion 0.05% unit dose and multidose, respectively, and lifitegrast ophthalmic solution 5%. DED prevalence was based on published literature and U.S. Census data. Only pharmacy costs were included, based on 2019 wholesale acquisition costs. The incremental annual health plan cost, cost per member per year (PMPY), and cost per member per month (PMPM) were estimated in U.S. $2019, assuming a 1% annual increase in uptake for cyclosporine ophthalmic solution 0.09% over 5 years.

RESULTS: Among a health plan of 1,000,000 members, 7,388 members in a commercial plan and 21,202 members in a Medicare plan would be treated with a branded prescription medication for DED each year. The total annual cost for a commercial plan after introducing cyclosporine ophthalmic solution 0.09% decreased by $33,716, $67,779, $100,368, $135,846, and $168,436 in years 1 through 5, respectively, resulting in a cumulative reduction of $506,144. For a Medicare plan, the total cost over 5 years decreased by $1,452,579 after adoption of cyclosporine ophthalmic solution 0.09% ($96,761, $194,517, $288,046, $389,683, and $483,392 reduction in years 1 to 5, respectively). The incremental PMPY and PMPM costs each year were negligible for both commercial and Medicare payers.

CONCLUSIONS: Adding cyclosporine ophthalmic solution 0.09% with a 1% annual uptake over 5 years has the potential to reduce the cost of treating patients with DED for health plans.

SPONSORSHIP: Sun Pharmaceutical Industries.
evaluated over the 12-month follow-up period. Visual acuity data was not available.

**RESULTS:** Among patients that met the selection criteria, 5,489 initiated aflibercept and 4,253 initiated ranibizumab. Aflibercept patients had a mean (SD) age of 78.8 (6.8) years and were 61.1% female, while ranibizumab patients had a mean (SD) age of 79.8 (6.5) years and were 62.1% female. Among aflibercept eyes that maintained treatment up to month 12 (n=3,262), 33.5% received an injection less than every 8 weeks (<q8w), 35.1% received an injection q8w to <q12w, and 31.4% received an injection ≥q12w. Among ranibizumab eyes that maintained treatment up to month 12 (n=2,035), 38.1% received an injection <q8w, 29.1% received an injection q8w to <q12w, and 32.8% received an injection ≥q12w. Aflibercept and ranibizumab eyes received a mean (SD) of 5.0 (2.8) and 5.0 (3.0) injections, respectively.

**CONCLUSIONS:** A substantial percentage of patients with nAMD that receive aflibercept or ranibizumab require treatment <q8w. Given the high burden associated with management of nAMD, patients can benefit from more effective therapies with less frequent dosing.

**SPONSORSHIP:** Novartis Pharmaceuticals.

**Impact of Valsartan Drug Recalls on Medication Adherence in Medicare Part D Patients**

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**BACKGROUND:** In July 2018, the U.S. Food and Drug Administration (FDA) announced a voluntary recall of medications containing valsartan, used to treat hypertension, due to a carcinogenic impurity introduced in the manufacturing process. Additional manufacturer recalls occurred through the remainder of the year. The scope of impact on the Medicare population and effect on year-end medication adherence rates are unknown.

**OBJECTIVE:** To estimate the impact of these recalls on medication adherence within a large Medicare Advantage (MAPD) and stand-alone Prescription Drug (PDP) plan.

**METHODS:** Pharmacy claims data were examined for members from WellCare MAPD and PDP plans meeting qualifying guidelines for the PQA adherence measure for Renin Angiotensin System Antagonists in 2017 or 2018. Members were defined as impacted by recalls if the National Drug Code (NDC) of their first prescription fill in the given year matched a recalled NDC. We compared year-over-year adherence rates between groups impacted and unaffected by valsartan recalls. An unadjusted estimate of the recall impact on adherence was calculated by multiplying this difference by the percentage of affected membership in 2018.

**RESULTS:** Overall, 7.0% of MAPD members and 8.5% of PDP members met the selection criteria. The recalls were estimated to have reduced 2018 adherence rates by 0.17 percentage points on average across MAPD contracts and by 0.13 points for the PDP contract. MAPD and PDP members affected by recalls on average missed 0.3% and 0.1% more medicated days than unaffected members, respectively. By year end, 70% of MAPD members and 68% of members impacted by recalls had switched to a new medication.

**CONCLUSIONS:** In 2018, a sizable percentage of Medicare patients were affected by recalls of blood pressure medications containing valsartan, used to treat hypertension, due to a carcinogenic impurity introduced in the manufacturing process. Additional manufacturer recalls occurred through the remainder of the year. The scope of impact on the Medicare population and effect on year-end medication adherence rates are unknown.

**Spots:**

**Cost-Effectiveness of Latanoprostene Bunod Compared to Prostaglandin Analogs for Primary Open-Angle Glaucoma**

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**BACKGROUND:** Primary open-angle glaucoma (POAG) is a leading cause of visual disability and costs in the United States. Treatment involves lowering of intraocular pressure (IOP), commonly with topical prostaglandin analogues (PGAs). Evaluation of new IOP-lowering agents requires assessing safety and efficacy; adoption often considers cost and patient-reported outcomes. The cost-effectiveness of a nitric oxide-donating PGA, latanoprostene bunod (LBN) ophthalmic solution 0.024%, has not yet been evaluated.

**OBJECTIVE:** To compare the cost-effectiveness of LBN with branded PGAs for the treatment of POAG.

**METHODS:** A decision-analytic model estimated clinical and health utility outcomes for LBN compared to an aggregate branded PGA alternative, developed using market-based distributions and weighted effectiveness, safety and cost estimates, over two years in three-month cycles. Clinical inputs (effectiveness, hyperemia rates) were derived from prescribing information and published papers. Treatment patterns from guidelines and published studies informed resource use estimates. Health utilities were assigned to health states based on published estimates. A U.S. Medicare payer perspective was used; costs are presented in $US 2018. Outcomes were discounted at 3% annually. Sensitivity analyses examined the influence of key parameters.

**RESULTS:** Among patients that met the selection criteria, 5,489 initiated aflibercept and 4,253 initiated ranibizumab. Aflibercept patients had a mean (SD) age of 78.8 (6.8) years and were 61.1% female, while ranibizumab patients had a mean (SD) age of 79.8 (6.5) years and were 62.1% female. Among aflibercept eyes that maintained treatment up to month 12 (n=3,262), 33.5% received an injection less than every 8 weeks (<q8w), 35.1% received an injection q8w to <q12w, and 31.4% received an injection ≥q12w. Among ranibizumab eyes that maintained treatment up to month 12 (n=2,035), 38.1% received an injection <q8w, 29.1% received an injection q8w to <q12w, and 32.8% received an injection ≥q12w. Aflibercept and ranibizumab eyes received a mean (SD) of 5.0 (2.8) and 5.0 (3.0) injections, respectively.

**CONCLUSIONS:** A substantial percentage of patients with nAMD that receive aflibercept or ranibizumab require treatment <q8w. Given the high burden associated with management of nAMD, patients can benefit from more effective therapies with less frequent dosing.

**SPONSORSHIP:** Novartis Pharmaceuticals.
These recalls measurably reduced therapy adherence at year-end. Additional recalls have taken place in 2019, and continued disruption to patients’ medication regimens should be expected. Patient outreach is vital to facilitate medication switching and ensure continued adherence during a recall.

**SPONSORSHIP:** RxAnte and WellCare Health Plans.

### Antihypertensive Agent Utilization Among Uncontrolled Hypertension Patients with Diabetes and Chronic Kidney Disease in the United States

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**BACKGROUND:** Hypertension affects roughly one out of every three adults and contributes to approximately 1,000 deaths per day United States. Objective: To investigate the landscape of antihypertensives utilized among patients, with health insurance, who have been diagnosed with hypertension and comorbid conditions that independently attributable to an increased risk of cardiovascular complications, received pharmaceutical treatment, and still experienced uncontrolled hypertension.

**METHODS:** Data were obtained from the Decision Resources Group Real World Evidence Data Repository U.S. database. Using the ICD-9-CM and ICD-10-CM codes and clinical lab values to define a cohort of uncontrolled hypertension patients with diabetes mellitus (DM) or chronic kidney disease (CKD). Defined by SBP $>$ 140 mmHg or DBP $>$ 90 mmHg for hypertension between Q1-2015 and Q4-2016. Univariate descriptive statistics, including means, standard deviations, and proportions were calculated for study variables.

**RESULTS:** The study cohort consisted of 5,067 patients, with an average age of 57.8 and 51.9% female. Patients were mostly Caucasian (86.8%), with 11% African American, and 1.3% Latino. Nearly 45% of the cohort had been diagnosed with at least one comorbid condition that independently attributable to an increased risk of cardiovascular complications. 1,662 (32.9%) patients were diagnosed with DM, 542 (8.2%) patient were diagnosed with CKD, and 200 patients (3.9%) were diagnosed with both DM and CKD. Among patients with a diagnosis of both DM and CKD, we observed the overall most common treatment observed in this cohort were diuretics (25.4%), followed by ACE inhibitors (17.8%), beta blockers (17.9%), CCBs (15.1%), ARBs (13.7%), centrally acting antihypertensives (2.0%), aldosterone antagonists (1.2%), and direct renin inhibitors (< 1.0). No prescriptions were written for ARNls. Among patients with a diagnosis of neither DM nor CKD, we observed the overall most common treatment observed in this cohort were diuretics (25.4%), followed by ACE inhibitors (17.8%), beta blockers (17.9%), CCBs (15.1%), ARBs (13.7%), centrally acting antihypertensives (2.0%), aldosterone antagonists (1.2%), and direct renin inhibitors (< 1.0). No prescriptions were written for ARNls.

**CONCLUSIONS:** This study demonstrates an overuse of beta-blockers and an underutilization of combination therapy. These findings illustrate the need to further investigate understanding of the barrier that both patients and providers face in treatment decision making.

**SPONSORSHIP:** None.
14 Implications of Payment for Acute Myocardial Infarctions as a Single Episode of Care

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BACKGROUND: In fee-for-service Medicare, CMS reimburses hospitals for inpatient services based on Medicare Severity Diagnosis Related Groups (MS-DRGs). With few exceptions, MS-DRG payments are invariant. To lower costs of care, CMS is experimenting with bundled payments: a single payment for services used during an episode of care. For acute myocardial infarction (AMI), the episode extends beyond discharge and hospitals are often the accountable provider for managing bundled payments.

OBJECTIVE: To compare Medicare reimbursement for AMI patients from the acute period through the 90-days following discharge (the “episode of care”) by inpatient treatment type: percutaneous coronary interventions (PCIs) vs. Medical Management (MM).

METHODS: We analyzed the CMS standard analytical files for 120,333 AMI hospitalizations between 10/1/15-9/30/16. Payments were standardized to remove geographic variation and separated into reimbursements for services during the hospitalization and from discharge to 90 days post-discharge. Results were stratified by MS-DRG individually and in aggregate for patients treated with MM and with PCI. All payments reported are means.

RESULTS: The highest total reimbursement for an AMI episode was for PCI and MM patients with major comorbidities or complications was $32,713 (MS-DRG 248), followed by $30,903 (MS-DRG 246), $29,251 (MS-DRG 280), $27,056 (MS-DRG 249), and $17,823 (MS-DRG 282). However, payment for the acute care services portion was a significantly higher proportion of the total reimbursement for PCI than for MM patients (71.4% vs. 40.3%). Patients receiving MM had acute reimbursement of $8,547 and post-discharge reimbursement of $12,674, with MS-DRG 280 receiving the highest payment for acute services ($13,062) and MS-DRG 282 the lowest ($6,786). Post-discharge reimbursement for MM ranged from $16,190 (MS-DRG 280) to $11,037 (MS-DRG 282). Patients receiving PCIs had acute reimbursement of $16,229 and post-discharge reimbursement of $6,498. Reimbursement for acute services ranged from $13,296 (MS-DRG 251) to $22,441 (MS-DRG 246). Post-discharge reimbursement for PCIs ranged from $8,461 (MS-DRG 246) to $12,079 (MS-DRG 250).

CONCLUSIONS: As the CMS Bundled Payments for Care Improvement Advanced and similar programs are implemented, there will be a need to account for heterogeneous post-discharge costs of care. MS-DRGs associated with the lowest reimbursements (and presumably, lowest costs of inpatient care) incur the highest post-discharge expenditures. Under an episode-based system of payment, it will be more difficult for conveners to manage a highly heterogeneous group of patients once discharged from the anchor stay.

SPONSORSHIP: CSL Behring.

15 Healthcare Resource Utilization and Costs Associated with Individuals with Type 2 Diabetes Only, Cardiovascular Disease, or Both

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BACKGROUND: Prior studies have assessed the risk of future cardiovascular events (CVE) in patients with type 2 diabetes (T2DM) alone, a prior history of CVE and those with both. Most of these studies have focused on the clinical outcomes and not examined the economic consequences associated with these cohorts and their CV risk.

OBJECTIVE: To estimate the healthcare resource utilization (HCRU) and costs in patients with either T2DM only, prior CVE only, both or controls.

METHODS: This retrospective study used administrative claims and mortality data in the HealthCore Integrated Research Database from 14 U.S. commercial/Medicare Advantage health plans. Patients were identified from 1/1/12 to 12/31/12 and placed into 1 of 3 groups: T2DM only, prior CVE only, or T2D and prior CVE both. Patients had 1:1 individually exact matched to controls on demographic characters. All-cause HCRU and costs were identified over follow-up and presented on a per patient per month (PPPM) basis due to variable follow-up. Generalized Linear Models were used to analyze HCRU and costs, adjusted for 1-year baseline all-cause HCRU/costs, age and gender.

RESULTS: A total of 638,301 patients were identified (377,205 with T2DM only, 130,964 with prior CVE only and 130,132 with both) and matched to controls. Follow-up time was similar between the groups (mean = 34-38 months). T2DM only patients were 8-9 years younger and had fewer comorbidities than prior CVE only and both groups. All-cause hospitalizations over the entire follow-up occurred in 22.6%, 40.7%, 46.4% and 19.6% of T2DM only, prior CVE only, both and controls respectively. All-cause total costs were $1,343, $1,910, $2,783, and $823 for the T2DM only, prior CVE only, both groups, and controls with all-cause medical costs reflecting 71%, 86%, 83% and 84% of the overall cost, respectively. Adjusted all-cause total costs were 1.48 (T2DM only), 1.49 (prior CVE only) and 1.93 (both) times higher compared to controls. All-cause medical costs followed this same pattern, while pharmacy costs were highest among the T2DM only group.

CONCLUSIONS: In this large, geographically broad U.S. cohort, increased HCRU and costs were observed across cohorts of patients with T2DM only, CV only and both conditions. Patients with both conditions were associated with the largest economic burden. These results provide some economic context around future CVEs in these patients and may suggest to payers and healthcare systems to focus on the joint management of CV and T2DM.

SPONSORSHIP: Boehringer-Ingelheim and Anthem.

16 Results from a High-Touch Clinical Program to Improve a Star Ratings Measure: Statin Therapy for Patients with Cardiovascular Disease

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Star Ratings Measure: Statin Therapy for Patients with Cardiovascular Disease

Magellan Rx Management
BACKGROUND: CMS implemented a 5-Star quality rating system for Medicare plans in order to drive quality improvement for beneficiaries. To assist a 17,000-member life Medicare plan in improving the quality of care delivered to their beneficiaries and maximizing Star Rating performance, the clinical team collaborated on the development and implementation of a pharmacist-led clinical program designed to specifically address the Star measure - Statin Therapy for Patients with Cardiovascular Disease (SPC). The SPC treatment rate is defined as the percentage of males 21-75 years old and females 40-75 years old who were identified as having clinical atherosclerotic cardiovascular disease (ASCVD) and who were dispensed at least one high or moderate-intensity statin medication during the measurement year.

OBJECTIVE: To improve the treatment rate for the CMS Star measure SPC by leveraging various methods of identification, prioritization, and clinical engagement.

METHODS: A clinical program was implemented to improve the SPC treatment rate through various methods of identification, prioritization, and clinical engagement. Through pharmacy and medical claims analyses, the target non-compliant population (those identified as having ASCVD with no moderate or high-intensity statin fill) was identified. The target population, consisting of 507 members, was prioritized for outreach based on several criteria including prior year use of a statin, presence of a statin claim rejection and/or reversal, current use of a low-intensity statin, and documented challenges with statin therapy (i.e., rhabdomyolysis). Various methods of clinical engagement were leveraged including pharmacist-led telephonic outreach to providers, members, and/or pharmacies in order get members initiated on high or moderate-intensity statin therapy and/or remove inappropriate members from the measure denominator.

RESULTS: For 2018 measurement year, the overall treatment rate improved from 83.0% to 86.0%, resulting in a 1-Star improvement from 2017 and 5-Star performance based on the current Star Rating thresholds.

CONCLUSIONS: Comprehensive identification, multifaceted prioritization, and active clinical engagement are all important tools in improving the treatment rates for clinical Star measures such as SPC. It has been estimated that a cumulative 1-Star improvement across all measures (from 3 to 4) is worth $50 per member per month. Such investment in clear clinical benefit, PCSK9is have been subject to stringent utilization management policies among payers since their introduction into the U.S. market in 2015.

OBJECTIVE: To assess changes over time in (1) baseline cardiovascular risk and (2) prescription approval rates in patients requesting PCSK9i therapy.

METHODS: This retrospective cohort study included patients with a PCSK9i prescription request in the nationally representative IQVIA medical and pharmacy databases (Formulary Impact Analyzer/Longitudinal Rx/Longitudinal Dx and Fully adjudicated claims) linked to the Prognos laboratory database (for low-density lipoprotein cholesterol [LDL-C] values). The study period was from 07/01/2013 to 12/31/2018 with an index period from 07/01/2015 (prior to the first approval of PCSK9i therapy in the U.S.) to 12/31/2018. The first request for PCSK9i was marked as the index date. A period of 28 days was allowed to determine the final approval status of the first requested PCSK9i coverage attempt for each patient.

RESULTS: Of the 199,349 patients in the PCSK9i cohort, mean (SD) age was 65 (11) years, 57.2% were ≥ 65 years old, 48.3% were men, 48.0% had commercial insurance, and 47.7% were Medicare beneficiaries. Approximately 62% of patients had at least 1 atherosclerotic cardiovascular disease (ASCVD) diagnosis. Risk factors, including mean LDL-C levels and the percentages of patients with ASCVD diagnoses and/or other comorbidities were relatively stable over the study period. Among those with LDL-C data, mean LDL-C values were 143.6 mg/dL at the most recent pre-index measurement, 150.3 mg/dL in the 4th quarter of 2015, and 134.6 mg/dL in the 3rd quarter of 2018. Although PCSK9i approval rates increased over time (28.3% approved in the 3rd quarter of 2015 vs. 42.2% approved in the 4th quarter of 2018), > 50% of PCSK9i prescription coverage requests were rejected.

CONCLUSIONS: In real-world clinical practice from 07/01/2015 to 12/31/2018, PCSK9is are documented to have been prescribed for patients at high risk for cardiovascular events, appropriately focusing on LDL-C reduction. Although the initial payer approval rates for PCSK9i therapy increased over time, overall approval rates remained below 50%.

SPONSORSHIP: Amgen.
METHODS: Using the IBM MarketScan Database, we identified patients with evidence of PAH between January 1, 2013 and July 31, 2018. Three cohorts were constituted: (1) prevalent PAH (all PAH patients in each calendar-year [CY]); (2) PPA new-starts; and (3) newly diagnosed PAH. Cochran-Armitage tests were used to assess temporal trends in PPA use in the prevalent cohort. Kaplan-Meir methods were used to estimate time to PPA following initial PAH diagnosis in the incident cohort. We also examined PPA treatment patterns by dosage form (i.e., oral, inhaled, parenteral).

RESULTS: A total of 13,519 patients were included in the analysis. PPA use increased from 14.7% of patients in CY2015 to 25.5% in CY2018 (P < 0.001), largely due to increases in oral (from 2.2% to 11.1%; P < 0.001) and parenteral agents (from 6.7% to 10.4%; P = 0.017), while inhaled PPA use remained stable. Inhaled PPA use was lower than oral and parenteral. PPA use started with oral therapy in 94.4% of patients. About 15%, 29%, and 53% of patients were hospitalized no more than 3 months before initiating oral, inhaled, and parenteral PPA, respectively. A total of 92%, 79%, and 55% of patients newly started on oral, inhaled, and parenteral PPA, respectively, subsequently added other PAH therapies. Among patients newly diagnosed with PAH, 14.3% ultimately received PPA, with a median time between diagnosis and PPA treatment of 180 days.

CONCLUSIONS: PPA use has increased over time, largely due to availability of oral agents. Further research should focus on how PPA use aligns with current treatment guidelines, and the impact of guideline-adherent therapy on clinical and economic outcomes in PAH.

SPONSORSHIP: United Therapeutics.

The Relationship Between Dose and Hospitalizations in Pulmonary Arterial Hypertension Patients Treated with Subcutaneous Treprostinil

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BACKGROUND: Pulmonary arterial hypertension (PAH) continues to carry a substantial burden of disease largely driven by hospitalizations, which are costly to healthcare payers. Treprostinil (TRE) is a prostacyclin analogue offered via several routes of administration (e.g. subcutaneous [SC], intravenous, inhaled, oral) for the treatment of PAH. Dose is titrated based on tolerability and clinical response, with no established maximum dose for parenteral.

OBJECTIVE: To evaluate doses achieved in the pivotal SC TRE studies in the context of PAH-related and all-cause hospitalizations.

METHODS: The manufacturer’s global drug safety database was retrospectively analyzed for hospitalizations after initiation of SC TRE. Hospitalizations were adjudicated for PAH relatedness by manufacturer pharmacovigilance physicians. Patients who completed placebo-controlled studies and entered the open-label study were included and grouped in tertiles (low dose [LD], medium dose [MD], and high dose [HD]) based on last recorded dose. Hospitalization rates were analyzed using Poisson regression models, which yielded a relative risk (RR) statistic.

RESULTS: Data from 857 SC TRE patients were analyzed. Mean (SD) age was 45.7 (15.3) years and 75.8% were female. The majority of patients were WHO Functional Class III and baseline mean (SD) six-minute walk distance was 337 (89.8) meters. Dose groups were <8.3 (LD), 8.3-30 (MD), and >30 (HD) ng/kg/min. The mean annual rate of PAH-related hospitalizations was 1.2, 0.4, and 0.2 for LD, MD, and HD groups, respectively. HD SC TRE reduced PAH hospitalization rate by 53% (RR: 0.47, P < 0.0001) and MD SC TRE reduced PAH hospitalization rate by 42% (RR: 0.58, P = 0.0003) compared to LD SC TRE. The mean annual rate of all-cause hospitalizations was 2.9, 1.2, and 0.7 for LD, MD, and HD groups, respectively. HD SC TRE reduced all-cause hospitalization rate by 36% (RR: 0.64, P < 0.0001) and MD SC TRE reduced all-cause hospitalization rate by 33% (RR: 0.67, P < 0.0001) compared to LD SC TRE.

CONCLUSIONS: PAH patients achieving higher doses of SC TRE had lower hospitalization rates, suggesting the importance of appropriate dose titration. A recent analysis of 1,500 patients on SC TRE observed median doses of 40, 50, 58, and 62 ng/kg/min achieved at 6, 12, 18, and 24 months on therapy. Taken together, these findings support that higher doses of SC TRE are feasible, and achieving higher doses of SC TRE may reduce disease burden for both healthcare payers and patients. Further analysis is warranted.

SPONSORSHIP: United Therapeutics.

Real-World Dosing for Oral Treprostinil and Selexipag Using Administrative Claims Data

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BACKGROUND: Treprostinil (TRE) and selexipag (SLX) are two oral therapies that target the prostacyclin (PCY) pathway and are approved for the treatment of pulmonary arterial hypertension (PAH). Both therapies are titrated to the appropriate dose determined by tolerability and clinical response. TRE has no maximum labeled dose and SLX dose is capped at 1600 mcg BID.

OBJECTIVE: While the safety and efficacy of these treatments has been well-researched, this analysis is the first to characterize real-world dosing using administrative claims data.

METHODS: A retrospective analysis was completed using the IBM Truven Health MarketScan Research Databases from July 2013 to September 2017. PAH patients were identified if they had an ICD-9 or ICD-10 code for pulmonary hypertension plus a prescription for TRE or SLX. The index date was defined as the date of the first claim for TRE or SLX. Patients were >18 years old and required to have continuous health insurance enrollment 6 months pre- and post-index date. Median and mean total daily dose (TDD) were calculated in monthly intervals for both TRE and SLX until study censor. Patients were excluded from the dosing analysis if they had a history of parenteral/inhaled PCY use in the 6 months prior to initiating TRE or SLX or implausible days’ supply and dose combinations.

RESULTS: 130 patients in the TRE cohort and 126 patients in the SLX cohort met initial inclusion criteria. 86 patients were excluded from the dosing analysis due to parenteral/inhaled PCY use (n=81) or implausible supply data (n=5). Patients were of similar age (TRE: mean [SD] years = 58.0 [16.2] vs. SLX: 58.5 [13.0]), had a similar Charlson Comorbidity Index (TRE: mean [SD] 3.5 [2.6] vs. SLX: 3.2 [2.6]). Using the IBM MarketScan Database, we identified patients with evidence of PAH between January 1, 2013 and July 31, 2018. Three cohorts were constituted: (1) prevalent PAH (all PAH patients in each calendar-year [CY]); (2) PPA new-starts; and (3) newly diagnosed PAH. Cochran-Armitage tests were used to assess temporal trends in PPA use in the prevalent cohort. Kaplan-Meir methods were used to estimate time to PPA following initial PAH diagnosis in the incident cohort. We also examined PPA treatment patterns by dosage form (i.e., oral, inhaled, parenteral).

RESULTS: A total of 13,519 patients were included in the analysis. PPA use increased from 14.7% of patients in CY2015 to 25.5% in CY2018 (P < 0.001), largely due to increases in oral (from 2.2% to 11.1%; P < 0.001) and parenteral agents (from 6.7% to 10.4%; P = 0.017), while inhaled PPA use remained stable. Inhaled PPA use was lower than oral and parenteral. PPA use started with oral therapy in 94.4% of patients. About 15%, 29%, and 53% of patients were hospitalized no more than 3 months before initiating oral, inhaled, and parenteral PPA, respectively. A total of 92%, 79%, and 55% of patients newly started on oral, inhaled, and parenteral PPA, respectively, subsequently added other PAH therapies. Among patients newly diagnosed with PAH, 14.3% ultimately received PPA, with a median time between diagnosis and PPA treatment of 180 days.

CONCLUSIONS: PPA use has increased over time, largely due to availability of oral agents. Further research should focus on how PPA use aligns with current treatment guidelines, and the impact of guideline-adherent therapy on clinical and economic outcomes in PAH.

SPONSORSHIP: United Therapeutics.
the results for the apixaban and dabigatran comparisons are reported descriptively: MB med costs for apixaban and dabigatran cohorts were $46 and $39 PPPM, respectively; AC med costs were $972 and $1,017 PPPM, and AC total cost $1,153 and $1,200 for apixaban and dabigatran cohorts, respectively.

CONCLUSIONS: This study of commercially insured NVAF patients demonstrated a cost benefit for prescribing apixaban when compared to rivaroxaban and warfarin.

SPONSORSHIP: Bristol-Myers Squibb.
standardized differences < 10%. During follow up, the weighted mean number of acute COPD-related HRU episodes was 0.059 per patient per month (PPPM) and 0.054 PPPM in the LAMA DPI and LAMA SMI cohorts, respectively, P < 0.001. Mean number of severe episodes was 0.034 PPPM and 0.030 PPPM in the LAMA DPI and LAMA SMI cohorts, respectively, P < 0.001.

CONCLUSIONS: After controlling for baseline differences with IPTW, initiating a LAMA SMI was associated with significantly fewer acute COPD-related HRU episodes than initiating a LAMA DPI.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals.

**J4** Association of Opioid Use and COPD Exacerbation: A Cohort Analysis Among Elderly Medicare Advantage Plan Beneficiaries

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**BACKGROUND:** Opioid use is prevalent in chronic obstructive pulmonary disease (COPD) patients with pain due to breathlessness. The impact of opioid use on COPD patients and its association with exacerbation leading to hospitalization has not been evaluated adequately.

**OBJECTIVE:** To assess use of opioid use in COPD patients and associated exacerbations leading to hospitalization and evaluate factors associated with COPD exacerbations.

**METHODS:** This was a retrospective cohort study observing beneficiaries of a Medicare Advantage Plan (MAP) from 2011-2014. Date of first prescription for any opioid drug from 2012-2013 served as index date. Beneficiaries who were diagnosed with COPD pre-index date, 65 years or older, continuously enrolled in the MAP for 1 year pre- and 1 year post- index date, did not have any diagnosis for end stage renal disease or cancer, and were not in hospice or institutionalized care were included in the analysis. Occurrence of COPD exacerbation and hospitalization within 30 days post index date was assessed. Patients with post 30-day hospitalization were excluded. Patients' age, gender, residency county, type of health plan, CMS risk score, comorbidities, and total annual health care cost at baseline and follow-up were compared between patients who had 30-day COPD exacerbation and those who didn't. Multiple logistic regression was used to determine characteristics associated with 30-day COPD exacerbation using SAS (version 9.4) at significance level of P < 0.05.

**RESULTS:** A total of 1,842 patients, mean (SD) age of 75 (6.8) and 50.8% female, were identified using opioids. Patients experiencing COPD exacerbation within 30 days (n = 88, 4.8%) were significantly older than those who did not (76 [6.8] vs. 74 [6.8], P < 0.05). Only county of residence (Harris county) was significantly different in the exacerbation group than the non-exacerbation group (37.5% vs. 25.5%, P < 0.05). Although not significant, total mean (SD) annual healthcare costs were higher for those with exacerbation ($19,471 [$24,440] vs. $17,764 [$25,853]). After controlling for gender and comorbid congestive heart failure, odds of experiencing a 30-day COPD exacerbation increased by a factor of 1.75 (93% CI 1.123-2.741) for Harris county residence and 1.03 (95% CI 1.002-1.064) by age, respectively.

**CONCLUSIONS:** The incidence of COPD exacerbation post opioid use was less than 5%. Patients with COPD exacerbation post opioid use may incur higher healthcare costs and should be monitored more closely by their healthcare providers.

SPONSORSHIP: None.
BACKGROUND: Cystic fibrosis (CF) is a genetic, multisystemic, progressive disease that impacts patients (pts) from birth. The burden of illness (BOI) in pediatric pts with CF is not well characterized. We performed a retrospective cross-sectional observational study using U.S. registry data to characterize CF BOI in pts of all genotypes aged <12 y.

OBJECTIVE: To evaluate BOI in pts with CF aged <12 y.

METHODS: U.S. CF Foundation Patient Registry data from 2011 were used to characterize the BOI before any CF transmembrane conductance regulator (CFTR) gene responsive to TEZ/IVA were assessed. Pts with a CF diagnosis, ≥1 encounter recorded in 2011, and age <12 y were included in this analysis. Descriptive analyses assessed lung function (only in pts aged 6 to <12 y as spirometry is not performed in pts aged <6 y), nutritional parameters, microbiology, hospitalization/pulmonary exacerbation (PEx) rates, routine CF therapies, and CF-related complications in 2011. Results were summarized by pt age and select genotype groups. Overall results are presented here.

RESULTS: 9,185 pts met the inclusion criteria in 2011. Among pts aged 6 to <12 y, the mean percent predicted forced expiratory volume in 1 second (ppFEV1) was 93% (SD, 18%), and 16% of pts had ppFEV1 <75%. Among pts aged <12 y, the mean hospitalization rate per year was 0.4 (SD, 1), and the mean PEx rate per year was 0.3 (SD, 0.8). Most pts (94%) had ≥1 positive lung microbiology culture, including Pseudomonas aeruginosa (31%). Use of inhaled bronchodilators (90%), inhaled corticosteroids (74%), hypertonic saline (42%), inhaled corticosteroids (34%), and chronic oral macrolides (25%) was common. Using the U.S. Centers for Disease Control and Prevention growth charts, the mean height percentile was 39% (SD, 28%), and the mean weight percentile was 43% (SD, 28%). The majority of pts (59%) received oral supplementation, and 14% received supplemental feeding via a gastrostomy tube. Pancreatic enzyme replacement therapy was used in 89% of pts. More than half of pts (55%) had ≥1 CF-related complication, most commonly gastroesophageal reflux disease (26%).

CONCLUSIONS: This study highlights the BOI on rate of growth, infection, hospitalizations/PEx, and CF-related complications and therapies in pts with CF aged <12 y. Although some children had a clinically recognizable reduction in ppFEV1, there is a need for better methods to assess lung disease as spirometry is not performed in pts aged <6 y and is recognized to have limited sensitivity in evaluating early lung disease.

SPONSORSHIP: Vertex Pharmaceuticals.

K10 Impact of Infliximab-dyvb (Infliximab Biosimilar) on Patient-Reported Outcomes: 3-Month Follow-Up Results from an Observational Real-World Study Among Patients with Inflammatory Bowel Disease in the U.S. and Canada (the ONWARD Study)

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BACKGROUND: In 2016, the U.S. FDA approved Inflectra (infilimab-dyvb), a biosimilar to Remicade (infliximab) for the treatment of
moderate to severe Inflammatory Bowel Disease (IBD) including Crohn's disease (CD) and ulcerative colitis (UC). There is minimal published data on the real-world patient-reported outcomes of infliximab-dyyb in North America.

**OBJECTIVE:** To assess the impact of infliximab-dyyb on quality of life and work productivity in patients with IBD in North America.

**METHODS:** This is an interim analysis of a prospective, observational, multi-center study of IBD patients prescribed infliximab-dyyb. The study included patients initiating infliximab-dyyb for the first time, switched from infliximab, or switching from another biologic. Outcomes were assessed at baseline and 3 months using the following questionnaires: Short Inflammatory Bowel Disease Questionnaire (SIBDQ), Work Productivity and Activity Impairment (WPAI), Visual Analog Scale (VAS), Personal Health Questionnaire-8 (PHQ-8), and Generalized Anxiety Disorder questionnaire (GAD-7). Scores at 3-month follow-up visits were compared to the baseline (BL) using bivariate analyses.

**RESULTS:** Of 106 patients, 41 newly initiated infliximab-dyyb, 14 switched from another biologic, and 51 switched from infliximab; 43 patients were diagnosed with UC and 63 with CD. The sample included patients aged 43 years (mean), 53% females, 87% Caucasians, and 50% HMO enrollees. These characteristics were similar across new initiators and patients who switched. For new initiators, the SIBDQ and VAS scores both improved by 8 points (P < 0.001 and P = 0.056, respectively), daily activity impairment score improved by 19 points (P < 0.001), overall work impairment score improved by 31 points from BL (P = 0.188), PHQ-8 improved by 3 points from BL (P = 0.015) and GAD-7 score improved by 1 point from BL (P = 0.166). For patients switched from infliximab, SIBDQ and VAS scores both improved by 3 points (P = 0.478, P = 0.757 respectively), overall work impairment score improved by 4 points (P = 0.221), PHQ-8 and GAD scores remained unchanged. In patients switching from other biologics, statistically non-significant improvements were observed for all outcomes. Larger improvements were seen among UC patients than CD patients.

**CONCLUSIONS:** Interim analysis suggested that new users of infliximab-dyyb showed improvements in quality of life and work productivity. Patients who switched from infliximab to infliximab-dyyb maintained their quality of life and work productivity.

**SPONSORSHIP:** Pfizer.
to the end of continuous health plan eligibility, or data end. Outcomes were compared between the matched cohorts using generalized estimating equations. Bootstrap procedures were used for cost outcomes (2017 USD). In addition, total direct and indirect costs among specific subsets of CD patients were described.

RESULTS: A total of 6,715 CD patients (age = 44.8; 54.3% female; follow-up = 4.7 years), and 33,575 non-IBD controls (age = 44.8; 53.6% female; follow-up = 4.6 years) were matched. CD patients had 1.8 inpatient (IP) days, 0.6 emergency department (ED) visits, and 15.4 outpatient (OP) visits PPPY over follow-up. Compared to controls, CD patients had greater HRU, including IP days (incidence rate ratio [IRR]: 3.94), ED visits (IRR: 2.02), and OP visits (IRR: 1.82; all \( P < 0.001 \)). Furthermore, CD patients incurred \$17,463 higher direct total healthcare costs PPPY, including \$12,034 more in medical costs (\$17,513 vs. \$5,479) and \$5,429 more in prescription drug costs (\$6,987 vs. \$1,558; all \( P < 0.001 \)). In employees with work-loss data, CD patients (N = 1,105) compared to matched controls (N = 5,525), had more medical related absenteeism days (IRR: 1.73), and disability days (IRR: 1.58; all \( P < 0.001 \)). CD patients incurred \$2,168 PPPY higher indirect costs compared to controls (\( P < 0.001 \)). In CD patients with CD-related surgery, direct total healthcare costs reached \$101,013, while indirect costs reached \$10,835 PPPY.

CONCLUSIONS: In this study with approximately 5 years average follow-up, CD was associated with significantly higher all-cause HRU, direct healthcare costs and indirect work-loss costs relative to non-IBD controls.

SPONSORSHIP: Janssen Scientific Affairs.

K4 Work Productivity Loss and Associated Indirect Costs by Severity for Patients with Ulcerative Colitis in the U.S.

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BACKGROUND: Estimating total work-productivity loss (WPL) and associated indirect costs for varying levels of disease severity are important to understand the economic burden of ulcerative colitis (UC).

OBJECTIVE: To compare demographics, clinical characteristics and patient-reported outcomes for UC patients (pts) in the U.S. and estimate the associated costs of WPL by UC severity based on partial Mayo score.

METHODS: Data were drawn from the Adelphi Disease Specific Programme (a cross-sectional survey of gastroenterologist-completed retrospective chart reviews and pt self-completion questionnaires) conducted in the U.S. in 2015 and 2017. UC pts with current or a history of moderate-to-severe (mod/sev) disease and/or those having ever been treated with steroids, an advanced therapy (immunomodulator or biologic therapy) or ever had a Mayo score > 4 were included. Using the pt self-completed the WPAI instrument, measures of absenteeism (% time missed from work due to UC), presenteeism (% impairment due to UC while at work), and WPL (% total productivity loss due to UC) were analyzed. These measures were converted to indirect costs using the human capital method. Comparisons between pts with a partial Mayo score of 0-1 (remission), 2-4 (mild) and 5-9 (mod/sev) at the time of the survey were made using Kruskal-Wallis and Chi-squared tests for continuous and categorical variables, respectively.

RESULTS: Of the 1,389 UC pts included, 410 were in remission, 646 mild and 333 mod/sev. Mean age was 44.8 years for remission pts, 42.6 for mild pts and 39.4 for mod/sev pts (\( P < 0.001 \)). There was no significant difference in gender distribution among disease severity states. 7.4% of remission pts, 16.8% mild and 66.8% of mod/sev were currently experiencing a flare-like symptom (\( P < 0.001 \)). Overall mean work impairment for remission, mild and mod/sev pts were 7.5%, 19.7% and 41.9% (\( P < 0.001 \), n = 282), respectively, with mean annual indirect costs per-pt of \$4,432, \$11,633 and \$24,754. Mean presenteeism for remission, mild and mod/sev pts were 7.4%, 19.6% and 35.9% (\( P < 0.001 \), n = 302) with annual costs per-pt \$4,321, \$11,347 and \$17,877, respectively. Mean absenteeism for remission, mild and mod/sev pts were 0.6%, 2.2% and 15.7% (\( P < 0.001 \), n = 286) with annual costs per-pt \$343, \$1,280 and \$9,921, respectively.

CONCLUSIONS: UC patients experienced increased absenteeism and presenteeism with worsening disease severity, resulting in higher indirect economic losses. Compared to remission patients, mild and mod/sev patients had 2.6 and 5.6 times more in WPL-associated annual indirect costs, respectively.

SPONSORSHIP: Janssen Scientific Affairs.

K5 Work Productivity Loss and Associated Indirect Costs for Patients with Crohn’s Disease in the U.S.

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BACKGROUND: Estimating total work-productivity loss (WPL) and associated indirect costs are important to understand the economic burden of Crohn’s disease (CD).

OBJECTIVE: To compare demographics, clinical characteristics and patient-reported outcomes for CD patients in the U.S. and estimate the associated costs of WPL using the Crohn’s Disease Activity Index (CDAI) score as a measure of severity.

METHODS: Data were drawn from the Adelphi Disease Specific Programme, a cross-sectional survey of gastroenterologist-completed retrospective chart review and patient self-completed questionnaires conducted in the United States in 2015 and 2017. Using the patient self-completed Work Productivity and Activity Impairment (WPAI) instrument, measures of absenteeism (% time missed from work due to CD), presenteeism (% impairment due to CD while at work), and WPL (% total restriction due to absenteeism and presenteeism) were analyzed. These measures were converted to indirect costs using the human capital method. Comparisons between patients with a CDAI of 0-150 (remission), 151-220 (mild) and > 220 (moderate to severe [mod/sev]) at the time of the survey were made using Kruskal-Wallis and Chi-squared tests for continuous and categorical variables, respectively.

RESULTS: Of the 468 CD patients included, 291 were in remission, 105 mild and 72 mod/sev. Remission patients had a mean time of 7.5, mild 6.9 and mod/sev 5.5 years (\( P = 0.055 \)) since diagnosis. There was no significant difference in mean age or gender distribution amongst
Hepatic Encephalopathy

104 (63.4%) of the 164 patients with 3-month follow-up adjusting for age, sex, low-income subsidy and CMS risk score. The risk of hospital readmissions was tested using logistic regression while association of dichotomized PDC in each follow-up duration with the any HE medication with a value ≥ 0.8 was considered adherent. The Proportion of days covered (PDC) was used to measure adherence to index discharge and the outcomes were assessed within each cohort.

From May 2018. Based on the continuous plan eligibility, the sample was administrative claims data from a Medicare Advantage plan from 2011 to 2017. The study included patients with a diagnosis of hepatic encephalopathy (ICD-10: K82.21) in the U.S.

**OBJECTIVE:** To (a) compare adherence to the drug regimens following an HE-related hospitalization and (b) investigate the association of medication adherence with hospital readmissions following hospitalization for HE.

**METHODS:** A retrospective cohort study was conducted using administrative data from a Medicare Advantage plan from 2011 to May 2018. The sample was divided into cohorts of 3- and 6-month follow-up duration post index discharge and the outcomes were assessed within each cohort. A proportion of days covered (PDC) was used to measure adherence to any HE medication with a value ≥ 0.8 was considered adherent. The association of dichotomized PDC in each follow-up duration with the risk of hospital readmissions was tested using logistic regression while adjusting for age, sex, low-income subsidy and CMS risk score.

**RESULTS:** 104 (63.4%) of the 164 patients with 3-month follow-up and 89 (66.4%) of the 134 patients enrolled with 6-month follow-up received the treatment. Patients using lactulose had a mean PDC of 0.56 (SD: 0.29) at 3 months and 0.48 (SD: 0.3) at 6 months. Fewer patients were using rifaximin with mean PDC of 0.75 (SD: 0.17) and 0.77 (SD: 0.15) at 3 and 6 months. Patients using a combination of lactulose with rifaximin or neomycin had a PDC of 0.82 (SD: 0.16) and 0.76 (SD: 0.23) in the 3- and 6-month follow-up. The results of logistic regression at 3 and 6 months did not show a significant association of being adherent with hospital readmissions. Increased age (OR: 1.09, 95% CI: 1.01-1.17) was associated with increased likelihood of 90-day readmissions.

**CONCLUSIONS:** Adherence to HE medications after discharge decreased as the follow-up duration increased. We did not find a significant association between medication adherence and the risk of hospital readmission in patients with HE which could be related to the low sample size. Efforts are needed in both care coordination of these patients to ensure they are prescribed the needed medication and to enhance adherence to these medications.

**SPONSORSHIP:** Salix Pharmaceuticals

### L1 Understanding Characteristics of Early Users of Dupilumab for Atopic Dermatitis in the U.S.

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**BACKGROUND:** Atopic dermatitis (AD) is a chronic disease characterized by T helper 2-mediated skin inflammation and intense, persistent, and debilitating itch, particularly in patients with moderate-to-severe disease. Type 2 inflammatory comorbidities (T2-IC) include allergies, allergic rhinitis, or asthma. Dupilumab is an interleukin-4 receptor α antagonist indicated for the treatment of patients age ≥ 12 years with moderate-to-severe AD not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupilumab can be used with or without topical corticosteroids (TCS).

**OBJECTIVE:** To understand real-world patient demographics, clinical characteristics, and treatment prior to dupilumab (pre-dup tx) initiation in adult patients with AD in the U.S.

**METHODS:** Descriptive analyses were conducted on data from 3/28/2016-9/30/2017 from the Symphony Health Integrated Dataverse (IDV), which integrates de-identified patient-linked claims data capturing ≥ 80% of prescription (Rx), 60% of medical office, and 25% of hospital claims in the U.S. Patient inclusion criteria were: ≥ 1 AD diagnosis, ≥ 1 pre-index date.

**RESULTS:** At index, demographics of the overall dupilumab cohort (n=2,473) were: mean age 46 years (±17); 53% female; patient ethnicity was representative of the U.S. population (60% White, 14% Black/African, 14% Hispanic, 12% other). Geographic distribution of patients across census regions was: 40.2% South, 23.3% Northeast, 20.2% Midwest, and 16.2% West. Pre-index T2-IC, including allergic
Characteristics and Treatment History of Early Users of Dupilumab for Atopic Dermatitis in the U.S.: Analysis of an Electronic Medical Records Dataset

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BACKGROUND: Moderate-to-severe atopic dermatitis (AD) is associated with significant disease burden in patients (pts) due to debilitating itch, sleep loss, anxiety/depression, and type 2 inflammatory comorbidities (T2-IC). Dupilumab, a fully human monoclonal antibody directed against interleukin-4 receptor α, is approved for pts age ≥12 years in the U.S. (adults in the European Union/other countries) with inadequately controlled moderate-to-severe AD. Several clinical trials have demonstrated that dupilumab monotherapy or with topical corticosteroids (TCS) improves AD signs, symptoms and health-related quality of life, with acceptable safety.

OBJECTIVE: To identify real-world pt characteristics and AD treatments prior to dupilumab initiation (pre-dup tx) in U.S. adults with AD.

METHODS: Data between 3/28/2016-11/30/2017 from Modernizing Medicine's dermatology-specific (MMDS) EMR, covering ~5,000 dermatologists in the U.S., and collected at point-of-care, were analyzed. Study inclusion criteria were: pts age ≥18 years; ≥1 dupilumab prescription (Rx) between 3/28/2017 (dupilumab U.S. approval date) and 11/30/2017 (index date for all pts=1st dupilumab Rx after U.S. approval); and ≥12 months pre-index observation. Descriptive analyses were conducted on index AD signs/symptoms: (0-5) Investigator Global Assessment [IGA] scale, % body surface area [BSA] affected, 0-10-point Peak Pruritus Numerical Rating Scale [PNRS]), comorbidities, and pre-index Rx.

RESULTS: Of the full study cohort (n=4,253), mean age 46 years (±17.8); 51% female); IGA levels (in n=1,488) were: 0/1 (clear): 4.8%; 2 (mild): 6.6%; 3 (moderate): 32.4%; 4 (marked): 46.3%; 5 (severe): 9.9%. Mean BSA (n=1,575) was 39.3 (±27.4); mean PNRS (n=836) was 5.5 (±3.2). The most prevalent T2-IC were: asthma (32.1%), allergic rhinitis (25.6%), allergic urticaria (4.0%); other common comorbidities were: anxiety (15.9%), depression (12.6%), skin infections (16.8%). Pre-dup tx (in n=3,813) were TCS (78.2%), oral/injectable corticosteroids (44.9%), topical calcineurin inhibitors (23.5%), phosphodiesterase-4 inhibitors (22.4%), systemic immunosuppressants (18.8%) or phototherapy (6.7%); 2, 3 or 4 different types pre-dup tx were used by 37.5%, 10.1%, 0.5%, respectively, of 1,450 patients.

CONCLUSIONS: This real-world study suggests that dupilumab meets a significant unmet medical need for patients with AD, for whom other prior off-label systemic medications have been insufficient.

SPONSORSHIP: Sanofi and Regeneron Pharmaceuticals.

Adult Patients with Mild or Moderate Atopic Dermatitis Are Significantly Impacted by Their Condition: Results from a Real-World Study in the United States

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BACKGROUND: Atopic dermatitis (AD), regardless of severity, can be associated with significant morbidity, negatively impacting patients, caregivers, and families.

OBJECTIVE: To investigate the impact of AD on patients experiencing mild or moderate disease.

METHODS: Data were drawn from the Adelphi AD Disease Specific Programme, a cross-sectional survey of physicians and their adult patients with AD conducted in the United States between November 2014 and February 2015. All patients had a history of moderate-to-severe AD, but they could have mild, moderate, or severe AD at the time of data collection.

RESULTS: 202 primary care physicians and dermatologists completed information for 994 patients with AD. Of these, 284 (44.7% male; mean age 41.0 y) and 554 (45.7% male; mean age 39.5 y) patients with physician-reported current AD severity of mild or moderate, respectively, were included in the analysis. Correspondingly, mean percentages of body surface area affected were 11% and 15%; mean EASI scores were 5.4 and 8.8; 36% and 38% had head and neck involvement; and 81% and 84% had chronic AD per their physician. Outside of flares (acute episodes), patients with mild or moderate AD experienced a mean of 3.5 and 4.7 symptoms day-to-day, of which, daily itch (87% in mild and 96% in moderate), daily dry skin (93% and 94%), and daily cracking/raw skin (44% and 67%) were most common. 80% of patients with mild AD and 68% with moderate AD experienced flares (with or without day-to-day symptoms), and 31% and 47% were currently experiencing a flare. Patients with mild or moderate AD were receiving 2.4 and 2.6 AD therapies on average. For 70% of patients with moderate AD, their current therapies did not improve overall AD severity, consistent with physician beliefs that better control could be achieved in 56% with moderate AD (and 34% with mild AD). Based on patient-reported data from 623 patients, mean Dermatology Life Quality Index scores (range 0-30) were 4.7 for mild and 6.8 for moderate AD, and mean Work Productivity and Activity Index scores (range 0-100) were 13.3 and 19.9.

SPONSORSHIP: Sanofi and Regeneron Pharmaceuticals.
CONCLUSIONS: Adult patients with clinically mild or moderate AD had poorly controlled symptoms, HRQoL impairment, and impact on daily life. The burden of mild AD was generally similar to moderate AD, but, for some measures, was worse for those with moderate AD. Based on these physician- and patient-reported data, multiple unmet needs remain, and more can be done to improve disease control in adults with mild or moderate AD.

SPONSORSHIP: Pfizer.

**Economic Burden of Concomitant Joint Disease in Psoriasis: A U.S.-Linked Claims and Electronic Medical Records Database Analysis**

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BACKGROUND: Psoriasis (PSO) and psoriatic arthritis (PsA) are immune-mediated diseases manifesting in the skin, joints or a combination of both.

OBJECTIVE: To examine secular cost trends for patients with PSO compared to patients with both PSO and PsA (“comorbid”).

METHODS: This was a retrospective study using Optum’s Electronic Health Records and Integrated Claims data spanning January 2007-March 2018. Patients with PSO and PSO patients with concomitant joint disease were matched using 1:1 propensity score matching. Matching characteristics were assessed in the year prior to the index date, defined as the first PSO diagnosis, or first PsA diagnosis for the comorbid population, and included age, gender, race, region, plan type, Charlson-Deyo score, myocardial infarction, hypertension, chronic pulmonary disease, diabetes, renal disease, mental health, number of healthcare resource use (HRU) claims and total costs in baseline. The primary outcomes of HRU and costs were evaluated using medical and pharmacy claims for up to 3 years. Medical costs were segmented as “disease related” based on the presence of a PSO or PsA diagnosis code in the primary or secondary position on the claim, and pharmacy costs if they were for therapies indicated for PSO and/or PsA.

RESULTS: This study identified 18,515 PSO patients, 4,430 comorbid patients and 3,584 matched pairs. Comorbid patients had significantly higher HRU and costs ($43,450 vs. $36,140), including Year 5 cumulative outpatient costs ($45,450 vs. $36,140), pharmacy costs ($44,026 vs. $24,039), total healthcare costs ($104,241 vs. $76,285) and total disease-related costs ($54,327 vs. $17,237) compared to matched PSO patients. Outpatient costs represented a larger proportion of comorbid patients’ total disease-related costs ($17,441; 32%) than that for PSO patients ($2,870; 17%). Pharmacy disease-related costs were over $20,000 higher (2.5-fold; P < 0.05) for comorbid patients, and outpatient disease-related costs were significantly higher in the comorbid vs. PSO cohort ($14,571 higher, > 6-fold, P < 0.05).

CONCLUSIONS: This study showed that comorbid PSO and PsA is associated with higher rates of resource utilization and costs over 5 years compared to PSO without PsA, stemming from pharmacy costs and outpatient visits. This study provides current and robust estimates of costs that may inform physicians and payers, with potentially important implications regarding management of PSO/PsA to reduce patients’ clinical and economic burden.

SPONSORSHIP: UCB Pharma.

**Opioid Use Among Privately Insured Patients with Moderate to Severe Psoriasis in the United States**

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BACKGROUND: The extent of opioid use in moderate-to-severe psoriasis (PSO) is largely unknown.

OBJECTIVE: To assess opioid use, including chronic use, in moderate-to-severe PSO patients.

METHODS: Adults with moderate-to-severe PSO (≥ 2 PSO diagnoses and ≥ 1 claim for systemic therapy [including biologics], the latest of the first systemic therapy claim and the first PSO diagnosis defined as the index date) and non-PSO controls (no PSO diagnoses, randomly generated index date) were identified in the OptumHealth Care Solutions database of privately-insured patients (01/2010-03/2017). PSO patients and non-PSO controls were matched 1:1 based on key demographics using propensity score models. Opioid use was described in the 12 months pre-index (baseline) and assessed post-index up to the eligibility end or data cutoff using Kaplan-Meier (KM) analysis with log-rank tests and univariate Cox models. Chronic opioid use was defined as > 3 months of continuous use (no supply gaps > 7 days). A subset of moderate-to-severe PSO patients treated with biologics was also evaluated.

RESULTS: 7,490 moderate-to-severe PSO patients (mean age 47 years, 51.7% female), and 3,917 biologic users (mean age 47 years, 48.2% female) were identified. At baseline, 33.0% of moderate-to-severe PSO patients and 35.3% of biologic users received opioids vs. 22.1% and 20.5% of controls matched to each group, respectively. Chronic use was noted in 4.0% of moderate-to-severe PSO patients and 4.9% of biologic users vs. 2.4% and 1.9% of controls, respectively. Post-index, the median time to initiating opioid use was 2.6 years in moderate-to-severe PSO patients and 2.3 years in biologic users vs. 4.8 years in controls. At year 5 post-index, rates of opioid use were 66.3% in moderate-to-severe PSO patients and 68.3% in biologic users vs. 51.6% and 50.2% in controls, respectively (all P < 0.01). Rates of chronic opioid use at year 5 were 8.2% in moderate-to-severe PSO patients and 9.3% in biologic users vs. 4.0% in controls (all P < 0.01). Post-index and relative to controls, moderate-to-severe PSO patients and biologic users had a 53% and 68% higher risk of opioid use (HR [95% CI], all 1.53 [1.45-1.62]; biologic: 1.68 [1.56-1.80]), respectively, and a 92% and 155% higher risk of chronic opioid use (all 1.92 [1.63-2.26]; biologic: 2.55 [2.03-3.20]), respectively.

CONCLUSIONS: In this study, compared to non-PSO controls, moderate-to-severe PSO patients were at increased risk of opioid use and chronic opioid use. The incremental risk was even higher in biologic users.

SPONSORSHIP: Janssen Scientific Affairs.
L9 Healthcare Costs Associated with Switching in Biologic-Naive Psoriasis Patients Initiating Apremilast or Biologics in a U.S. Claims Database

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BACKGROUND: Psoriasis is a chronic inflammatory disorder. Psoriasis treatment switching is common among patients. Information on real-world healthcare costs associated with patients who switch psoriasis therapies is limited.

OBJECTIVE: To examine the total healthcare costs associated with psoriasis treatment switching among biologic-naive psoriasis patients initiating apremilast or biologics.

METHODS: Adult patients with psoriasis were identified if they initiated treatment with either apremilast, a tumor necrosis factor (TNF) inhibitor (adalimumab, certolizumab, etanercept, golimumab, or infliximab), or an interleukin (IL) inhibitor (ixekizumab, secukinumab, or ustekinumab) between January 1, 2015, and December 31, 2016, and had a minimum of 12 months pre-index and post-index continuous enrollment in the Truven Health (now IBM Watson Health) MarketScan Commercial and Medicare Supplemental Database. The study used 1:1 propensity score matching between apremilast and biologic patients based on available demographics and clinical characteristics. Switch was defined as a claim for a new psoriasis therapy after initiation of the index medication. Total per-patient per-month (PPPM) healthcare costs were measured by type of service (inpatient, outpatient, and outpatient pharmacy) and based on paid amounts of adjudicated claims. Total PPPM costs were reported at 6, 12, and 18 months. T-test, Wilcoxon rank-sum test, and chi-squared test were used to evaluate differences between the cohorts for continuous and categorical variables, as appropriate.

RESULTS: 1,645 biologic-naive psoriasis patients initiating apremilast were matched to 1,645 biologic-naive psoriasis patients initiating biologics (TNF: n = 1,207; IL: n = 438). Patient characteristics were similar between the 3 cohorts (mean age: 47.5 [apremilast], 48.1 [TNF], and 46.4 [IL] years; Charlson Comorbidity Index score: 0.45 [apremilast], 0.47 [TNF], and 0.39 [IL]). Among switchers, those initiated on apremilast had lower PPPM vs. TNF and IL patients at 12 months ($4,599 vs. $5,615 and $5,882; both P<0.001). Among non-switchers, those initiated on apremilast had lower PPPM costs vs. TNF and IL patients at 12 months ($2,546 vs. $4,344 and $5,303; both P<0.0001). Similar results were seen at 6 and 18 months post-index.

CONCLUSIONS: Regardless if patients switched or did not switch, biologic-naive psoriasis patients initiating apremilast had significantly lower PPPM costs compared with patients initiating TNF and IL inhibitors in a large U.S. administrative claims database.

SPONSORSHIP: Celgene.

L10 Total Healthcare Costs and Long-Term Treatment Patterns of Biologics and Apremilast Among Patients with Moderate to Severe Plaque Psoriasis by Metabolic Syndrome Status

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BACKGROUND: Patients with metabolic syndrome incur significant economic burden. However, long-term healthcare costs and treatment patterns of psoriasis patients with metabolic syndrome are not well characterized.

OBJECTIVE: To examine the healthcare costs and treatment patterns of psoriasis patients who newly initiated a biologic or apremilast (APR) by metabolic syndrome status.

METHODS: Adult psoriasis patients were selected into 5 mutually exclusive cohorts based on their initial index medication (secukinumab [SEC], adalimumab [ADA], ustekinumab [UST], etanercept [ETA], or APR) filled between 01/01/2015 and 08/31/2018 using a large U.S. claims database. Eligible patients had no index medication use in the 12-month pre-index period, and had continuous medical and pharmacy benefits in the 12-month pre-index and 24-month post-index periods. Subgroups were stratified by a metabolic syndrome diagnosis captured in the 12-month pre-index period. Total costs were compared between patients with and without metabolic syndrome with each cohort. Adjusted costs were estimated via multivariate analyses controlling for patient demographics and comorbidities. Adherence (measured by proportion of days covered), discontinuation, and switching were also examined.

RESULTS: Out of the 7,773 patients included, the proportions of patients with metabolic syndrome were: SEC: 56.7%; ADA: 50.6%; UST: 47.5%; ETA: 52.9%; and APR: 55.2%. Over the 24-month follow-up period, patients with metabolic syndrome incurred significantly higher adjusted total costs (SEC: $128,126 vs. $120,808; ADA: $113,788 vs. $96,375; UST: $130,190 vs. $109,958; ETA: $110,390 vs. $101,746; APR: $80,647 vs. $68,720; all P<0.05 except SEC). Adherence ranged 0.42-0.57 over the 24-month follow up, and switching was 25.3%-53.6%. Overall discontinuation was high (35.1%-53.9%), with patients with metabolic syndrome having higher discontinuation except for APR.

CONCLUSIONS: Many moderate-to-severe psoriasis patients who initiated biologics or APR had metabolic syndrome. Patients with metabolic syndrome generally incur significantly higher healthcare costs, and had higher discontinuation rates than those without metabolic syndrome. Overall adherence was poor and switching was high regardless of metabolic syndrome status. There is still a significant unmet need for long-term psoriasis management, especially in patients with comorbid metabolic syndrome.

SPONSORSHIP: Sun Pharmaceutical Industries.
L11 Real-World Treatment Patterns of Biologics and Apremilast Among Patients with Moderate to Severe Plaque Psoriasis by Metabolic Syndrome Status

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BACKGROUND: Long-term real-world treatment patterns among psoriasis patients are not well characterized, especially for those with metabolic syndrome.

OBJECTIVE: To examine the treatment patterns of patients with psoriasis who newly initiated a biologic or apremilast (APR) by metabolic syndrome status.

METHODS: Using a large U.S. claims database, adult psoriasis patients who newly initiated a biologic or apremilast between 01/01/2015 and 08/31/2018 were classified into 5 mutually exclusive cohorts based on their initial index medication between 01/01/2015 and 08/31/2018: secukinumab (SEC), adalimumab (ADA), ustekinumab (UST), etanercept (ETA), or APR. Selected patients had continuous medical and pharmacy benefits in the 12-month pre-index and 24-month post-index periods. Subgroups were stratified by any metabolic syndrome diagnosis captured over the 12-month pre-index period. Adherence (proportion of days covered), non-persistence, discontinuation, and switching were compared within each cohort. Treatment gaps were defined as 4 weeks for ETA and APR, 8 weeks for ADA, 10 weeks for SEC, and 18 weeks for UST.

RESULTS: This analysis included 7,773 patients. The proportions of patients with metabolic syndrome were: SEC: 56.7%; ADA: 50.6%; UST: 47.5%; ETA: 52.5%; and APR: 55.2%. Over the 24-month follow-up period, discontinuation rates were higher among patients with metabolic syndrome than those without metabolic syndrome except for APR (SEC: 50.6% vs. 43.7%; ADA*: 53.9% vs. 48.7%; UST*: 41.9% vs. 35.1%; ETA: 42.8% vs. 41.2%; APR: 43.1% vs. 46.1%. *P<0.05). Adherence rates were similar between patients with and without metabolic syndrome (SEC: 0.55 vs. 0.57, ADA: 0.51 vs. 0.51, UST: 0.49 vs. 0.52, ETA: 0.47 vs. 0.45, APR*: 0.47 vs. 0.42. *P<0.05). Non-persistence (55%-88%) and switching (25.3%-53.6%) were also high among patients in both subgroups.

CONCLUSIONS: About 50% of moderate-to-severe psoriasis patients who initiated biologics or APR had metabolic syndrome. Overall adherence was poor, discontinuation and switching were high for patients with or without metabolic syndrome across all cohorts. Maintaining long-term therapy is still a challenge for patients on self-administered medications.

SPONSORSHIP: Sun Pharmaceutical Industries.

L12 Treatment Patterns of Biologics and Apremilast Among Patients with Moderate to Severe Plaque Psoriasis by Psoriatic Arthritis Status

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BACKGROUND: Long-term real-world treatment patterns of psoriasis patients are not well characterized, especially for those with psoriatic arthritis (PsA).

OBJECTIVE: To examine the treatment patterns among psoriasis patients with and without PsA, who newly initiated a biologic or apremilast (APR).

METHODS: Using a large U.S. claims database, adult patients with psoriasis were selected into 5 mutually exclusive cohorts based on their initial index medication between 01/01/2015 and 08/31/2018: secukinumab (SEC), adalimumab (ADA), ustekinumab (UST), etanercept (ETA), or APR. Eligible patients had no index medication use in the 12-month pre-index period, and all had continuous medical and pharmacy benefits in the 12-month pre-index and 24-month post-index periods. Subgroups were created by the presence of a PsA diagnosis over the 12-month pre-index period. Discontinuation, adherence (proportion of days covered), non-persistence, and switching were compared between patients with and without PsA within each cohort. Treatment gaps were defined as 4 weeks for ETA and APR, 8 weeks for ADA, 10 weeks for SEC, and 18 weeks for UST.

RESULTS: A total of 7,773 psoriasis patients were included: 275, 2,684, 910, 1,063, and 2,841 patients for SEC, ADA, UST, ETA, and APR, respectively, and the proportions of patients with PsA were 35.3%, 35.1%, 22.0%, 45.7%, and 24.8%, respectively. Over the 24-month post-index period, discontinuation rates for patients with and without PsA were: SEC: 54.6% vs. 43.8%; ADA: 48.3% vs. 53%; UST: 52.5% vs. 34.4%; ETA: 38.1% vs. 45.4%; APR: 47.7% vs. 43.4% (all P<0.05 except SEC). Adherence rates were: SEC: 0.54 vs. 0.57, ADA: 0.52 vs. 0.50, UST*: 0.44 vs. 0.52, ETA*: 0.50 vs. 0.43, APR: 0.44 vs. 0.45. *P<0.05). Non-persistence rates were: SEC: 69.1% vs. 65.7%, ADA: 71% vs. 74.4%, UST*: 68.5% vs. 55.5%, ETA*: 82.1% vs. 90.3%, and APR: 86.6% vs. 84.8% (*P<0.05). Overall switching rates were high for all groups (24.8%-55.1%, all comparisons were P<0.05 except ETA).

CONCLUSIONS: About 22%-46% patients with moderate-to-severe psoriasis who initiated biologics or APR had comorbid PsA. Over the 24-month post-index period, the overall adherence was poor and discontinuation, non-persistence, and switching were high for all groups. Maintaining long-term therapy is still a challenge for psoriasis patients. Treatments that overcome the hurdle of poor adherence to self-administration may be helpful.

SPONSORSHIP: Sun Pharmaceutical Industries.

L13 Predictive Value of Early PASI Response to Tildrakizumab in Treating Moderate to Severe Plaque Psoriasis

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BACKGROUND: Predicting treatment response early on is important in psoriasis management. Tildrakizumab—an IL-23 inhibitor—is approved for the treatment of adult patients with moderate-to-severe plaque psoriasis. The differences in Psoriasis Area Severity Index
(PASI) improvements from baseline among tildrakizumab-treated patients achieving week-28 PASI <50, 50 to <75, 75 to <90, 90 to <100, and 100 were observed as early as week 4.

**OBJECTIVE:** To evaluate whether PASI improvement achieved at an early time point (i.e., week 4 or 16) could potentially predict week-28 PASI responses.

**METHODS:** Patients from two tildrakizumab phase-3 trials (resURFACE 1 [NCT01722331] and resURFACE 2 [NCT01729754]) who were randomized to receive tildrakizumab 100 mg at weeks 0, 4, 16, and 28 were included in this pooled analysis. Four mutually exclusive groups were created based on each patient’s week-28 PASI response (observed data): PASI < 50, 50 to < 75, 75 to < 90, and 90-100. Week-4 and week-16 PASI cutoffs (PASI < 50 or PASI ≥ 50) were used to predict patients’ week-28 PASI responder (PASI ≥ 75), super responder (PASI > 90), and non-responder (PASI < 75) status, and positive predictive value (PPV) and negative predictive value (NPV) were reported.

**RESULTS:** A total of 375 patients were included in this analysis with mean age of 45.6 years and 69.5% of male. At week 4, 23.1 (4%) patients achieved PASI ≥ 50, and the PPV and NPV were 87.0% and 29.2% for predicting week-28 non-responder (PASI < 75) status, respectively. At week 4, 231 (41%) patients achieved PASI ≥ 50, and the PPV and NPV were 87.0% and 57.9% for predicting week-28 super responders (PASI ≥ 90), respectively.

**CONCLUSIONS:** The majority of patients with moderate-to-severe psoriasis treated with tildrakizumab achieved PASI ≥75 at week 28. Over 40% of patients achieved PASI ≥ 50 at week 4, which was predictive of week-28 PASI response or even super response. Few patients did not achieve at least a PASI 50 response by week 16, and the majority of them did not become PASI 75 responders at week 28.

**SPONSORSHIP:** Sun Pharmaceutical Industries.

**L18 Cost of Recurrence Among Patients Treated with Nivolumab or Ipilimumab in Resected Stage III B, III C, or IV Melanoma**

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**BACKGROUND:** The CheckMate 238 clinical trial demonstrated that nivolumab (NIVO) improved recurrence-free survival compared with ipilimumab (IPI) as adjuvant therapy for patients with resected stage IIIB, IICC, or IV melanoma. However, the economic burden of recurrence in patients receiving adjuvant therapy is not well defined.

**OBJECTIVE:** To assess the cost of recurrence in patients with resected stage IIIB, IICC, or IV melanoma who received adjuvant therapy with NIVO or IPI.

**METHODS:** The study utilized individual patient data from the CheckMate 238 clinical trial. Patients included in the analysis had at least 3 months of follow-up for healthcare resource utilization (HCRU) after recurrence (n=216). The cost per recurrence was estimated as the sum of subsequent treatment costs and medical costs during the 3 months following the first recurrence. Subsequent treatment costs (including surgery, radiotherapy, and systemic therapy) and medical
Costs (hospitalization, emergency room visits, outpatient visits, and home healthcare visits) were estimated by multiplying the proportion of patients receiving each subsequent treatment and the mean HCRU by the respective unit costs obtained from literature and public data sources. All costs were adjusted to 2018 USD. Recurrence rates were estimated using Kaplan-Meier analysis of the intent-to-treat population (NIVO, n=453; IPI, n=453). The costs of recurrence at 12 and 24 months were estimated by multiplying the recurrence rates at the respective time points by the expected cost per recurrence.

RESULTS: The 3-month cost per recurrence was $27,133, which includes a subsequent treatment cost of $22,198 and medical cost of $4,935. The cost of systemic therapy ($20,245) comprised the majority of the subsequent treatment cost; medical cost was primarily attributable to cost of hospitalization ($4,473). The recurrence rates were 29.5% at 12 months and 35.3% at 24 months in patients receiving NIVO, and 39.2% at 12 months and 49.0% at 24 months in patients receiving IPI. NIVO was associated with a lower cost of recurrence compared with IPI at 12 months ($7,994 vs. $10,632) and a more pronounced cost savings at 24 months ($9,591 vs. $13,307).

CONCLUSIONS: Recurrence following resected melanoma incurs a substantial economic burden due to high subsequent therapy and hospitalization costs. On average, patients receiving NIVO had lower recurrence costs compared with those receiving IPI as adjuvant therapy.

SPONSORSHIP: Bristol-Myers Squibb.

Objective: To assess the cost-effectiveness of GT relative to topical aluminum chloride for the treatment of Primary Axillary Hyperhidrosis

Methods: A Markov model was developed consisting of four health states based on the Hyperhidrosis Disease Severity Scale (HDSS) over a time horizon of five years with a discount rate of 3%. Transitions between health states were driven by HDSS response rate. Non-responders and those who discontinue could switch to later line treatments or no treatment. Health utility and the proportion of patients with anxiety or depression were based on HDSS scores, as supported by published literature. The model calculated costs, life years (LYs), quality-adjusted life years (QALYs), and LY lived with anxiety and/or depression for each treatment arm (based on the proportion of patients in each HDSS health state) and the incremental cost per outcome achieved with GT. One-way and probabilistic sensitivity analysis (PSA) were conducted to assess the level of uncertainty in model results.

Results: Treatment with aluminum chloride resulted in a total cost of $4,863, 4.65 LYs, 3.65 QALYs, and 1.39 LY lived with anxiety and/or depression. Treatment with GT resulted in a total cost of $14,935, 4.65 LYs, 3.75 QALYs, and 1.27 LY lived with anxiety and/or depression. Relative to aluminum chloride, GT resulted in an incremental cost-effectiveness ratio of $103,087 per QALY gained. Results of sensitivity analysis showed that rate of discontinuation for both treatments and cost of GT were the largest drivers of model results. Based on PSA, GT had 76% likelihood of being cost effective at a willingness to pay threshold of $150,000 per QALY.

Conclusions: Based on the results of this analysis, GT is cost-effective relative to aluminum chloride at commonly accepted willingness to pay thresholds.

Sponsorship: Dermira.

M1 Real-World Evidence: Clinical and Economic Burden of Anemia, Venous Thromboembolism, and Malignancy Among Rheumatoid Arthritis Patients Switching from First Biologic Disease-Modifying Antirheumatic Drug to Another Treatment in the United States

Methods: In a U.S. health plan claims database, we selected adult RA pts (≥2 diagnoses ≥30 days apart) who initiated a first bDMARD (1/1/2012-3/31/2017) and switched to another bDMARD or Janus kinase inhibitor (JAKi; index date, ID). All pts had continuous plan enrollment 12 months pre- and ≥12 months post-ID. Prevalence (12-month pre-ID) and incidence (new events per 100 pt years [yrs; P100PY]) during treatment of anemia, DVT, PE, and malignancy risks vary by prior disease-modifying antirheumatic drug (DMARD) exposure. Such conditions may lead to treatment discontinuation and increased healthcare costs.

Objective: To estimate prevalence, incidence, and associated costs of anemia, DVT, PE, and malignancy in RA pts switching from first biologic (b) DMARD to another treatment.

Methods: To estimate prevalence, incidence, and associated costs of anemia, DVT, PE, and malignancy in RA pts switching from first biologic (b) DMARD to another treatment.

Results: The study included 4,656 pts (median age 54 yrs, 78% female, median RA duration 1.5 yrs). Upon discontinuing first
bDMARD, 46% of pts received monotherapy (61% tumor necrosis factor-a inhibitor [TNFi], 24% non-TNFi, 15% JAKi), and 54% received conventional synthetic (cs)DMARD-combination therapy (69% TNFi+csDMARD, 23% non-TNFi+csDMARD, 8% JAKi+csDMARD). Across index therapies, prevalence ranged 14.6%-19.8% for anemia, 1.0%-2.5% for DVT, 0.7%-2.2% for PE, 1.8%-3.7% for DVT or PE, and 3.5%-8.8% for malignancy. Overall incidence was 6.9 P100PY for anemia, 0.7 P100PY for DVT, 0.3 P100PY for PE, 0.9 P100PY for DVT or PE, and 2.0 P100PY for malignancy, and varied among treatment classes. Total PPPY unadjusted healthcare costs were higher (all P<0.001), primarily due to medical costs, in pts with vs. without anemia, $66,896 vs. $53,853, DVT, $78,461 vs. $54,462, PE, $99,321 vs. $54,483; DVT/PE, $88,610 vs. $54,305; and malignancy, $76,741 vs. $54,172.

CONCLUSIONS: In pts switching from first bDMARD to another treatment, anemia, DVT, PE, and malignancies occurred before switch and while on next treatment, and were associated with increased unadjusted healthcare costs. Future studies adjusting for differences in pt cohorts are needed to validate our findings. Prevalence of these conditions and risk of their development should be factored into treatment selection.

SPONSORSHIP: Gilead Sciences.

M2 Treatment Patterns and Persistency Following the First Biologic Disease-Modifying Antirheumatic Drug in Patients with Rheumatoid Arthritis: Real-World Analysis of 2012-2016 U.S. Medicare Data

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BACKGROUND: For rheumatoid arthritis (RA) patients (pts) not meeting treat-to-target goals despite biologic disease-modifying antirheumatic drug (bDMARD) treatment, American College of Rheumatology guidelines recommend another targeted immunomodulator (TIM): tumor necrosis factor-a inhibitor (TNFi), non-TNFi bDMARD, or Janus kinase inhibitor (JAKi). Data on patient disposition and treatment persistency are lacking for Medicare recipients initiating their first bDMARD.

OBJECTIVE: To describe treatment patterns and persistency in Medicare RA pts on first bDMARD.

METHODS: From a 20% sample of Medicare fee-for-service beneficiaries, we identified RA pts (≥1 RA + ≥1 DMARD claim) who initiated (index date) first bDMARD (01/2012-12/2015; no bDMARD use ≥12 months pre-index), without cancer or non-RA autoimmune disease. We described treatment patterns during a follow-up period ending 12/31/2016, with censoring at death or end of Medicare coverage. Pts were grouped as Persisters (persisted on first bDMARD) or Non-Persisters (did not persist), including Switchers (switched to another TIM), Restarters (restarted the first bDMARD after a gap), and Stoppers (stopped TIMs altogether). Persistency loss was estimated through Kaplan-Meier time-to-event analysis, with event being discontinuation or first gap in initial bDMARD coverage >60 days past next-refill due date (for all pts and stratified by Non-Persisters, Switchers, Restarters, and Stoppers).

RESULTS: The sample of 10,314,539 enrollees contained 154,311 RA pts, including 21,012 pts initiating bDMARD (52% intravenous, 48% subcutaneous; 79% female, mean age 66 yrs) comprising 1,012 (4.8%) Persisters, 5,723 (27.2%) Switchers, 4,705 (22.4%) Restarters, and 9,572 (45.6%) Stoppers. Among all bDMARD initiators, 22.0% lost persistency by month 2 and 56.0% by month 12. Within Non-Persisters, probability of losing persistency at month 12 was 58.9% overall, 72.4% for Switchers, 73.0% for Restarters, and 43.8% for Stoppers. Among Non-Persisters, discontinuation events peaked at months 1, 3, 6, 9, 12, 24, 36, 48, and 60, all groups contributed to persistency loss similarly until month 12, after which Stoppers largely drove further discontinuations.

CONCLUSIONS: After initiating first bDMARD, Medicare RA pts experienced treatment interruptions, which deviate from the standard treatment advancement advised by the ACR guidelines. More than half of pts lost persistency on first bDMARD by year 1; among those, more than half remained off TIM therapy altogether, suggesting substantial unmet need for treatment in this patient population.

SPONSORSHIP: Gilead Sciences.

M3 Switching and Cycling Among Patients with Rheumatoid Arthritis at an Integrated Health System Specialty Pharmacy

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BACKGROUND: Biologic disease-modifying anti-rheumatic drugs (bDMARDs) slow disease progression and improve symptoms for patients with rheumatoid arthritis (RA). Treatment inefficacy and adverse effects warrant a change in bDMARD therapy, either cycling (to medication with same mechanism of action [MOA]) or switching (to a different MOA). Financial and logistical barriers to such medication changes may impact adherence and persistence to treatment. Integrated specialty pharmacists streamline the medication change process to avoid gaps in therapy.

OBJECTIVE: To explore rates and outcomes of switching and cycling among RA patients using an integrated specialty pharmacy.

METHODS: We conducted a retrospective review of medical and pharmacy claims from 07/2013 to 06/2017. Eligible patients were treatment-naive adults with RA, prescribed a bDMARD by a Vanderbilt Rheumatology Clinic provider, who filled 2+ prescriptions from Vanderbilt Specialty Pharmacy within 12 months of the index date. Treatment-naive was defined as absence of a bDMARD claim in 120 days before index. We excluded patients who received only sample medication. We collected patient demographics and the medication supply and dispense date of each fill. Outcomes were: rate of switching/cycling within 12 months of index date, adherence (measured by proportion of days covered [PDC] from index to last fill date), persistence (defined as absence of a 60-day treatment gap). Wilcoxon rank-sum test and Pearson’s chi-squared test were used to compare PDC and persistence, respectively, between patients with versus without a switch and/or cycle.
RESULTS: We included 512 patients (80% female, 90% white, mean age 55 years). Median PDC was 0.93 (IQR 0.79-1.00). Most patients (84%) neither switched nor cycled, 8% switched, 6% cycled, and 2% both switched and cycled; median PDC for each cohort was 0.93, 0.92, 0.92, and 0.90, respectively. Persistence in each cohort was 71%, 78%, 72%, and 92%, respectively. Neither adherence nor persistence significantly differed between patients with a switch and/or cycle compared with the no switch/cycle cohort.

CONCLUSIONS: We found low rates of switching and cycling, and high adherence and persistence regardless of therapy changes. Integrated specialty pharmacies play a pivotal role in ensuring appropriate use of therapy and helping patients access and afford their medication, thus promoting high adherence and persistence throughout treatment changes. More research is needed to increase generalizability of the findings beyond this single center study.

SPONSORSHIP: Sanofi and Regeneron Pharmaceuticals.

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UCB Pharma

BACKGROUND: Ankylosing spondylitis (AS) is often accompanied by extra-synovial manifestations (ESMs) which may affect the skin, eyes, and other organs. The impact of ESMs on costs and healthcare resource utilization (HCRU) is not well described.

OBJECTIVE: To assess the overall economic burden of AS among patients with or without ESMs, and with or without anti-TNF treatment.

METHODS: This retrospective observational study analyzed U.S. commercial claims data (IBM MarketScan) from January 2012-September 2017. Eligible patients were ≥ 20 years and had ≥ 1 primary inpatient or ≥ 1 outpatient AS diagnosis claim assigned by a rheumatologist. The index date was defined as 6 months after the index AS claim. The baseline period was 6 months before and after the index AS claim, and was used to categorize the patient as having an ESM (≥ 1 claim for psoriasis, psoriatic arthritis [PsA], ulcerative colitis, Crohn’s disease, enthesitis, or uveitis) and as being anti-TNF-exposed (≥ 1 claim for an anti-TNF). The follow-up period included the 12 months after index date. Medical and pharmacy costs (per member per year [PMPY]) as well as outpatient, inpatient, and emergency room visit rates were summarized and described in baseline and follow-up periods. Cost summary and HCRU rates (per 100 person-years [PYs]) were presented for all-cause and AS-related causes.

RESULTS: A total of 9,043 patients met the inclusion criteria. At baseline, 58.9% of patients had anti-TNF exposure and 31.3% had a claim for ≥ 1 ESM (27.6% of the anti-TNF unexposed cohort and 33.8% of the anti-TNF exposed cohort). The most frequently reported ESMs were uveitis (10.8%), enthesitis, or uveitis) and as being anti-TNF-exposed (≥ 1 claim for an anti-TNF). The follow-up period included the 12 months after index date. Medical and pharmacy costs (per member per year [PMPY]) as well as outpatient, inpatient, and emergency room visit rates were summarized and described in baseline and follow-up periods. Cost summary and HCRU rates (per 100 person-years [PYs]) were presented for all-cause and AS-related causes.

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patients with an ESM vs. without was also present ($20,841 vs. $15,428), regardless of anti-TNF exposure (anti-TNF-unexposed: $16,845 vs. $12,609; anti-TNF-exposed: $23,145 vs. $17,561).

CONCLUSIONS: The economic burden of AS is considerable. ESMs are associated with increased HCRU rates and healthcare costs. Further exploration of prevention and treatment of ESMs may help to identify whether there are opportunities to reduce HCRU and/or costs in AS patients.

SPONSORSHIP: UCB Pharma.

M9 Real-World Botulinum Toxin Utilization and Treatment Cost for Cervical Dystonia and Limb Spasticity Among 15 Million Commercially Insured Members

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BACKGROUND: Competition exists between the Botulinum Toxin (BT) products (OnabotulinumtoxinA (ObA), AbobotulinumtoxinA (AbO), incobotulinumtoxinA (InC), and rimbobotulinumtoxinB (RiM)) for treating cervical dystonia (CD) and limb spasticity (LS). All four products are FDA-approved and guideline-supported for treating CD and three (ObA, AbO and InC) for limb spasticity (LS). Understanding real-world costs and utilization for BTs treating CD and LS can help identify the most cost-effective management opportunities.

OBJECTIVE: To (1) determine BT utilization and spend for CD and LS and (2) determine each BTs average CD and LS treatment cost.

METHODS: Integrated medical and pharmacy claims for 15 million commercially insured members were queried for all BT claims, regardless of diagnosis, from Jan 2018 to Dec 2018. All BT claims and allowed costs, member and plan paid after discounts, were summed for the 12-month period, and proportion of BT used for CD and LS were determined along with average cost per treatment and average days between treatments. A BT claim was determined to be used for CD or LS when a member had a corresponding ICD-10 code on their BT claim.

RESULTS: In 2018, among all 58,199 BTs claims and their $76.4 million expense, LS accounted for 14.1% of claims and 21.3% BT expense. ObA represented 88.3% ($65.5 Million) and 92.2% ($15.0 Million) of spend for CD and LS respectively. For ObA, AbO, and InC, and RiM, the average cost per treatment for CD was $1,634, $1,099, $1,374 and $1,519 and the average days between treatments were 106, 105, 103, and 105, respectively. For ObA, AbO and InC for LS, the average cost per claim was $2,023, $1,582, and $1,497 and the average days between treatments were 110, 125 and 110, respectively.

CONCLUSIONS: In this large commercially insured population, BTs for CD and LS accounted for 22% of all BT claims and 31% of all BT expenditures. ObA had the highest treatment cost for both indications. AbO had the lowest treatment cost for CD (32.7% lower than ObA) and InC had the lowest for LS (26.0% lower than ObA). Time between BT treatments were not substantially different suggesting that formulary preferring one BT will not increase treatment frequency. By shifting all ObA utilization to the lowest cost BT for LS and CD would result in an estimated $5.8 million in annual savings. These findings highlight real world identified cost savings opportunities for payers and stakeholders within the BT category.

SPONSORSHIP: Prime Therapeutics.

M10 Characterization of Patients New to Osteoporosis Therapies

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BACKGROUND: Osteoporosis (OP) and associated fractures (fx) are a public health burden, with the number of Americans at risk projected to increase by 32% from 2010 to 2030. Understanding baseline characteristics and risk factors is essential in comparative effectiveness evaluation in the real world.

OBJECTIVE: To identify and characterize patients (pts) initiating abaloparatide (ABL), teriparatide (TPTD) or denosumab (DMAB) treatment in a real-world setting since approval of ABL in May 2017.

METHODS: A retrospective cohort study including pts new to ABL, TPTD, or DMAB. The study used pharmacy claims linked to medical and hospital claims including commercial and Medicare Advantage from Symphony Health. Data are payer agnostic and provide access to de-identified, individual-level healthcare claims for more than 280 million U.S.-based pts. Pts ≥ 18 years at index date with a prescription fill of ≥ 1 of ABL, TPTD, or DMAB were included. Index was defined as the date of the initial prescription fill for ABL, TPTD, or DMAB May 1, 2017-February 28, 2019 (identification period). New/recent users were defined as pts with no recorded treatment with the same drug in the 12 months prior to index. Pts with a prior fx or with a condition or medication associated with increased risk of falls were considered at high risk for fx.

RESULTS: Overall, 8,005 ABL, 18,646 TPTD, and 133,721 DMAB pts were new to therapy in the identification period with ≥ 1 record of a pharmacy claim, and 1 record of a medical claim within the 12 months prior to their index date. Mean age (±SD) for ABL, TPTD, and DMAB cohorts, respectively, was 67.5 (9.2), 67.6 (10.3), and 71.7 (8.1), with a greater proportion being females 97.2%, 87.1%, and 93.8%. Data were censored for those ≥ 80 years in compliance with the HIPAA requirements. The most relevant comorbid conditions for ABL pts were gastrointestinal disorders (40.9%), osteoarthritis (27.0%), respiratory diseases (25.1%), type 2 diabetes (17.6%), renal insufficiency (13.7%), and cardiovascular disease (68.7%). Approximately half of pts had a condition associated with increased risk of falls. The mean (±SD) time since OP diagnosis was 2.8 (2.0) years for ABL pts and 40% had history of fx. Overall, 41.4%, 10.2%, and 11% of pts new to ABL had been treated with a bisphosphonate, DMAB, or TPTD previously. The majority had a history of oral glucocorticoids use and 21.3% were current users.

CONCLUSIONS: Results suggest that pts new to ABL are at high risk of OP fx based on their demographic, clinical and treatment history.

SPONSORSHIP: Radius Health.
**M11 Economic Burden of Osteoporosis-Related Fractures in Medicare Patients**

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**BACKGROUND:** Osteoporosis (OP)-related fractures (Fx) are an important public health burden. With an aging population, the number of Americans at risk of Fx is projected to increase 33% by 2030. Documentation of economic consequences of fractures may help payers identify high cost drivers and improve resource allocation.

**OBJECTIVE:** To examine the cost of illness of OP-related Fx in Medicare patients (pts).

**METHODS:** Medicare fee-for-service (FFS) members with a closed fragility (or OP-related) Fx between 01/01/2010-9/30/2014 were evaluated. Inclusion criteria for the proposed analyses were age ≥65 at index date, continuous enrollment in Medicare FFS with medical and pharmacy benefits for ≥1 y pre- and ≥1- y post-index (unless they died on or after index date, in which case they were included). Pts with Paget’s disease or malignancy (except non-melanoma skin cancer) at baseline were excluded. A non-fracture (NF) comparator group was selected by propensity score (PS) matching. Total costs were computed as total Medicare allowed amount, stratified by service type. Generalized linear models using a gamma distribution were conducted. All costs were adjusted to 2015 U.S. dollars using the annual medical care component of the Consumer Price Index.

**RESULTS:** Of 18,936,386 beneficiaries, 885,676 had Fx(s) and met inclusion criteria. Average age was 80.5 (±8.4), 90.9% were white, and 93.8% female. Over half had a comorbidity or medication that increased fall risk, with ~50% using opioids. Among pts with ≥12-mo follow-up, mean all-cause costs were greater in the Fx vs. NF cohort ($47,163.25 vs. $16,034.61) and the majority of costs (64.3%) for the Fx cohort were incurred within the first three mo of Fx. The highest mean costs were for inpatient ($24,190.19), skilled nursing facility ($29,216.05), and hospice care ($20,996.83). Costs for the 3 most common fragility Fx vs. NF cohort were: hip ($71,057.83 vs. $16,807.74), spine ($37,543.87 vs. $16,860.49) and radius/ulna ($24,505.27 vs. $14,673.86). Total medical and pharmacy costs for pts who subsequently experienced another Fx were higher vs. those who did not ($78,137.59 vs. $44,467.47). A higher proportion of pts in the Fx cohort died vs. NF (18% vs. 9%). Across the models for the 3 Fx sites, higher Charlson comorbidity score and renal disease had the highest impact on cost.

**CONCLUSIONS:** Findings suggest a high economic burden associated with Fx in the Medicare population. Early identification and treatment of pts at high-risk for Fx are key to reducing recurrence, costs, and mortality.

**SPONSORSHIP:** Radius Health.

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**N1 Metabolic Acidosis Is Associated with Higher Costs in Patients with Chronic Kidney Disease: A Longitudinal Analysis from Electronic Medical Records of > 50,000 Patients**

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**BACKGROUND:** The incidence of chronic kidney disease (CKD) and costs of non-dialysis CKD care have been rising in the United States, accounting for > $79B in Medicare costs in 2016 according to the United States Renal Data System. Metabolic acidosis, defined by serum bicarbonate <22 mEq/L, is a common complication of advanced CKD and a risk factor for CKD progression, with previously unreported costs.

**OBJECTIVE:** To investigate the direct costs of metabolic acidosis in patients with pre-dialysis CKD.

**METHODS:** De-identified electronic medical records (Optum EMR), 2007-2017 were queried to identify non-dialysis CKD patients with ≥2 consistent serum bicarbonate test values 28-365 days apart, ≥3 eGFR values > 10 and < 60 mL/min/1.73m2 and ≥2 years of post-index data or until death. Patients were followed for 2 years for the composite outcome (DD40) of death, chronic dialysis, renal transplant, or eGFR decline ≥40%. General linear regression models in a subset of patients with linked medical claims established predicted costs, which were then applied to the larger EMR population based on age, sex, clinical factors and DD40 outcome. All-cause predicted costs were compared between patients with confirmed metabolic acidosis (12 to < 22 mEq/L) and normal serum bicarbonate (22-29 mEq/L) within CKD stage. Predictors of costs were examined using linear regression.

**RESULTS:** 51,558 patients were included in the analysis. Mean all-cause per patient per year costs were $65,172 vs. $24,681 ($P < 0.0001) for patients with metabolic acidosis vs. normal serum bicarbonate and were significantly higher with acidosis at each CKD stage (P < 0.0001). Linear regression showed metabolic acidosis to be a strong independent predictor of costs after controlling for age, sex, race, eGFR, pre-existing diabetes, hypertension, heart failure, Charlson comorbidity score, and albumin-to-creatinine ratio. Each 1 mEq/L increase in serum bicarbonate was associated with a 7% decrease in all-cause monthly healthcare costs; parameter estimate, -0.076, P < 0.0001. Inpatient costs were a major contributor to cost differences, representing about 50% and 30% of total costs in patients with metabolic acidosis vs. normal serum bicarbonate, respectively. Patients with CKD and metabolic acidosis utilized significantly more healthcare services (inpatient, emergency, outpatient, physician) compared to CKD patients with normal serum bicarbonate, (P < 0.0001).

**CONCLUSIONS:** The presence of metabolic acidosis in CKD patients was associated with markedly higher patient costs independent of CKD stage, sex, age, and common comorbidities.

**SPONSORSHIP:** Tricida.
Impact of Comorbid Overactive Bladder on Healthcare Resource Utilization and Costs in Patients with Depression: A Retrospective, Matched Case-Control Cohort Analysis

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BACKGROUND: Studies have shown an association between depression and overactive bladder (OAB) and although the economic burden of these conditions has been characterized separately, the burden of co-occurring OAB and depression has not been examined.

OBJECTIVE: To examine healthcare resource utilization (HCRU) and costs among patients with depression with and without OAB.

METHODS: A retrospective, case-control cohort analysis was conducted comparing HCRU and costs among patients with both depression and OAB (cases) to patients with depression but not OAB (controls), using IBM MarketScan claims databases. Cases were matched with a 1:1 ratio to controls using propensity scores based on baseline demographic and clinical characteristics. To be eligible for inclusion, patients had to be aged ≥ 18 years, enrolled in a commercial or Medicare Supplemental health plan, have a diagnosis of depression between October 2011-December 2015 and a prescription claim for antidepressant medication. The first date of an OAB-related index was assigned a proxy index for the case cohort; controls were assigned a proxy. HCRU and costs, all-cause and depression-related, were determined with medical and pharmacy claims during the 12 months post-index. Bivariate comparisons of HCRU and costs were conducted. Simple linear regression models using a log-link function were used to assess the relationship between OAB and healthcare costs.

RESULTS: Of the 39,085 cases and 308,736 controls who fulfilled study criteria, 37,997 cases were successfully matched on baseline characteristics to 37,997 controls. The matched cohorts had a mean age of 55 years and were 81% female. During the 12-month post-index period, cases experienced higher all-cause HCRU and costs than controls. Depression-related HCRU was generally similar across cohorts; however, outpatient, emergency room visits and unique depression medications were statistically significantly higher (all P < 0.05) among cases. Cases had 32% higher total all-cause and 13% higher total depression-related healthcare costs than controls (P < 0.001 for both comparisons). Total mean (SD) all-cause costs were $23,617 ($36,268) for cases vs. $17,841 ($29,349) for controls (P < 0.0001). Total mean (SD) depression-related costs were $1,796 ($4,235) for cases vs. $1,597 ($3,863) for controls (P < 0.0001).

CONCLUSIONS: While higher all-cause costs and resource utilization is expected among patients with comorbid OAB and depression, this comorbidity was associated with 13% higher depression-related costs.

SPONSORSHIP: Astellas Pharma Global Development.

Pilot Study to Estimate the Healthcare Cost Associated with Clinical Events in Vascular Ehlers-Danlos Syndrome

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BACKGROUND: Ehlers-Danlos syndromes (EDS) are a heritable, heterogeneous group of connective tissue disorders, all of which are included under a single ICD-10 code. The most serious subtype is vascular EDS (vEDS), caused by defective Type III collagen protein, leading to tissue fragility and increased susceptibility to serious, high-cost clinical events including ruptures in arteries and other organs.

OBJECTIVE: To utilize insurance claims patterns to differentiate vEDS patients from other subtypes of EDS and to estimate vEDS-associated clinical event rates and costs.

METHODS: We performed a retrospective analysis of insurance claims for >90 million individuals in the United States to identify vEDS patients from 1/1/2014-12/31/2017. In the absence of a specific vEDS ICD-9/10 code, we identified patients most likely to have vEDS by selecting patients with an EDS diagnosis who also have a history of a vEDS-related clinical event and absence of hypermobility. The rate of clinical events and healthcare cost per event was calculated overall and separately for aneurysm, arterial rupture, intracranial hemorrhage, intestinal perforation, and pneumothorax. We also examined use of anti-hypertension medications.

RESULTS: We identified 3,614 vEDS patients with a mean age of 36 ± 17 years. Of patients in the study, 15.9% had at least one vEDS-related clinical event, and 31.8% of those had more than one event. Of all captured clinical events, 47% involved an arterial aneurysm, 20% arterial dissection/rupture, 8% intestinal perforation, 17% intracranial hemorrhage, and 5% pneumothorax. The average cost per event was >$15,000 for arterial aneurysm, >$81,000 for arterial dissection/rupture, >$80,000 for intracranial hemorrhage, >$146,000 for intestinal perforation, and >$30,000 for pneumothorax. 34% of vEDS patients were treated with anti-hypertension medications, but these were not associated with lower event rates.

CONCLUSIONS: This study assessed the clinical burden and healthcare utilization of vEDS patients in the United States. We identified a presumed vEDS population based on phenotypic presentation in administrative claims. The rate of serious clinical events reflects a high clinical burden and healthcare costs for these patients. These data suggest that treatments that reduce the number of events in vEDS patients would have a substantial effect on healthcare resource utilization.

SPONSORSHIP: Acer Therapeutics.
**R1** Using Pharmacy Claims to Measure Opioid Misuse and Prospectively Identify At-Risk Patients

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**BACKGROUND:** Approximately 46 people die per day in the U.S. from prescription opioid overdose according to the CDC. This national crisis warrants action, including the preemptive identification of patients at risk of opioid misuse.

**OBJECTIVE:** To (1) create an Opioid Misuse Index (OMI) from pharmacy claims that is designed to globally identify patients at risk of inappropriate opioid use (e.g., opioid abuse, overdose, illicit use) and (2) create a predictive model that will prospectively identify patients at risk of opioid misuse using pharmacy claims data only

**METHODS:** The OMI is a summative index of 6 indicators (e.g., pharmacy shopping, prescriber shopping, MME, concurrent benzodiazepine use), and can have a value that ranges from 0 to 6 where 6 indicates the highest level of risk. Using a sample of 14,619 Medicaid patients, regression analyses were conducted where the OMI was used to predict concurrent and future medical outcomes (i.e., opioid overdose, opioid use disorder diagnosis, excessive emergency department [ED] visits). Subsequently, 225 independent variables were created from pharmacy claims data and used to predict the OMI in a backwards stepwise linear regression analysis in a sample of 12,684 Medicaid members from several different U.S. states in order to create a predictive model that identifies members at risk of opioid misuse. The model was cross validated using an independent sample composed of 5,316 members.

**RESULTS:** OMI concurrent validity - The OMI significantly predicted ED visits (odds ratio = 1.60, P ≤ 0.001), opioid substance use disorder diagnosis (odds ratio = 1.82, P ≤ 0.001), and opioid overdose (odds ratio = 1.85, P ≤ 0.001) during the same measurement period. OMI predictive validity—the OMI significantly predicted ED visits (odds ratio = 1.34, P ≤ 0.001), opioid substance use disorder diagnosis (odds ratio = 1.71, P ≤ 0.001), and opioid overdose (odds ratio = 1.76, P ≤ 0.001) during a future measurement period. A regression model predicting the OMI was developed with 20 predictors, R2 = 0.39, and the linear correlation between the predicted OMI and the observed OMI was 0.63.

**CONCLUSIONS:** Pharmacy claims data can be used to prospectively identify patients at risk of opioid misuse with a fair level of accuracy. The OMI is a theory based index of opioid misuse that has demonstrated both a concurrent and prospective relationship to adverse medical events associated with opioid misuse. Additionally, the regression model developed to predict the OMI has demonstrated the ability to prospectively identify patients at risk of opioid misuse.

**SPONSORSHIP:** Magellan Health.

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**R2** Costs of Mandating Blister Packaging for Solid-Dose Opioids in the U.S. Retail Setting

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**BACKGROUND:** In the U.S., the majority of solid-dose opioids are currently packaged in cost-efficient bulk bottles. The FDA recently announced its intention to mandate unit-of-dose packaging or “blister packs” from opioid manufacturers to help combat the opioid epidemic.

**OBJECTIVE:** To quantify the minimum U.S. financial burden in terms of product price increases that may result from a mandated change in opioid packaging to blister packs.

**METHODS:** We matched 2018 prescription figures for all solid-dose Schedule II and III opioid products from the IQVIA National Prescription Audit Database with packaging detail from the FDA National Drug Code Directory to determine current packaging trends in the retail setting. The difference in Redbook Wholesale Acquisition Costs for a representative opioid (oxycodone) in blister vs. bottle packaging was calculated to estimate the per pill drug price increase that could be expected from a switch to blister packs. This per pill price increase was scaled up to the 2018 dispensed prescription count for all bottled opioids subject to the packaging change to arrive at a total estimated increase in wholesale acquisition expenditure. Factors contributing to this extra cost are qualitatively considered.

**RESULTS:** Of the 142MM solid-dose opioid prescriptions dispensed in the retail setting in 2018, packaging information was available for 98.3% of them. This subset represented 39.8B dispensed tablets, of which 99.95% were packaged in bottles. Currently, blister-packaged oxycodone is sold at a premium of $0.26 per pill compared to the bottled version of the same strength, quantity and manufacturer. Applying this price increase across the entire relevant dispensed opioid volume in 2018 resulted in a total additional wholesale acquisition expenditure of $10.3B that would be necessary to purchase the same drugs in blister configuration. This additional financial burden would be driven by the need for manufacturers to utilize costlier packaging material, perform new validation testing, and procure new capital equipment.

**CONCLUSIONS:** Compliance with a mandated change to blister packs for opioid packaging is likely to result in drug price increases to offset manufacturer cost burdens. Insurers and/or patients might then also be affected, even if per pill packaging costs may decrease over time as blister pack use increases. More research is required to establish the benefit/risk of mandating blister packs and to determine whether the initiative is worth the costs.

**SPONSORSHIP:** Health Advances.

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**R3** Current Lung Nodule Management and the Use of Risk Prediction Models

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**BACKGROUND:** The majority of lung cancer cases in the U.S. are discovered as asymptomatic nodules discovered on chest x-ray or CT scan. These patients typically undergo CT scan imaging every 6 months, and if no change is observed, are re-imaged. The Days from Initial Discovery to Final Decision (DFD) is the measure of this wait-time. A goal of reducing DFD is to avoid further exposure to potential lung cancer while minimizing unnecessary radiation exposure. Risk assessment and risk threshold models have been shown to decrease DFD and improve patient care. This study examines the use of decision support using the use of risk prediction models (RPMs) for lung nodule management.

**OBJECTIVE:** To determine the current state of RPMs in the retail setting.

**METHODS:** A retrospective analysis of clinical data was conducted for the use of RPMs in lung nodule management. RPMs were identified from the National Lung Screening Database, PM prospects, and peer-reviewed literature. The RPMs were categorized as clinical information, CT attributes, or combined. A clinical review was conducted to determine the use of RPMs in the retail setting and to assess the use of RPMs to guide the timing of follow-up imaging.

**RESULTS:** The RPMs were categorized as clinical information, CT attributes, or combined. A clinical review was conducted to determine the use of RPMs in the retail setting and to assess the use of RPMs to guide the timing of follow-up imaging.

**CONCLUSIONS:** The use of RPMs in lung nodule management has the potential to improve patient care by reducing the time from initial discovery to final decision and by minimizing unnecessary radiation exposure. The use of RPMs in the retail setting has the potential to further improve patient care by providing guidance on the timing of follow-up imaging.

**SPONSORSHIP:** Health Advances.
BACKGROUND: Pulmonary nodules are frequently encountered in clinical practice and steps in the nodule evaluation may include serial CT surveillance, use of FDG-PET, or invasive nonsurgical biopsy or surgical resection. Most guidelines suggest using quantitative risk models to estimate the pre-test probability of malignancy prior to choosing the subsequent evaluation step. Prior studies of pulmonologists demonstrated that invasive procedures for low-risk nodules remain common, suggesting poor adherence to nodule management guidelines.

OBJECTIVE: To assess the adherence to lung nodule management guidelines and utilization of risk prediction models in follow up procedure decision-making.

METHODS: A survey of 180 physicians who diagnose and/or treat lung cancer was fielded in September/October 2016. The study focused on community-based physicians to better understand current behavior in community practices (70% of the physicians practiced in community settings), other eligibility criteria included adult patients only, 3+ years post-residency practice, and at least 75% of time spent in direct clinical care. Physicians were surveyed on their current recommendations for nodules that correspond to LungRADS 3 and 4 categories in order to determine a baseline of current clinical practices and use of risk prediction models.

RESULTS: The use of risk prediction models for lung nodule evaluation was low among physicians (39.4%), with fewer pulmonologists using models compared to thoracic surgeons (38.9% vs. 53.3%). Among physicians who incorporate models in their evaluation, the Mayo and Brock models were the most commonly used. Among patients with a lung nodule between 5 to 7 mm in size, physicians recommended 23% patients into biopsy, this increased to 29% for patients with a lung nodule between 8 to 10 mm with thoracic surgeons more likely to recommend an invasive diagnostic evaluation compared to pulmonologists remaining common, suggesting poor adherence to nodule management guidelines.

CONCLUSIONS: To our knowledge, this is the first study to assess the use of risk prediction models and preferences for invasive diagnostic procedures for indeterminate pulmonary nodules in a geographically diverse group of physicians. This study has two findings. First, risk prediction models are not regularly used in clinical practice and second, physicians use invasive diagnostic procedures in about 25% to 30% of evaluations for patients with nodules less than 10 mm size. Although the use of invasive testing was reported by all providers, its use was less commonly noted by pulmonologists.

SPONSORSHIP: OncoCyte.

U1 Use of Biosimilar and Specialty Generic Medication in Medicaid: Differences Between Managed Care and Fee for Service

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BACKGROUND: Biosimilars and generics can help lower drug costs. However, policies such as statutory rebates and statewide preferred drug lists (PDLs) may result in differential use of biosimilars and generics between Medicaid fee-for-service (FFS) and Managed Care Organizations (MCOs), particularly for drugs with high price increases subject to large inflation rebates.

OBJECTIVE: To compare the use of 2 new biosimilar/specialty generics of branded drugs with large price increases across states with only FFS Medicaid, states with MCOs not subject to statewide PDLs, and states with MCOs subject to statewide PDLs.

METHODS: Using 2018 Medicaid drug utilization data, we extracted reimbursement records in the first three quarters of 2018 for all insulin glargine 100 IU/ml and glatiramer products. We calculated the market share of Basaglar (a glargine ‘biosimilar’) and generic glatiramer among the corresponding drugs. We compared the market share of these products across 3 state groups: states with only FFS Medicaid, states with MCOs not subject to statewide PDLs for each drug, and states with MCOs subject to PDLs. We evaluated the correlation between state-level penetration of MCOs and share of biosimilar/generic products, and between the market share of two products.

RESULTS: Nationally, the market share of these biosimilarspecialty generics was higher among MCOs than FFS: 60.5% vs. 3.7% for Basaglar, 59.4% vs. 5.7% for generic glatiramer (all P < 0.001). The market share of these products was highest in states where MCOs were not subject to statewide PDLs for these drugs (51.0% for Basaglar, 44.5% for glatiramer) compared to states with MCOs subject to PDLs (2.4%, 18.0%) or with only FFS Medicaid (0.9%, 1.7%), all P < 0.001. There was a significant correlation between state-level MCO penetration and share of new products: R = 0.50 for Basaglar and 0.57 for glatiramer (all P < 0.001). States with higher Basaglar utilization also had higher generic glatiramer use, R = 0.90 (P < 0.001).

CONCLUSIONS: For 2 drug classes with large price increases, use of biosimilars and specialty generics was substantially greater in MCOs than FFS Medicaid, states with MCOs not subject to statewide PDLs for each drug, and states with MCOs subject to PDLs. We compared the market share of these products across 3 state groups: states with only FFS Medicaid, states with MCOs not subject to statewide PDLs, and states with MCOs subject to statewide PDLs. We evaluated the correlation between state-level penetration of MCOs and share of biosimilar/generic products, and between the market share of two products.

SPONSORSHIP: National Heart, Lung and Blood Institute.

U2 Trends in List Prices, Net Prices, and Discounts for Branded Prescription Drugs in the U.S., 2007-2018

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BACKGROUND: To compare the use of 2 new biosimilar/specialty generics of branded drugs with large price increases across states with only FFS Medicaid, states with MCOs not subject to statewide PDLs, and states with MCOs subject to statewide PDLs.

METHODS: Using 2018 Medicaid drug utilization data, we extracted reimbursement records in the first three quarters of 2018 for all insulin glargine 100 IU/ml and glatiramer products. We calculated the market share of Basaglar (a glargine ‘biosimilar’) and generic glatiramer among the corresponding drugs. We compared the market share of these products across 3 state groups: states with only FFS Medicaid, states with MCOs not subject to statewide PDLs for each drug, and states with MCOs subject to PDLs. We evaluated the correlation between state-level penetration of MCOs and share of biosimilar/generic products, and between the market share of two products.

RESULTS: Nationally, the market share of these biosimilarspecialty generics was higher among MCOs than FFS: 60.5% vs. 3.7% for Basaglar, 59.4% vs. 5.7% for generic glatiramer (all P < 0.001). The market share of these products was highest in states where MCOs were not subject to statewide PDLs for these drugs (51.0% for Basaglar, 44.5% for glatiramer) compared to states with MCOs subject to PDLs (2.4%, 18.0%) or with only FFS Medicaid (0.9%, 1.7%), all P < 0.001. There was a significant correlation between state-level MCO penetration and share of new products: R = 0.50 for Basaglar and 0.57 for glatiramer (all P < 0.001). States with higher Basaglar utilization also had higher generic glatiramer use, R = 0.90 (P < 0.001).

CONCLUSIONS: For 2 drug classes with large price increases, use of biosimilars and specialty generics was substantially greater in MCOs than FFS Medicaid, states with MCOs not subject to statewide PDLs, and states with MCOs subject to statewide PDLs. We evaluated the correlation between state-level penetration of MCOs and share of biosimilar/generic products, and between the market share of two products.

SPONSORSHIP: National Heart, Lung and Blood Institute.
BACKGROUND: Pre-approval Information Exchange (PIE) is the communication of information regarding prescription drugs and medical devices to healthcare decision makers (HCDMs) about unapproved products and unapproved uses of cleared drugs. The U.S. Food and Drug Administration provided final guidance on appropriate communication of both healthcare economic information (HCEI) and PIE products and unapproved uses of cleared drugs. The U.S. Food and Drug Administration provided final guidance on appropriate communication of both healthcare economic information (HCEI) and PIE products and unapproved uses of cleared drugs. The U.S. Food and Drug Administration provided final guidance on appropriate communication of both healthcare economic information (HCEI) and PIE products and unapproved uses of cleared drugs. The U.S. Food and Drug Administration provided final guidance on appropriate communication of both healthcare economic information (HCEI) and PIE products and unapproved uses of cleared drugs. The U.S. Food and Drug Administration provided final guidance on appropriate communication of both healthcare economic information (HCEI) and PIE products and unapproved uses of cleared drugs. The U.S. Food and Drug Administration provided final guidance on appropriate communication of both healthcare economic information (HCEI) and PIE products and unapproved uses of cleared drugs.

RESULTS: The 2018 survey (N = 44) included HCDMs overseeing approximately 231 million lives at a regional (68%) or national (32%) level, including representatives from managed care organizations (MCOs; 68%), pharmacy benefit managers (PBMs; 27%), and/or integrated delivery networks (IDNs; 16%). The 2019 survey (N = 47) included HCDMs overseeing approximately 203 million lives with similar respondent characteristics. From 2018 to 2019, HCDM respondents reported a slight increase in the average number of months that they would like to receive preapproval information from a manufacturer prior to approval, although the difference was not statistically significant (5 ± vs. 6.0, respectively; P > 0.05). In 2019, more HCDMs preferred to have Medical Science Liaisons and Health Economics Liaisons share preapproval information, while fewer HCDMs preferred Account Managers (P < 0.05).

CONCLUSIONS: From 2018 to 2019, HCDMs reported a preference for receiving PIE approximately 6 months prior to approval and from scientific/economic field team members, rather than commercial field team members. In addition, the perceived quality or usefulness of preapproval information has numerically doubled during this time frame, reflecting potential opportunities for pharmaceutical manufacturers. Given pending H.R. 2026 legislation, PIE is likely to become increasingly more prevalent and essential for timely HCDM formulary decision making.

SPONSORSHIP: None.

Differences in Dose Intensity of Benzodiazepine Prescriptions Dispersed by Pharmacies in Rhode Island in 2018

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BACKGROUND: Benzodiazepines (BZD) are often prescribed for patients having anxiety disorders, and other conditions including muscle spasms, alcohol withdrawal, and epilepsy. Judicious use of BZD is warranted given their propensity for addiction, and increased risk of falls and death from opioid overdose. Much of the pharmacoepidemiologic literature assessing the safety of BZDs does not address intensity of BZD exposure.

OBJECTIVE: To develop and apply a standardized benzodiazepine milligram equivalency conversion and assess the dosing intensity of BZD prescriptions dispensed in Rhode Island (RI) in 2018.

METHODS: We conducted a systematic literature review using PubMed/Medline to identify research that defined BZD milligram (mg) equivalents. From these source articles we created a dosing equivalency algorithm taking into account drug half-life and dosing recommendations listed in the FDA prescribing information. We standardized BZD to diazepam 5 mg to create a diazepam milligram equivalent (DME) conversion. We then implemented a cross-sectional study using de-identified data from the RI Prescription Drug Monitoring Program (PDMP) to determine the DME for an adult patient’s most recently dispensed BDZ during 2018. Analysis of variance with pairwise comparisons were used to test for differences in DME according to age category, insurance type, and state region. T-tests for
independent samples were used to test for differences in DME by gender and any opioid dispensing within the calendar year.

RESULTS: There were 146,862 patients who received 557,271 prescriptions for BZD in RI in 2018. The overall mean DME of patients’ most recent BZD dispensing was 14.68 (Standard deviation 16.25). Males had higher mean DME than females (16.24 vs. 13.88 [P<0.01]). The age group with the highest mean DME was 35 through 49 with a DME of 16.40 while patients age 75 years or older had the lowest DME at 10.96 (P<0.01). The payment method associated with the highest mean DME was Medicaid (18.84) whereas commercial insurance had the lowest mean DME (13.57 [P<0.01]). Patients with at least one opioid dispensing had a higher mean DME as compared with patients who did not receive opioids (15.74 vs. 14.33 [P<0.01]).

CONCLUSIONS: Our study showed higher mean DME for males, patients aged 35-49, and for those co-prescribed opioids. Determining dose intensity using this DME approach may aid efforts to reduce adverse outcomes associated with BZD utilization, particularly among patients who are concurrently prescribed opioids.

SPONSORSHIP: Healthcentric Advisors.

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BACKGROUND: Recent advances have led to cell and gene therapies that offer curative treatment for previously incurable conditions. Understanding the costs of inpatient (IP) hospitalizations in target disease areas is necessary for estimating financial impact to the United States healthcare system.

OBJECTIVE: To estimate the direct costs of pediatric IP stays within select disease areas with potential gene therapy cures.

METHODS: We conducted a cross-sectional analysis using the Healthcare and Cost Utilization Project (HCUP) Kids’ Inpatient Database (KID) of 2016. We included pediatric patients (<21 years) discharged from KID participating states. We required at least one ICD-10-CM diagnosis in any position of: adenosine deaminase deficiency with severe combined immunodeficiency (ADA-SCID; D81.3), beta thalassemia (BT; D56.1), cystic fibrosis (CF; E84.x), hemophilia A or B (HAA; D66/HAB, D67), mucopolysaccharidosis III (MPS-III; E72.4), Pompe disease (PD; E74.02), sickle cell disease (SCD; D57.x sans D57.3x), or Von Gierke disease (VG; E74.01). Our primary outcomes of interest were nationally representative mean costs for IP stays within and across these disease areas.

RESULTS: We identified an estimated 55,188 stays nationally in 2016, ranging from 34 stays for ADA-SCID to 32,000 for SCD. Average hospitalization costs were lowest for SCD: $9,141, 95% CI ($9,141 to 14,351) (P<0.0001). Total healthcare expenditures for pediatric IP stays in all selected disease areas were $998.8 million in 2016.

CONCLUSIONS: IP costs vary significantly across orphan diseases. Overall financial impact to the U.S. healthcare system in 2016 was substantial ($998.8 million). Curative therapies provided to pediatric populations have the potential to avoid significant resource utilization across disease areas. Additional research is necessary to characterize complete direct and indirect cost burdens to patients and caregivers.

SPONSORSHIP: FoCUS Consortium in the MIT Center for Biomedical Innovation NEWDIGS Initiative.

U6 Inclusion of Real-World Evidence and Patient Input by U.S. Value Assessment Organizations
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BACKGROUND: Passage of the 21st Century Cures Act and PDUFA VI has drawn attention to use of real-world evidence (RWE) and patient input in regulatory decision-making. As the use of value assessment (VA), such as ICER reports, in determining access in the United States grows, understanding the use of RWE and patient input by U.S. VA organizations is important so that users of VA reports, such as payers and clinicians, can evaluate their usefulness in formulary or other health care decisions.

OBJECTIVE: To evaluate U.S. VA organizations’ requirements on and use of RWE and patient input in VA assessments and reports.

METHODS: VA methods documents from 7 U.S. VA organizations were obtained and systematically abstracted for mentions of inclusion/exclusion or other requirements regarding RWE and patient input. Two reviewers evaluated each document, a third reviewer acted as tie-breaker when needed. Up to three published 2018 reports for each organization were reviewed to assess actual use of RWE and patient input in VA to assess corroboration with methods documents.

RESULTS: Of 7 U.S. VA methods documents evaluated, 3 organizations (ICER, IVI, FasterCures) explicitly stated acceptance of RWE, 3 organizations restricted evidence to non-RWE sources such as randomized control trials (RCTs; ASCO, MSK, NCCN), and 1 organization made no mention of RWE but did not implicitly exclude RWE (ACC/AHA). 2 organizations explicitly discussed inclusion of patient input (ICER, FasterCures), 3 organizations did not accept input from patients (ASCO, MSK, NCCN), and 2 organizations made mention of patient or stakeholder input but were unclear as to the process or extent of input and/or involvement (ACC/AHA, IVI). Nine 2018 reports were publicly available for 4 organizations (ACC/AHA, ICER, IVI, NCCN), three organizations had no 2018 reports. Of available reports, 22% (2/9) included RWE as a source of evidence (ICER, IVI), and 11% (1/9) included patient input (ICER).

CONCLUSIONS: As interest in VA increases in the U.S., the inputs into these assessments should be critically assessed. Alignment is needed between regulatory agencies and VA bodies. To support high-quality decision making, U.S. VA organizations will need to continue to evolve their methods to reflect changes in standards for evidence selection.
RWE and patient input are two examples of areas where evolution is taking place.

**SPONSORSHIP:** Pfizer.

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### Medicaid Missed Refill Letter Intervention Impact on Refill Rate Versus Randomized Controls

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**BACKGROUND:** The Missed Refill letter campaign (MR) was a Medicaid member outreach intended to prevent chronic medication gaps among members utilizing asthma, depression and oral diabetes drugs by encouraging members to refill their medication.

**OBJECTIVE:** To assess the impact of MR on refill rates compared to a randomized control group among three drug categories: asthma, depression, or oral diabetes.

**METHODS:** Among 390,000 Medicaid members those with a 7-day gap in drug supply for asthma, depression, or oral diabetes medications were identified weekly from 10/15/2018-12/17/2018 (ten weeks). Identified members were randomly assigned to the MR or a control group (MR 70% and Control 30%). An educational letter was mailed 7 days after identification. Members were required to be continuously enrolled for 40 days after identification. A refill was defined as a matched drug claim within 25 days after gap identification. Refill percentages for each drug category were compared between the MR and control group using a t-test. Refill rates were examined using a Kaplan-Meier (KM) Curve with a Log-rank test by disease category. Cox Proportional hazards regression models were fit generating Hazard Ratios (HR), with statistical significance set at \( P < 0.05 \).

**RESULTS:** During the ten-week period, 10,890 members were identified with missed refill among the three drug categories: asthma, depression, or oral diabetes.

**CONCLUSIONS:** The results indicate significant refill rate impact from the MR for the asthma and depression drug categories. The change in rates was consistent with timing of a member receiving the letter intervention. Health plans may consider a missed refill letter campaign to increase chronic medication refill rates among Medicaid members, an under researched population.

**SPONSORSHIP:** Prime Therapeutics

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### Drug Super Spenders: 2016-2018 Growth in Number of Members and Total Pharmacy Plus Medical Benefit Drug Cost for Members with Extremely High Annual Drug Cost in a 17 Million-Member Commercially Insured Population

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Prime Therapeutics

**BACKGROUND:** New drugs for rare diseases and one-time (e.g., gene) therapies have progressively increased the number of drug super spenders defined as an individual with >$250,000 in drug cost during a year. Health plans need to be aware of this important health care cost driver, understand the growth rate in drug super spenders, and ensure cost-effectiveness of these new therapies to maintain health insurance affordability.

**OBJECTIVE:** To categorize all members in a large commercially insured population by their total combined claims cost from the pharmacy benefit plus drugs covered by medical benefits and to determine the recent trend in drug super spender prevalence.

**METHODS:** All unique members with any period of enrollment between January 2016 and December 2018 were identified from a 17.7 million commercially insured population. The sum of allowed cost for all pharmacy claims plus all medical benefit claim lines with HCPCS codes for drugs (e.g., “J codes”) was determined for each member for each calendar year with any enrollment. Cost was defined as the plan plus member liability at network-discounted price with no further adjustment for any coupons or rebates. Descriptive statistics were used to describe the growth in super-spenders.

**RESULTS:** There was an average of 17.7 million members per month eligible through the 3-year study period with an average of 9.7 member-months per unique member with eligibility per year. In 2016, 2,994 members with >$250 thousand (k) drug cost per member accounted for $1,324 million (M) drug spend. In 2018, >$250k drug cost per was 4,869 members (63% increase) for $2,119 M drug spend (60% increase). The number of unique members in the highest cost band, ≥ $750k, was 256 in 2016 and 354 in 2018 (38% increase), with their total drug cost increasing from $297 M in 2016 to $417 M in 2018 (40% increase).

**CONCLUSIONS:** In this large commercially insured population, drug super spender members with >$250,000 a year in drug costs increased 63% from 2016 to 2018. In 2018, 4,869 drug super spenders accounted for over $2 billion in drug expenditures. Commercial health plans are insuring a very small but growing number of members with extraordinarily high drug cost, “drug super-spenders,” who account for a highly disproportionate fraction of insured costs. Health plans need robust strategies for anticipating, tracking, and optimizing drug and one-time (e.g., gene) therapy for these members as drug super spenders are expected to rapidly grow with new rare drug treatments, gene and one-time therapies approvals.

**SPONSORSHIP:** Prime Therapeutics
**U10 A Descriptive Analysis of 2016 Medicare Part D Medication Therapy Management Comprehensive Medication Review Completion Rates**

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**BACKGROUND:** Since 2006, the Centers for Medicare & Medicaid Services (CMS) has required medication therapy management (MTM) for eligible Part D beneficiaries, which includes one annual comprehensive medication review (CMR). CMS calculates Star Ratings to provide performance information to Medicare beneficiaries. For MTM, the Star Rating is plan-level CMR completion rate.

**OBJECTIVE:** To describe and compare (1) Part D MTM eligibility criteria, (2) CMR completion rates, (3) MTM provider type, and (4) drug therapy problem resolution rate (DPRR) by CMS Star Ratings among Medicare Advantage Prescription Drug Plans (MAPDs) and prescription drug plans (PDPs).

**METHODS:** The 2016 CMS MTM Public Use (n = 447 MAPDs; n = 55 PDPs) and Program Eligibility Information Files were linked. CMR completion rate was calculated as the number of beneficiaries who received a CMR/total number of beneficiaries CMR eligible. The 2018 CMS Star Rating cut points for CMR Completion (based on 2016 plan performance) were used to stratify CMR completion rates. Our CMR completion rates calculated from the MTM PUF did not take into account certain exclusions in the denominator that CMS considers such as hospice patients, plan-switching, etc. Descriptive (means and frequencies) and bivariate (ANOVA and chi-square) statistics were used.

**RESULTS:** The majority of MAPDs (84.1%) and PDPs (78.2%) required 3 chronic conditions and 59.5% and 56.4%, respectively, required at least 8 Part D drugs for MTM eligibility. MAPDs with 5 stars had a higher proportion of plans requiring 3 vs. 2 conditions compared to MAPDs with fewer stars (P = 0.04). Mean CMR completion rate for MAPDs and PDPs was 56.7% and 32.1%, respectively, and CMR mean completion rate significantly differed by star category for both MAPDs (P < 0.001) and PDPs (P < 0.001). For PDP beneficiaries (n = 408,359), the most common CMR providers were MTM vendor in-house pharmacist (45.4%) and local pharmacist (23.1%). For MAPD beneficiaries (n = 901,789) it was MTM vendor in-house pharmacist (36.2%) and MTM vendor local pharmacist (22.4%). Provider type varied significantly by Star Rating for both MAPDs and PDPs. Mean DPRR for MAPDs and PDPs was 27.3% and 25.0%, and MAPDs with 5 stars had higher DPRR (P < 0.0001) compared to other stars.

**CONCLUSIONS:** MAPDs had higher CMR completion rates than PDPs. MTM vendor in-house pharmacists were the most common CMR providers for both MAPDs and PDPs and there was variation in the type of CMR provider by Star Rating. There is opportunity to further examine MTM provider type and to improve DPRR for both MAPDs and PDPs.

**SPONSORSHIP:** Texas Center for Health Outcomes Research and Education and SinfoniaRx.

**U11 Evaluating the Relationship Between Increased Patient Engagement and Adherence to Specialty Medications**

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**BACKGROUND:** A patient management program (PMP) can improve health outcomes, quality, and patient satisfaction. The goal of a successful PMP is to improve medication use and overall wellness, which can be achieved through patient engagement and empowerment. The main challenge for a PMP, however, is often engaging patients. Improving engagement rates in a targeted PMP may also positively impact overall adherence and outcomes.

**OBJECTIVE:** To examine a PMP’s ability to improve engagement and its effect on adherence outcomes.

**METHODS:** This retrospective study analyzed pharmacy claims data from 1/1/2016–4/1/2019 for a specialty pharmacy (SP) with 14,300 patients. Inclusion criteria were patients ≥18 years old with at least 1 paid claim for a self-administered specialty drug in 10 eligible categories. Eligible patients were offered monthly PMP coaching services. Engagement was tracked by completion of ≥1 clinical assessment with a PMP clinician. Baseline results were collected from 1/1/2016–12/31/2016. Over the course of the intervention period (1/1/2017-4/1/2019), changes were made to the PMP to improve patient participation. These changes included, but were not limited to, increased staffing, prioritization of patients new to the SP, continuous attempts to re-engage patients, and expanded digital offerings. Secondary outcomes for medication adherence were measured by proportion of days covered (PDC) and categorized based on achievement of target adherence, defined as PDC ≥85%. Descriptive statistics were used to describe the results of the analysis.

**RESULTS:** A total of 12,897 patients met the inclusion criteria. Compared to baseline, patient engagement in the PMP during the measurement period increased from 21.6% to 33.4% (difference 11.8%, P < 0.0001). Increased participation was also observed across each individual disease category. In addition, patients eligible for the PMP demonstrated improved adherence (PDC 89.4% [n = 9,213] vs. 88.1% [n = 5,744], P = 0.012), and a greater percentage of patients reached a target adherence of ≥85% over that same time (83.3% vs. 76.0%, P < 0.0001).

**CONCLUSIONS:** For a PMP offered at a SP, strategic changes and enhancements were associated with increased patient engagement. This increased participation was associated with improved PDC and a greater likelihood to reach target PDC among eligible patients. Longer follow-up periods may provide further insights on the true impact of patient engagement on improved adherence and medical outcomes. Nevertheless, the observed association between engagement with PMP and better adherence supports the impact of PMP to optimize adherence to specialty medication.

**SPONSORSHIP:** Magellan Rx Management.
Patient Characteristics and Outcomes Following 6 Orthopedic Procedures Performed at Different Surgical Venues in the United States: Findings from a Large National Health Plan

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BACKGROUND: Hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs) have emerged as alternatives to inpatient venues (IPs) in the United States for various surgical procedures, with the potential to reduce costs by allowing patient discharge shortly after surgery. However, clinical characteristics and outcomes across these venues have not been fully explored.

OBJECTIVE: To identify patient characteristics, health outcomes, and costs associated with orthopedic procedures performed at IPs, HOPDs, or ASCs in a large national health plan.

METHODS: Using the Optum Research Database, we retrospectively analyzed commercially insured patients in the United States undergoing 1 of 6 surgical procedures between April 2012 and December 2017 (total knee arthroplasty [TKA], partial knee arthroplasty, total hip arthroplasty [THA], rotator cuff repair [RCR], total shoulder arthroplasty, and lumbar spine fusion). Baseline patient characteristics included demographics, Charlson Comorbidity Index (CCI), and prior opioid use. Outcomes included postsurgical opioid use and all-cause costs and were examined by surgery type and venue.

RESULTS: Of the 126,172 patients included, 51% were male and the mean age was 58 years. Most procedures were performed at IPs (68%), followed by HOPDs (18%) and ASCs (14%). The most common procedures were TKA (32%), RCR (27%), and THA (20%). The total number of IP procedures was consistent from 2012-2017, whereas procedures at ASCs and HOPDs increased by 58% and 15%, respectively. Mean CCI was low across all patients (0.55) and by venue (IP: 0.60; HOPD: 0.47, ASC: 0.37). Evidence of opioid use in the 12 months prior to surgery ranged from 63%-65% across all venues. Among opioid-naive patients, opioid prevalence in the 6 months after surgery was higher for HOPDs (96%) than IPs (91%) and ASCs (90%; P<0.001). Among those with presurgery opioid use, postsurgical prevalence was 95% for IPs and HOPDs and 82% for ASCs (P<0.001). Total all-cause postsurgical costs at 30 days were more than twice as high for IPs ($44,566) than HOPDs ($20,468) and ASCs ($19,110; P<0.001). After multivariate adjustment, 30-day postsurgical costs for HOPDs and ASCs were 14% and 27% lower, respectively, than those for IPs (P<0.001).

CONCLUSIONS: HOPD and ASC costs were significantly lower than IP costs for these 6 orthopedic procedures, even after adjustment for patient clinical characteristics. This suggests that many orthopedic procedures performed at IPs in patients with favorable clinical status could be migrated to HOPDs or ASCs to reduce medical costs.

SPONSORSHIP: Pacira Biosciences.

Are Payers Using Value Assessment Frameworks in the United States?

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Xcenda

BACKGROUND: Given the increasing prominence of value assessment frameworks (VAFs) in the U.S., it is important to understand if, and how, these tools are impacting payer coverage decisions.

OBJECTIVE: To assess trends in payer perceptions and utilization of VAFs in coverage decisions in the U.S. from 2016 to 2018.

METHODS: Two double-blinded, web-based surveys were fielded through an established research panel of managed care professionals in 2016 and 2018. Each survey asked respondents questions regarding perceptions and use of the Institute for Clinical and Economic Review (ICER) VAF, the Memorial Sloan Kettering Cancer Center (MSKCC) DrugAbacus tool, and the National Comprehensive Cancer Network Evidence Blocks (NCCN-EB). A modest honoraria was paid for participation.

RESULTS: 56 payers completed the survey in 2016, and 43 payers completed the survey in 2018. Payer demographics were similar in both surveys, with a majority from managed care organizations. Payers reported a large increase in use of economic data from the ICER VAF (32% in 2016, 98% in 2018) and clinical data from NCCN-EB (63% vs. 98%) to inform decisions over the 2-year period. Conversely, reported utilization of the MSKCC DrugAbacus decreased substantially for both economic data (14% vs. 2%) and clinical data (14% vs. 5%). The percentage of payers using VAFs for patient preference data increased over the 2 years for the ICER VAF (11% vs. 23%) and decreased with NCCN-EB (32% vs. 19%) and MSKCC DrugAbacus (7% vs. 5%). When asked to describe reasons for not using VAFs to inform coverage decisions, payers most commonly cited insufficient validation of the framework, cumbersome/difficulty of use, and the need for a revised version of the VAF in both years. A slightly higher percentage of payers reported non-use due to insufficient validation over the 2 years: ICER (20% vs. 36%), NCCN-EB (21% vs. 30%), and MSKCC DrugAbacus (23% vs. 26%). When asked to describe changes needed for future VAFs, payers cited similar features at both time points, including the need for (1) more objective outputs, (2) more emphasis on the payer perspective, and (3) a simpler design/scoring system.

CONCLUSIONS: Payer utilization of VAFs to inform coverage decisions generally increased from 2016-2018, though the use of specific aspects of some VAFs decreased. The key attributes of VAFs valued most by payers remained largely consistent over time. As the VAF landscape continues to evolve and shift, it is essential that payers actively engage in shaping it based on experience to ensure that the tools will be meaningful and fit-for-purpose to inform coverage decisions.

SPONSORSHIP: Xcenda.

Development of a Tool to Assess Community Pharmacist Ability to Impact Quality Measures

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BACKGROUND: The Merit-based Incentive Payment System (MIPS) is a Quality Payment Program that moves Medicare Part B providers to a performance-based system. The MIPS is a value-based model that ties financial incentives to clinician performance on a broad range of quality measures. Many measures are medication-related, yet pharmacists are not considered MIPS-eligible clinicians even though they can play an important role in helping clinicians achieve their performance objectives. Currently, there is no tool to assess pharmacist ability to impact quality measures.

OBJECTIVE: To develop and assess reliability of a tool to evaluate community pharmacist ability to impact quality measures.

METHODS: Multidisciplinary, healthcare subject matter experts were interviewed to determine criteria that evaluate community pharmacist ability to impact quality measures. The draft tool was then reviewed by researchers and subject matter experts in various healthcare professional to assess face validity and make refinements. Iterative, interrater reliability was assessed by two independent reviewers using a random 20% sample of the 2017 MIPS measure set. Absolute agreement and kappa statistics were calculated, and the tool was refined based on the results. The tool was then applied to the full 2017 MIPS measure set by two reviewers, and interrater reliability was evaluated.

RESULTS: The quality measure impact tool-community pharmacy (QMIT-CP) is comprised of five criteria to assess quality measures for community pharmacist impact potential. The criteria evaluate whether quality measures: (1) addressed use of medications or immunizations; (2) included chronic diseases; (3) treated patients in the outpatient setting; (4) included outcomes; and (5) evaluated whether data were available to community pharmacists. All criteria utilized a dichotomous scale; and the summed scores were used to categorize pharmacist impact potential as “high” (4-5), “moderate” (2-3), or “low” (0-1). Kappa statistics ranged from substantial (≥0.6) to almost perfect (≥0.8) for individual QMIT-CP criterion and pharmacist impact categorization.

CONCLUSIONS: The QMIT-CP is a reliable tool to characterize quality measures that community pharmacists may have a high, moderate, or low impact. Furthermore, the QMIT-CP can be used to support innovative team-based care and enhance value-based contracting. Evaluating the relative magnitude of pharmacist impact on quality measures is warranted.

SPONSORSHIP: Community Pharmacy Foundation.

U16 A Review of the Use of Work Productivity Endpoints in Clinical Trials

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BACKGROUND: Patient-reported outcomes (PROs) are incorporated as endpoints in clinical trials to capture how patients feel or function. For conditions affecting working-age patients, work productivity (WP) can be assessed via PROs to measure and describe important functional and financial implications for both patients and their employers.

OBJECTIVE: To explore trends in the utilization of WP endpoints in clinical trials.

METHODS: A search of ClinicalTrials.gov was conducted using the search term “work productivity” to identify trials conducted between November 1, 2011 and October 19, 2018. The search yielded 239
results, which were further narrowed to only include completed or ongoing trials involving drug therapy. Data extracted from eligible trials included title, status, location (i.e., country), therapeutic category, sponsor, type (i.e., design), and WP measures.

**RESULTS:** 120 trials met the inclusion criteria. Trials were primarily manufacturer-sponsored (80%), interventional (67%), phase IV (47%), and conducted outside of the U.S. (54%). A small minority of trials (3%) investigated WP as a primary endpoint, while most (97%) examined WP as a secondary endpoint. The most common therapeutic areas investigated were autoimmune (50%), neurology (13%), and gastroenterology (8%). Specifically, rheumatoid arthritis was the most commonly studied disease among the autoimmune trials (23%). The Work Productivity and Activity Impairment (WPAI) questionnaire was the most commonly used WP instrument (19%). Overall, a large majority of WP endpoints were a disease-specific or modified version of the WPAI (66%).

**CONCLUSIONS:** It is important for manufacturers to have a strong understanding of the PRO landscape to inform clinical trial design, particularly as it relates to endpoint selection. Results from this study indicate that WP endpoints are most commonly investigated in autoimmune disorders, as secondary outcomes, and in manufacturer-sponsored trials. The WPAI questionnaire was the most commonly used generic and disease-specific tool for WP assessment. Capturing an intervention’s impact on WP presents an additional opportunity for manufacturers to demonstrate the value of their product. This evidence is particularly relevant for organizations administering employer-sponsored health insurance and may be considered during the formulary decision making process.

**SPONSORSHIP:** Xcenda.

**U17 Has There Been a Change in the Payer Perspective on the AMCP Format Version 4.0 Pre-Approval Dossier?**

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**BACKGROUND:** AMCP Format v4.0 offers guidance to manufacturers on providing product information to healthcare decision-makers (HCDMs) prior to approval by the FDA. However, the pre-approval information exchange (PIE) landscape is evolving; this topic is covered in the FDA’s final guidance published in June 2018 titled “Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities” (FDA Guidance).

**OBJECTIVE:** To evaluate if HCDM perspectives on the utility of pre-approval dossiers have changed from 2018 to 2019.

**METHODS:** An initial web-based survey (N = 44) was fielded December 2017-January 2018 to members of Xcenda’s proprietary market research panel of payer practitioners in the United States. In this follow-up analysis, a web-based survey was fielded January-February 2019 with similar questions; responses were compared in aggregate to the initial data. Descriptive and inferential statistics were used to compare differences between years.

**RESULTS:** In 2019 (N = 47), a majority of HCDMs (66%) represented managed care organizations, followed by pharmacy benefit managers (26%). Over half (57%) represented regional plans, and most were either pharmacy (62%) or medical directors (28%). HCDM characteristics were similar between 2018 and 2019 surveys. HCDM requests for pre-approval dossiers increased from 2018 to 2019 but remained low (8/44 [18%] vs. 12/47 [26%], respectively; P < 0.05). Notably, there was a slight increase in frequency of receiving a pre-approval dossier from a manufacturer after an unsolicited request from the HCDM (2018 vs. 2019, respectively: always/frequently/sometimes, 22/44 [50%] vs. 28/47 [60%]). Of the 12 HCDMs in 2019 who requested a pre-approval dossier, most requests were made 1-6 months prior to anticipated approval date (10/12 [83%])—consistent with 2018 survey results (8/8 [100%]). In 2019, primary reasons for requesting a pre-approval dossier were ease of information gathering (36%), expectation of additional data provided (23%), education on a novel product mechanism of action (13%), and education on disease state (11%). In 2019, for the optimal length of the pre-approval dossier, a majority (79%) preferred a shorter document (10-40 pages: 47%; < 10 pages: 32%)

**CONCLUSIONS:** From 2018 to 2019, there was an increase in the proportion of HCDMs who requested a preapproval dossier and an upward trend in the frequency HCDMs were receiving a preapproval dossier. Given recent FDA Guidance on PIE and the upcoming AMCP Format v4.1, it is anticipated this increasing trend will continue.

**SPONSORSHIP:** Xcenda.
RESULTS: Of 38 survey respondents, most were pharmacy and medical directors (61% and 29%, respectively) and were employed by a health plan (66%). Among 11 respondents who indicated that they could not provide a BI threshold, 6 (55%) stated that there was either not enough information or they assessed BI in another manner. An additional 8 responses were excluded from the BI threshold results as the investigators deemed these to be implausible. For the 19 remaining respondents, the median thresholds for low, moderate, and high BI were $0.08 PMPM (interquartile range [IQR], $0.04-$0.13), $0.10 PMPM (IQR, $0.09-$0.21), and $0.37 PMPM (IQR, $0.20-$0.50), respectively. Among all surveyed participants, the most common measures used to evaluate BI were PMPM (46%) and total BI (31%); other methods included total cost within a drug class or subpopulation (n = 2).

CONCLUSIONS: These data suggest that payers perceive new, branded drugs in general to have a low BI when the PMPM BI is < $0.08, though generalization is limited by a small sample. Most payers utilize either PMPM or total BI to understand the consequences of adopting a health technology.

SPONSORSHIP: Xcenda.

Z1 Impact of Shingrix (Recombinant Zoster Vaccine) Second Dose Reminder Member Calls by a Commercial Health Plan

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BACKGROUND: Since January 2018, Shingrix (recombinant zoster vaccine, RZV) is the preferred shingles vaccine per the Centers for Disease Control (CDC), with two shots 60 days-six months apart for adults > 50 years. Prior, Zostavax (zoster vaccine live, ZVL), a single-dose vaccine, was the only shingles vaccine since 2006. CDC reported (May 2018) that providers may confuse administration methods of RZV and ZVL, with many patients not being told to return for 2nd RZV dose. RZV was in shortage in 2018 due to high demand, further limiting 2nd dose availability due to shortage. For program analysis, members must be continuously enrolled 4/1/18-5/31/19. Members that spoke to an intern were assigned to the call group, while those that did not were assigned to the control group. Differences between call and control groups were compared using chi-square for categorical and t-test for continuous variables.

RESULTS: A total of 1,395 members received 1st dose RZV during 4/1/18-6/1/18 (pharmacy benefit) received 2nd dose reminder calls by interns 6/28/18-7/31/18. Members were called as they approached 60 days post 1st dose. Interns explained how RZV is 2-6 months after 1st dose. Interns spoke to 434 (31.1%) members. Analyzable population includes 1,090 members (call: 336
vs. control: 754) since 305 members disenrolled from the plan. Mean age (61.3 ± 6.5 vs. 61 ± 6.5, P = 0.41) and sex [male: 144 (42.9%) vs. 336 (44.6%), P = 0.65] were similar between call and control groups, respectively. Among call group, 311 (92.6%) members received 2nd RZV dose vs. 657 (87.1%) in control group (P = 0.01). Mean number of days between doses was 111.8 and 122.4 for call and control groups, respectively (P < 0.001). Timing for 2nd RZV dose differed between groups (P = 0.002), with member distribution as follows for call and control groups, respectively: < 60 days: 1 (0.3%) vs. 2 (0.3%), recommended 60-180 days: 295 (94.9%) vs. 583 (88.7%), > 180 days: 15 (4.8%) vs. 72 (11.0%).

CONCLUSIONS: RZV 2nd dose reminder calls were effective in improving 2nd dose rates and timely occurrence of 2nd dose.

SPONSORSHIP: Blue Cross Blue Shield of Michigan.

Z3 The Impact of Manufacturers’ Copay Card Ban Lift on Disease-Related Hospitalizations and Medical Costs in Massachusetts in Six Disease Areas

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BACKGROUND: Prior studies showed increases in biologic drug utilization for autologous malignancies after the ban prohibiting co-pay card use was lifted in Massachusetts (MA) in 2012. Data on clinical outcomes and costs are however limited.

OBJECTIVE: To assess the impact of increased co-pay card availability on hospitalizations and medical costs in 6 diseases: asthma, chronic heart failure (CHF), chronic obstructive pulmonary disease (COPD), inflammatory bowel disease (IBD), multiple sclerosis (MS), and rheumatoid arthritis (RA).

METHODS: The study utilized IQVIA Real-World Data Adjudicated Claims from 1/1/2007 to 12/31/2017. Adults in MA or 5 neighboring states (control: CT, ME, NH, RI, VT) with full calendar year of medical and pharmacy coverage and 2 diagnoses of asthma, CHF, COPD, IBD, MS, or RA in that year were included. A controlled interrupted time-series analysis was used to assess population-level annual changes in disease-related number of hospitalizations per 1,000 patients and total medical costs per patient per year (PPPY) in MA relative to control in the post-ban lift period (2007-2011), compared to the pre-ban lift period (2013-2017). Population estimates by age and gender based on U.S. census data were used to extrapolate costs and hospitalizations avoided for the entire state of MA in 2017.

RESULTS: 424,172 patients in MA and 275,031 patients in control states were included (Disease [MA, control]: Asthma [258,914, 258,914], CHF [24,843, 24,843], COPD [52,297, 52,297], IBD [38,072, 38,072], MS [39,376, 39,376], RA [30,904, 30,904]). Compared to that of the control and pre-ban lift period, there was a statistically significant annual reduction of hospitalizations in MA across all diseases, ranging from 63 asthma-related hospital admissions per 1,000 patients (P = 0.003) to 84.2 CHF-related hospital admissions per 1,000 patients (P = 0.004), with the mean cost per hospitalization ranging from $21,820 to $34,070. All diseases showed a trend in annual reduction in medical costs post-ban lift; statistical significance was reached in Asthma, IBD, MS, and RA, and ranged from $212 PPPY (P = 0.001) in Asthma to $1,583 PPPY (P < 0.001) in MS. When considering the total prevalence of these 6 diseases in MA in 2017, a total medical cost savings of $158 million was estimated.

CONCLUSIONS: Increased availability of co-pay cards is associated with reductions in hospitalizations and medical costs in the 6 diseases studied. Patient-level analyses controlling for patient characteristics should be conducted to confirm the study findings.

SPONSORSHIP: Genentech.

Z4 Comparison of Pharmacy Benefit and Medical Benefit Sites of Service for Appropriateness of Shingrix (Recombinant Zoster Vaccine) Administration

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BACKGROUND: Blue Cross Blue Shield of Michigan (BCBSM) covers select vaccines through both pharmacy (rx) and medical benefits for improved member experience. Shingrix (recombinant zoster vaccine, RZV) was added to coverage on both benefits in April 2018. RZV is the preferred shingles vaccine per Centers for Disease Control and Prevention (CDC), with two shots 60 days-six months apart for adults > 50 years. BCBSM conducts surveillance on vaccines that cross both benefits to ensure appropriate use. Since there were concerns for 2nd dose adherence due to shortage and providers not instructing patients to return for 2nd RZV dose, BCBSM analyzed RZV utilization comparing rx and medical benefit sites of service.

OBJECTIVE: To compare rx and medical benefit sites of service for appropriateness of RZV administration.

METHODS: BCBSM commercial members with 1st dose RZV during 4/1/18-6/1/18 (rx or medical benefit) were evaluated for appropriateness of RZV administration. Members must be continuously enrolled 4/1/18-5/31/19 to be included in the analysis. Age, sex, 2nd dose adherence were compared based on which benefit (rx or medical) was used for first RZV dose. Additionally, RZV 2nd dose was further evaluated on timing of its dose (mean days between 1st and 2nd dose, < 60 days, recommended 60-180 days, > 180 days) based on which benefit was used. Differences between groups were compared using chi-square for categorical and t-test for continuous variables.

RESULTS: A total of 3,725 members received 1st dose RZV during 4/1/18-6/1/18 (rx: 2,755, medical: 970) that were continuously enrolled during the analysis period. Members using rx for 1st dose were older vs. those that used medical (mean age: 62.2 ± 6.5 vs. 60.2 ± 4.9, P < 0.001). Male distribution was 1,260 (45.7%) for 1st dose rx and 455 (46.9%) medical (P = 0.55). Higher proportion of members in 1st dose rx group received 2nd RZV dose vs. medical (2,472, 89.7% vs. 649, 66.9%, P < 0.001). Of these, 2,427 (98.2%) members used rx benefit for both doses vs. 581 (89.5%) used medical for both (P < 0.001). A total of 2,495 members received RZV 2nd dose through rx and 626 members through medical. Mean number of days between doses was 113.0 and 148.9 for rx and medical, respectively (P = 0.001). Timing for 2nd RZV dose differed between groups (P < 0.001), with member distribution as follows for rx and medical, respectively: < 60 days: 25 (1.0%) vs. 14 (2.2%), recommended 60-180 days: 2,244 (89.9%) vs. 433 (69.2%), > 180 days: 226 (9.1%) vs. 179 (28.6%).
CONCLUSIONS: Pharmacies had better RZV 2nd dose rates and timely occurrence of 2nd dose compared to medical sites of service.

SPONSORSHIP: Blue Cross Blue Shield of Michigan.