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# Meeting Abstracts

## AMCP 2020

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# AMCP Abstracts Program

The abstracts presented in this program were originally slated to be presented at the AMCP 2020 meeting in Houston, Texas, April 21-24. The meeting was canceled because of the COVID-19 crisis. In lieu of the scheduled poster presentations, many poster presenters have shared additional information about their research at https://plan.core-apps.com/amcp2020.

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

## Abstract Review Process

Eighty reviewers and 5 *JMCP* editorial reviewers were involved in the abstract review process for the AMCP 2020 meeting. Each abstract (with author name and affiliation blinded) was reviewed and scored using a 1-5 scale with the following 5 criteria (15 rating scores per abstract), which are used by *JMCP* to evaluate manuscripts for publication:

• Relevance • Originality • Quality • Bias • Clarity

Each of the reviewers also made an independent accept/reject recommendation. The 15 rating scores and 3 accept/reject recommendations for each abstract were reviewed by a *JMCP* editorial reviewer, who made an accept/reject decision. These decisions were further reviewed by the *JMCP* editor-in-chief to ensure consistency in decision making. The mean rating scores were used to award Platinum, Gold, Silver, and Bronze medals for the best abstracts submitted. The abstract reviewers for the AMCP 2020 meeting were as follows:

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# Table of Contents

## Meeting Abstracts

*AMCP 2020*

# 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.


**Melodie Baja, PharmD,** [B2] Characteristics of Pre-Exposure Prophylaxis Utilization in Transgender and Homeless Medicaid-Covered Patients in New York City

**Sun A. Choi, PharmD candidate,** [F2] Cost-Effectiveness of Office-Based Medications for Opioid Use Disorder in the U.S. from the Health Care Sector Perspective

**Steve Lam, PharmD,** [U3] Pharmacy Benefit Carve-In Versus Carve-Out: Cost and Medical Events 2-Year Retrospective Cohort Study

**Joaquin F. Mould-Quevedo, PhD,** [J2] Economic Assessment of Adjuvanted Trivalent Influenza Vaccine Compared to Trivalent High-Dose Influenza Vaccine Among the U.S. Elderly: A Comprehensive Real-World Evidence Evaluation of Direct Healthcare Costs for the 2017-2018 Influenza Season

**Carl Possidente, PharmD,** [U9] Development and Assessment of a Real-World Evidence Training Program for Pharmaceutical Field Medical Professionals

**David Proudman, MPH, MS,** [C13] The Cost Impact of Increased Molecular Testing Rates for the Treatment of Patients with Gastrointestinal Stromal Tumors


**Jenya N. Antonova, MS, PhD,** [M7] Prevalence of Opioid Use and Associated Costs Among Rheumatoid Arthritis Patients at Different Stages of Disease-Modifying Antirheumatic Drug Management

**Isha Bangia, PharmD,** [U32] A Survey-Based Analysis of Formulary Decision Making and Utilization Management Trends Across Managed Care Organizations

**Durgesh Bhandary, BPharm, MS,** [I13] Translating the Landmark DAPA-HF Trial Findings to a US Payer Setting: Medical Care Cost-Offsets Associated with Dapagliflozin Compared to Standard of Care

**Claudio A. Flores, MS,** [U33] Efficacy of Using Artificial Intelligence to Determine Whether Adding Pharmacy-Based Interventions in Addition to Call Center Interventions Will Improve Patients' Refill Rates

**Patrick P. Gleason, PharmD,** [U11] Specialty Drug Managed Care Pharmacist Clinical Review Program Savings Among 1.5 Million Commercially Insured Lives

**Eva Hammerby, MSc,** [U12] Variation in Subcutaneous Allergy Immunotherapy Billing Practices in the United States: A Claims Analysis of Allergic Rhinitis Patients

**Taline Jaghasspanian, PharmD,** [E7] Impact of a Prescriber Call Program in Promoting the Prescribing of the Cardio-Protective Medication Bundle

**Dee Lin, PharmD, MS,** [F17] Healthcare Resource Use and Costs Among Medicaid Beneficiaries with Prior Schizophrenia Relapse Before and After Initiation of Once-Monthly Paliperidone Palmitate

**Arash Mahajerin, MD, MSC,** [D13] An Early View Analysis of Characteristics of Persons with Hemophilia A Treated with Emicizumab Using Secondary Claims Data

**Alexander Niyazov, PharmD, MPH,** [C23] Real-World Treatment Patterns and Safety Outcomes Among Patients with HER2 Negative Advanced Breast Cancer and BRCA1/2 Mutations: Evidence from a Retrospective Medical Record Review Study in the United States

**Naomi Schwartz, MPH,** [C20] Epidemiology of Human Epidermal Growth Factor Receptor 2-Positive Metastatic Breast Cancer in the United States in 2019

**Jamie T. Ta, PharmD, MS,** [F21] Healthcare Resource Utilization and Costs Associated with Non-Adherence and Non-Persistence to Antidepressants for Major Depressive Disorder

**Sheila M. Thomas, BSPharm, PharmD,** [J6] "In the Patient's Own Words": Lateralizing Data Using Artificial Intelligence to Improve Quality of Life in Moderate to Severe Asthma

**Nancy Wong, PharmD,** [T1] Analysis of a Narcotic and Polypharmacy Case Management Program at a Health Plan

**Lixian Zhong, PhD,** [C24] Evaluating the Cost-Effectiveness of Adding Ribociclib to Endocrine Therapy for Patients with HR-Positive, HER2-Negative Advanced Breast Cancer Among Premenopausal or Perimenopausal Women

# Medal-Winning Abstracts *(continued)*


**Abdalla Aly, PhD,** [C2] Productivity Loss Costs Among Hepatocellular Carcinoma Patients and Caregivers in a Commercially Insured Population in the United States

**Tiffany O. Jones, PharmD,** [D17] Real-World Retrospective Data on the Uptake of Neulasta Biosimilars Without Preferred Status on Medicare Part B in a Multi-State Regional Health Plan

**Allison Keshishian, MPH,** [B4] Assessment of Economic Burden and Hospitalization on Patients with Human Immunodeficiency Virus in the US Veterans Health Administration Population

**Yi Liang, MS,** [D10] Health Care Costs and Utilization Among Adult Patients with Immune Thrombocytopenia Enrolled in Texas Medicaid

**Mehdi Najafzadeh, PhD,** [E13] Empagliflozin and the Risk of Heart Failure Hospitalization and Hospital Readmission in Type 2 Diabetes Patients: An Interim Analysis from the EMPagliflozin compaRative effectIveness and SafEty (EMPRISE) Study

**Samuel Peasah, PhD,** [T2] Evaluating Medication-Related Risk Factors for Developing Opioid Use Disorder Post-Hospitalization

**Qiujun Shao, MSPS,** [G32] Patterns and Predictors of Opioid Use Among Migraine Patients at Emergency Departments

**Elizabeth Swart, BS,** [G37] Identifying Outcome Measures for Migraine Value-Based Contracting Using the Delphi Method

**Candice Yong, PhD,** [C7] Treatment Patterns, Healthcare Resource Utilization, and Costs of Care in Patients with Extensive Stage Small Cell Lung Cancer


**Anthony Aiudi, PharmD, MBA,** [R1] Vaccine Compared to Trivalent High-Dose Influenza

**Shawn Black, PhD,** [M10] United States Rheumatology Practice-Based Real-World Evidence of Methotrexate Utilization and Response to Therapy in Rheumatoid Arthritis Patients Treated with Intravenous Golimumab: 52-Weeks from the AWARE Study

**Diana Brixner, RPh, PhD, FAMCP,** [M8] Impact of a Two to One Step TNFi Policy Change on Treatment Patterns and Costs in Patients with Rheumatoid Arthritis in a Regional Managed Care Organization

**Er Chen, MPP,** [G7] Nusinersen Adherence Among Patients with Spinal Muscular Atrophy in the Real World

**Keziah Cook, PhD,** [D11] Severe Hemophilia A Patients Receiving Prophylactic Factor VIII in US Claims Data: Identification, Resource Use, and Costs

**Timothy Fitzgerald, PhD,** [M3] Real-World Analysis of Treatment Switching Among Patients Stable on Originator Infliximab (REMICADE) Switching to an Infliximab Biosimilar or Remaining on Originator Infliximab

**Edward Hackim, PharmD candidate,** [N1] Assessing for Potentially Inappropriately Dosed Medications Among Patients with Chronic Kidney Disease

**Siddhi Korgaonkar, MS,** [I7] Evaluation of Treatment Patterns for Chronic Heart Failure and Associated Costs of Different Dosing Levels of Sacubitril/Valsartan Among Mississippi Medicaid Beneficiaries

**Anne M. Loos, MA,** [U29] ICER's Influence on Health Care Delivery: How Managed Care Organizations Use ICER Reports in Decision Making

**Qinli Ma, PhD,** [K8] Incremental Burden of Nonalcoholic Steatohepatitis Among Patients with Type 2 Diabetes Mellitus

**Nicholas D. Mendola, MPH,** [U30] Systematic Literature Review on Value Assessment Criteria Used in MCDA Frameworks Evaluating Orphan Drugs

**Amy Tung, PharmD, MS,** [F22] Clinical Events Associated with Increased Healthcare Resource Utilization and Costs Among Patients with Major Depressive Disorder

**Chioma Uzoigwe, MPH,** [E6] Persistence of Semaglutide OW Versus Other Long-Acting GLP-1RAs in a Real-World Setting

# Podium Abstracts

## B2 Characteristics of Pre-Exposure Prophylaxis Utilization in Transgender and Homeless Medicaid-Covered Patients in New York City

*Baja M, Malek M, Ng K; mbaja@amidacareny.org*
*Amida Care*

**BACKGROUND:** According to the Center for Disease Control and Prevention, transgender non-conforming (TGNC) people are at high-risk for acquiring human immunodeficiency virus (HIV); in 2017, 14% of TGNC women and 3% of TGNC men were living with HIV in the United States. However, these numbers are limited since the TGNC population is often underrepresented in studies. Amida Care has been a Medicaid Special Needs Plan in New York City (NYC) for the HIV-positive population only. As of November 2017, the plan was permitted to enroll HIV-negative persons with transgender experience or without a home who may be at risk for acquiring HIV. This positioned Amida Care to help End the HIV Epidemic through facilitating access to Pre-Exposure Prophylaxis (PrEP) for high-risk persons.

**OBJECTIVE:** To characterize utilization of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for PrEP in Medicaid-covered members at high risk of HIV infection living in NYC.

**METHODS:** A pharmacy-claims based analysis was performed to include members who filled ≥ 1 30-day prescription for PrEP between 1/1/18-9/30/19. Plan data was used to identify those who were HIV-negative, TGNC, and/or homeless. These groups were analyzed further based on demographic data including member age, gender, ethnicity, and enrollment status.

**RESULTS:** In 2018 there were 349 unique HIV-negative members enrolled of whom 24% (n = 82) had filled ≥ 1 prescription for PrEP, and in the first 3 quarters of 2019, 527 members of whom 26% (n = 135) had filled. A total of 935 prescriptions were filled during the study window; 295 were filled in 2018 and 640 in the first 3 quarters of 2019. 47% of prescriptions were filled in a pharmacy located in Manhattan, 23% in the Bronx and 20% in Brooklyn. Overall, 161 unique members filled PrEP; 71% (n = 115) were identified as TGNC, 4% (n = 7) as cisgender homeless; 11% (n = 17) as both TGNC and homeless, and 14% (n = 22) with a pending status confirmation. Of the members on PrEP, 20% were African American, 11% Hispanic, 7% Multiracial, 7% White, and 55% other/unknown. Those who filled PrEP were 19 to 60 years of age; the mean age was 32 (SD = 9.2, median = 31). On average, 15% of the actively enrolled population had filled PrEP each month.

**CONCLUSIONS:** As the HIV-negative membership grew from 2018 to 2019, 30-day PrEP prescription fills also increased. PrEP was accessed primarily by young adults and people of color who identify as TGNC in Manhattan. Further analysis is needed to assess PrEP persistence through evaluating healthcare gaps and identifying clinical interventions specific to the needs of the TGNC and homeless population.

**SPONSORSHIP:** Amida Care Health Plan

## C13 The Cost Impact of Increased Molecular Testing Rates for the Treatment of Patients with Gastrointestinal Stromal Tumors

*Proudman D[1], Miller A[1], Nellesen D[1], Mankoski R[2], Norregaard C[2], Sullivan E[2]; david.proudman@analysisgroup.com*
*[1]Analysis Group; [2]Blueprint Medicines Corporation*

**BACKGROUND:** The effectiveness of approved therapies used to treat gastrointestinal stromal tumors (GIST) varies by type of cancer driver mutation. Because adherence to guideline-recommended molecular testing of patients with GIST is limited, measuring the costs associated with increased testing is relevant for healthcare decision makers.

**OBJECTIVE:** To estimate the cost impact associated with an increase in molecular testing rates of *PDGFRA* exon 18 and *KIT* exon 9 for US GIST patients, including the effects of treatment allocation decisions and adverse events (AEs).

**METHODS:** A cost impact model was developed in Microsoft Excel with a US health plan perspective on a 12-month incidence basis, and included both adjuvant and advanced/metastatic patients. The model compared costs based on current testing rates at diagnosis: 49% for *PDGFRA* exon 18 and 60% for *KIT* exon 9, to a scenario where 100% of patients are tested. The model incorporated testing costs assuming PCR-based tests. Un-tested patients or those with other mutations were assumed to receive treatment with standard generic imatinib 400 mg, while *KIT* exon 9+ patients were assumed to receive imatinib 800 mg. *PDGFRA* exon 18 patients received best supportive care, based on the lack of response observed for any treatment in patients with the exon 18 D842V mutation, the majority of exon 18 patients. Duration of treatment in the adjuvant setting was a standard 36-month period, and duration in the advanced/metastatic setting was based on median progression free survival from clinical trials in patients with each mutation type.

**RESULTS:** The base case of the model used a mixed 69% commercial, 22% Medicare, and 9% Medicaid plan, and a GIST incidence rate of 11 per million members. The number of additional patients needed to test for one patient to receive optimized treatment was 10. An increase in testing rates to 100% for both mutation types was associated with a total annual cost increase of $15,213 per million members, or $0.015 per member per year (PMPY). Testing costs were $2,748 higher, AE costs were $293 lower, and pharmacy costs increased by $12,758, driven by increased dosing and longer progression free survival in KIT exon 9 patients. If only PDGFRA exon 18 testing is included, the result is a cost savings of $0.008 PMPY, due to lower pharmacy costs. The magnitude of the cost impact associated with increased testing remained small across all plan types.

**CONCLUSIONS:** Increased molecular testing in GIST is associated with minimal additional cost and a meaningful increase in the number of patients receiving optimized treatment.

**SPONSORSHIP:** Blueprint Medicines Corporation

## F4 Cost-Effectiveness of Office-Based Medications for Opioid Use Disorder in the U.S. from the Health Care Sector Perspective

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**BACKGROUND:** Studies show that office-based medications for opioid use disorder (MOUD) reduces illicit opioid use, opioid related overdose and death, emergency healthcare services, and improves treatment retention. While many patients with OUD are commonly treated with office-based MOUD along with counseling, few studies have investigated the cost-effectiveness of these therapies.

**OBJECTIVE:** To estimate the cost, utility, quality-adjusted life years gained (QALY), and incremental cost-effectiveness ratios (ICER) of five office-based MOUD compared to counseling in the U.S. from a health care sector perspective.

**METHODS:** A Markov model was developed to conduct cost-effectiveness analysis of five MOUD compared to counseling: oral buprenorphine/naloxone (Suboxone), buprenorphine implant (Probupine) for one year followed by buprenorphine/naloxone, buprenorphine extended-release (XR) injection (Sublocade), naltrexone XR injection (Vivitrol), and oral methadone. The Markov model included five health states representing combinations of on or off treatment while either using or not using opioids, and death. Costs and utilities of Markov states and emergency department and hospital visits were included. Cycle length was one month; time horizon was 10 years. Model inputs were obtained from systematic reviews of published literature and public data. The primary outcomes included total costs, QALYs, life-years (LYs), and cost/QALY. One-way and probabilistic sensitivity analyses were conducted.

**RESULTS:** In the base-case, the total costs, QALYs, and LYs, respectively, were counseling: $6,753, 6.24, 8.29; buprenorphine/naloxone: $15,444, 6.27, and 8.30; buprenorphine implant: $19,307, 6.27, 8.31; buprenorphine XR: $38,929, 6.26, 8.30; naltrexone XR: $36,577, 6.30, 8.32; and methadone: $13,492, 6.27, 8.31. ICERs ranged from approximately $191,000 (methadone) to $1,485,000 (buprenorphine XR). To be considered cost-effective at $150,000 per QALY gained, buprenorphine/naloxone's price had to be discounted 61% instead of the 28% assumed in the base-case, buprenorphine implant 74%, buprenorphine XR 91%, naltrexone XR 78%, and methadone 42%.

**CONCLUSIONS:** MOUD results in important gains in quality of life and life expectancy. However, the price of MOUD should be discounted significantly to make treatments more affordable to patients and insurers to encourage broader use. The lack of availability of important parameter estimates were the most important limitations to this analysis.

**SPONSORSHIP:** None

## J2 Economic Assessment of Adjuvanted Trivalent Influenza Vaccine Compared to Trivalent High-Dose Influenza Vaccine Among the U.S. Elderly: A Comprehensive Real-World Evidence Evaluation of Direct Healthcare Costs for the 2017-2018 Influenza Season

*Postma M[1], Pelton S[2], Divino V[3], Mould-Quevedo J[4], DeKoven M[3], Krishnarajah G[4]; m.j.postma@rug.nl*
*[1]Department of Health Sciences, University Medical Center Groningen; [2]Boston University School of Medicine and Public Health; [3]IQVIA; [4]Seqirus Vaccines*

**BACKGROUND:** Influenza incurs a substantial economic burden (as much as $11.2B in the U.S. annually) due to physician office visits, emergency room visits (ER), and hospitalizations, especially in the older adult population. Within recent published literature, comparisons of adjuvanted trivalent influenza vaccine (aTIV) and trivalent high dose influenza vaccine (TIV-HD) have shown different clinical benefits; however, study populations and statistical methodologies varied.

**OBJECTIVE:** This research aimed to assess the annualized mean all-cause and influenza-related total healthcare costs of aTIV compared to TIV-HD among subjects 65+ years for the 2017-18 flu season.

**METHODS:** A retrospective cohort analysis of older adults was conducted using professional fee, prescription claims and hospital charge master data in the U.S. Baseline characteristics included age, gender, payer type, region, Charlson Comorbidity Index, location of vaccine receipt, comorbidities, indicators of frail health status, and pre-index hospitalization rates. Treatment selection bias was adjusted through 1:1 propensity score matching (PSM). Economic outcomes were compared using paired t-test including annualized mean all-cause costs and influenza-related costs, which included the costs of influenza-related hospitalizations, ER visits and physician office visits (along with associated outpatient pharmacy). Costs were adjusted using generalized estimating equation (GEE) models, with two-part models used for influenza-related costs. With the GEEs, adjustment for outliers (99th percentile) was also performed and predicted healthcare costs were obtained through bootstrapping (500 replications).

**RESULTS:** During the 2017-18 flu season, the PSM sample comprised 234,313 recipients of aTIV and 234,313 recipients of TIV-HD. Following GEE adjustment, predicted mean annualized all-cause and influenza-related costs per patient were statistically similar between aTIV and TIV-HD (US $9,999 vs. US $10,022 and US $28.21 vs. US $31.77, respectively). Both aTIV and TIV-HD were comparable in terms of predicted mean annualized costs for influenza-related hospitalizations (US $27.59 vs. US $26.29) and influenza-related ER visits (US $3.97 vs. US $4.49). However, aTIV was associated with significantly lower mean annualized costs for influenza-related physician office visits (US $1.10 vs. US $1.36).

**CONCLUSIONS:** In adjusted analyses, total all-cause and influenza-related healthcare costs during the 2017-18 flu season were comparable for older adults vaccinated with aTIV or TIV-HD.

**SPONSORSHIP:** Seqirus Vaccines

## U3 Pharmacy Benefit Carve-In Versus Carve-Out: Cost and Medical Events 2-Year Retrospective Cohort Study

*Lam S[1], Lockwood C[1], Pegus C[1], Smith J[1], Qiu Y[2], Gleason P[2]; steve.lam@regence.com*
*[1]Cambia Health Solutions; [2]Prime Therapeutics*

**BACKGROUND:** Pharmacy benefit can be purchased as an integrated total health package—a Carve-in model—or purchased as a separate benefit administered by an external pharmacy benefit manager—a Carve-out model.

**OBJECTIVE:** To compare the per member per year (PMPY) allowed total medical costs and health care utilization between commercially self-insured members receiving Carve-in to those receiving Carve-out pharmacy benefits overall and by 7 chronic condition sub-groups.

**METHODS:** This study utilized a limited dataset convenience sample of members who were continuously enrolled in a self-insured product from 2017 through 2018 with no major benefit changes from Cambia Blue plans covering 1.6 million members in Oregon, Washington, Utah and Idaho. The total medical PMPY comparison was made using a multivariate general linear model with gamma distribution to adjust for Optum Symmetry Risk Score (proxy for illness severity), age, gender, state of residence, 7 chronic diseases, insured group size, member enrollment in case or disease management, and plan paid to total paid ratio (proxy for benefit richness) between the 2 groups. Medical event objectives were statistically assessed using multivariate logistic regression models comparing the odds of hospitalization or emergency department (ED) visit adjusting for the same covariates. Sub-analyses for members with each of 7 chronic conditions including asthma, coronary artery disease, COPD, heart failure, diabetes, depression and rheumatoid arthritis were performed using the same methods.

**RESULTS:** 205,835 Carve-in and 125,555 Carve-out members met study criteria. Average age was 34.2 yrs (SD 18.6) and risk score 1.1 (SD 2.3) for Carve-in; and 35.2 yrs (SD 19.3) and 1.1 (SD 2.4) for Carve-out. Members were found to have 4% ($P < 0.0001$) lower medical costs after adjustment, translating into an average $148 lower PMPY medical cost ($3,749 Carve-out versus $3,601 Carve-in). The Carve-in

group had an adjusted 15% ($P<0.0001$) lower hospitalization odds and 7% ($P<0.0001$) lower ED visit odds, during the 2-years studied. Of 7 chronic conditions, 5 were found to have significantly lower costs, hospitalization and ED visits with Carve-in benefits.

**CONCLUSIONS:** These findings suggest members with integrated benefits had lower medical costs, fewer hospitalizations and ED visits. These results may be due to access to both medical and pharmacy data leading to improved care management and coordination. Further research is required to confirm.

**SPONSORSHIP:** Cambia Prime and Therapeutics

## U9 Development and Assessment of Real-World Evidence

*Possidente C[1], Johnsrud M[2], McClain W[1], Colavecchia A[1], Hartman T[1], MacLean E[1], Richards K[3], Rascati K[2], Lawson K[4], Barner J[3]; carl.possidente@pfizer.com*
*[1]Pfizer; [2]TxCORE, The University of Texas at Austin; [3]University of Texas at Austin*

**BACKGROUND:** With the proliferation of real-world data (RWD) that supports growth in real-world evidence (RWE) generation and publications alongside the recent FDA RWE Initiative, there is a need to build competency in RWE research concepts across stakeholders to optimize the use of RWE for decision-making in healthcare.

**OBJECTIVE:** To describe the process and outcomes related to developing a novel RWE training program customized for pharmaceutical company field medical professionals.

**METHODS:** Researchers at the Texas Center for Health Outcomes Research and Education (TxCORE) and members of Pfizer Medical Affairs collaborated over a 6-month period to customize the content of an RWE training program. Knowledge gaps were assessed, and 11 content categories addressing these gaps and the variability of knowledge depth were prioritized based on relevance to the medical role. Final program format included 22 hours of self-directed web-based modules, live didactic presentations, and case study workshops. Pre- and post-program testing (30 items each) was conducted that followed a matrix of content categories and complexity levels to gauge competency change. Pre-testing was completed on a sample of 5 participants and finalized prior to launch of the modules and live workshop, which participants completed over a 1-month period.

**RESULTS:** A total of 71 field medical professionals completed the training program. Example content topics included RWD sources, RWE designs, medication adherence, multivariable regression, use of propensity scores, and RWE method tools/checklists. Mean post-program assessment scores increased significantly compared to baseline, 83.2% (SD 11.8) versus 67.6% (SD 11.2), respectively; $P<0.001$. Post program scores increased from baseline in 10 of the 11 content categories, with multivariable regression and propensity score topics having the lowest post program scores, representing more complex topics. Participants expressed high satisfaction with the RWE training program.

**CONCLUSIONS:** Results revealed a positive impact of designing/implementing an RWE training program to improve knowledge across a pharmaceutical field medical team. Review of pre-post scores by content category indicated areas for additional training in multivariable regression and propensity score matching. Key to facilitating success of the RWE training program was an assessment of knowledge gaps prior to designing content and customizing program content to specifically address those gaps. Similar educational programs may optimize generation and use of RWE for stakeholders in healthcare.

**SPONSORSHIP:** Pfizer

# Professional Reviewed Abstracts

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

### A1 Healthcare Burden and Costs of Recurrent *Clostridioides difficile* Infection in the Medicare Population

*Unni S[1], Scott T[1], Boules M[1], Teigland C[2], Parente A[2], Nelson W[1]; sudhir.unni@ferring.com*
*[1]Ferring Pharmaceuticals; [2]Avalere Health*

**BACKGROUND:** *Clostridioides difficile* infection (CDI), especially recurrent CDI (rCDI), is associated with high morbidity and healthcare resource utilization (HRU), imposing significant burden on older adults.

**OBJECTIVE:** This study evaluated HRU and all-cause, direct medical costs in CDI patients with and without rCDI in the Medicare population.

**METHODS:** Retrospective analysis of claims data from the 100% Fee-for-Service Medicare database was performed. Patients with an index CDI episode requiring inpatient stay (diagnosis codes: ICD-9 008.45; ICD-10 A04.7, A04.71, or A04.72) or an outpatient CDI visit with CDI treatment were identified between January 2010 and December 2016. Patients included were those continually enrolled in Medicare Part A, B, and D for 12 months before and 12 months after the first date of the index CDI episode. Each CDI episode was followed by a 14-day period with no CDI claims after the end of treatment to distinguish rCDI from index episode CDI. rCDI was defined as another CDI episode within an 8-week window immediately after the claim-free period. HRU and costs were captured for 12 months of follow-up, stratified by increasing number of rCDI episodes.

**RESULTS:** 268,762 patients had an index CDI episode. Mean (SD) age was 78.3 (8.0) yrs, 69.0% were female. 175,554 (65.3%) had no rCDI, 38,163 (14.2%) had 1 rCDI, 22,898 (8.5%) had 2 rCDI, and 32,147 (12.0%) had 3+ rCDI in the 12-month post-index period. During the 12-month follow-up, 85% of patients had at least 1 hospitalization and a substantial number of patients had ≥3 hospitalizations (no rCDI: 23.8%, 1 rCDI: 34.0%, 2 rCDI: 37.4%, and 3+ rCDI: 40.9%). Mean (SD) length of hospital stay was 13.4 (17.2) days and approximately 18 (20) days for those without and with rCDI, respectively. Total, all-cause, direct medical costs per patient during follow-up, by increasing number of rCDI episodes, were $76,024, $99,348, $96,148, and $96,517, with 53% to 60% driven by inpatient and post-acute care costs.

**CONCLUSIONS:** More patients with recurrent CDI had repeat hospitalizations than those with no recurrence, and a longer duration of hospital stay. All-cause, direct medical costs were also substantial and higher in these patients. Reduction of recurrences is warranted to reduce the overall burden of CDI.

**SPONSORSHIP:** Ferring Pharmaceuticals

### A3 Prevalence of Sexually Transmitted Infection Screenings and Diagnoses in the Mississippi Medicare Population

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**BACKGROUND:** Since 2013, diagnoses for sexually transmitted infections (STI) has increased across the US. Adolescents and young adults account for a majority of cases, however studies have indicated rates may be increasing in the older populations as well. A recent report noted diagnosis rates for common STIs increased 23% between 2014 and 2017 for patients over 60 years of age.

**OBJECTIVE:** The objective of this study was to assess the epidemiological trends for the diagnosis and screen of common STIs in the Mississippi Medicare population.

**METHODS:** Mississippi Medicare claims were analyzed to determine the prevalence of common STIs and utilization of preventative services in the Medicare FFS population in 2014 and 2016. Sexually transmitted infections explored include syphilis, gonorrhea, chlamydia, chancroid, trichomoniasis, herpes, and other venereal diseases.

**RESULTS:** The overall prevalence of STI diagnoses in the Mississippi Medicare population decreased between 2014 and 2016. The prevalence of syphilis, trichomoniasis, and herpes decreased 34%, 57%, and 18%, respectively in 2016. Overall the number of STI diagnoses decreased 9.57%. Diagnosis of a STI was more prevalent in women and the population younger than 75 years old. The number of Annual Wellness Visits more than doubled between 2014 and 2016, but the rate of STI screenings decreased 80.7% during that same time period.

**CONCLUSIONS:** The study found the overall prevalence of common STIs and rate of STI screenings decreased between 2014 and 2016 in the Mississippi Medicare population.

**SPONSORSHIP:** None

### B1 Weight Gain and Related Comorbidities Following Antiretroviral Initiation in the 2000s: A Systematic Literature Review

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**BACKGROUND:** Antiretroviral therapies (ART) have benefited millions with HIV. However, concerns about subsequent weight gain and related metabolic complications have emerged. First-generation ART is associated with adipose tissue changes, including lipodystrophy and chronic metabolic consequences. While newer ART may have fewer adipose alterations, it is unclear whether they lead to increased weight gain and related comorbidities.

**OBJECTIVE:** To elucidate relationships between use of newer ART and weight related comorbidities with a specific focus on studies performed since 2000.

**METHODS:** A systematic literature review was performed using the PRISMA approach, including publications since 2010 from PubMed, Medline, EMBASE, and Google Scholar. Titles and abstracts of 2326 publications were screened, with 222 identified for assessment. Eligibility review based on publication type, methodology, comorbidities, and other analyses including economic impacts, yielded a comprehensive review of 50 publications covering a range of secondary outcome measures including diabetes and hypertension, particularly US studies with large patient cohorts (N > 100 for prospective studies; N > 1000 for retrospective studies).

**RESULTS:** The majority of the studies describing weight gain found the most significant gains during the first year after initiating ART. Of the 4 studies that quantitatively reported weight changes, patients gained approximately 5 kg, 18-96 months after initiating ART. Recent data from at least 2 studies reported greater gains in those taking an integrase strand transfer inhibitor vs. another ART. One study reported

that uninsured minority non-white patients gained significantly more weight (≥3% annual body mass index increase). Thirty-nine studies discussed weight-related comorbidities, including increased risk of diabetes and hypertension following ART initiation. An increase in healthcare resource utilization and economic burden associated with weight gain and comorbidities was described following ART initiation, with one study estimating an average annual increase of $2,000-$4,000 per patient.

**CONCLUSIONS:** Despite an expectation that newer ART may not be associated with weight gain, this literature review suggests that use of some ART is associated with more pronounced weight gain and related comorbidities. Future studies should define and quantify the direct role of newer ART, by specific drug classes, in weight gain and related metabolic disturbance. This, along with balancing pros and cons of use of newer ART in patient subsets at greater risk of weight gain, can help improve patient intervention strategies.

**SPONSORSHIP:** Janssen Scientific Affairs

## B2 Characteristics of Pre-Exposure Prophylaxis Utilization in Transgender and Homeless Medicaid-Covered Patients in New York City

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**BACKGROUND:** According to the Center for Disease Control and Prevention, transgender non-conforming (TGNC) people are at high-risk for acquiring human immunodeficiency virus (HIV); in 2017, 14% of TGNC women and 3% of TGNC men were living with HIV in the United States. However, these numbers are limited since the TGNC population is often underrepresented in studies. Amida Care has been a Medicaid Special Needs Plan in New York City (NYC) for the HIV-positive population only. As of November 2017, the plan was permitted to enroll HIV-negative persons with transgender experience or without a home who may be at risk for acquiring HIV. This positioned Amida Care to help End the HIV Epidemic through facilitating access to Pre-Exposure Prophylaxis (PrEP) for high-risk persons.

**OBJECTIVE:** To characterize utilization of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for PrEP in Medicaid-covered members at high risk of HIV infection living in NYC.

**METHODS:** A pharmacy-claims based analysis was performed to include members who filled ≥1 30-day prescription for PrEP between 1/1/18-9/30/19. Plan data was used to identify those who were HIV-negative, TGNC, and/or homeless. These groups were analyzed further based on demographic data including member age, gender, ethnicity, and enrollment status.

**RESULTS:** In 2018 there were 349 unique HIV-negative members enrolled of whom 24% (n=82) had filled ≥1 prescription for PrEP, and in the first 3 quarters of 2019, 527 members of whom 26% (n=135) had filled. A total of 935 prescriptions were filled during the study window; 295 were filled in 2018 and 640 in the first 3 quarters of 2019. 47% of prescriptions were filled in a pharmacy located in Manhattan, 23% in the Bronx and 20% in Brooklyn. Overall, 161 unique members filled PrEP; 71% (n=115) were identified as TGNC, 4% (n=7) as cisgender homeless; 11% (n=17) as both TGNC and homeless, and 14% (n=22) with a pending status confirmation. Of the members on PrEP, 20% were African American, 11% Hispanic, 7% Multiracial, 7% White, and 55% other/unknown. Those who filled PrEP were 19 to 60 years of age; the mean age was 32 (SD=9.2, median=31). On average, 15% of the actively enrolled population had filled PrEP each month.

**CONCLUSIONS:** As the HIV-negative membership grew from 2018 to 2019, 30-day PrEP prescription fills also increased. PrEP was accessed primarily by young adults and people of color who identify as TGNC in Manhattan. Further analysis is needed to assess PrEP persistence through evaluating healthcare gaps and identifying clinical interventions specific to the needs of the TGNC and homeless population.

**SPONSORSHIP:** Amida Care Health Plan

## B3 Trends in Provider Specialty and Payor Type for Pre-Exposure Prophylaxis, 2014-2017

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**BACKGROUND:** In the U.S., F/TDF is approved for HIV pre-exposure prophylaxis (PrEP) in adults and adolescents, and PrEP uptake has been significantly associated with declines in HIV diagnoses independent of community virologic suppression. Previous studies have shown gender and age differences among individuals started on F/TDF for PrEP.

**OBJECTIVE:** We aim to describe characteristics and differences in PrEP utilization by provider specialty and payor type.

**METHODS:** We used a nationally representative sample of de-identified data provided by Symphony Health (2014-2017) to quantify the number of unique individuals who received F/TDF for PrEP prescriptions, representing >80% of retail pharmacies in the U.S. A validated algorithm was used to exclude F/TDF for non-PrEP use (e.g. HIV treatment, PEP, and off-label HBV treatment). Data included patient and provider demographics, prescription refill data, and medical claims. Data was analyzed by payor type and provider specialty.

**RESULTS:** Between 2014-2017, a total of 158,183 unique individuals were started on F/TDF for PrEP. Females were 8.7 times (95% CI 8.1-9.3) more likely to receive PrEP prescriptions from emergency medicine providers than males ($P<0.001$). Males were 3.0 times (95% CI 2.8-3.2) more likely to receive PrEP prescriptions from internal medicine providers than females ($P<0.001$). Individuals ≤24 years old were 2.8 times (95% CI 2.6-3.0) more likely to receive PrEP prescriptions from emergency medicine providers and 13.9 times (95% CI 12.3-15.9) more likely to receive PrEP prescriptions from pediatricians than those 25 and older ($P<0.001$). Individuals 25 years and older were 2.2 times (95% CI 2.1-2.3) more likely to receive PrEP prescriptions from internal medicine providers than those ≤24 years old ($P<0.001$). Female PrEP users were 4.7 times (95% CI 4.5-4.8) more likely to access PrEP using Medicaid compared to male PrEP users ($P<0.001$). Male PrEP users were 1.9 times (95% CI 1.9-2.0) more likely to access PrEP using commercial insurance compared to female PrEP users ($P<0.001$). Individuals ≤24 years old were 1.9 times (95% CI 1.8-1.9) more likely to access PrEP using Medicaid than those 25 and above ($P<0.001$).

**CONCLUSIONS:** There were gender and age differences in PrEP payor types and provider specialties who prescribe PrEP, which highlights the need for different strategies for provider education and linkage to PrEP services among those at risk for HIV.

**SPONSORSHIP:** Gilead Sciences

## B4 Assessment of Economic Burden and Hospitalization on Patients with Human Immunodeficiency Virus in the US Veterans Health Administration Population

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**BACKGROUND:** Human immunodeficiency virus (HIV) is a lifelong infection that, if left untreated, results in severe morbidity and mortality. Evaluating the healthcare utilization and costs and predictors of hospitalization among affected patients is important to understand the overall burden of HIV.

**OBJECTIVE:** To assess economic burden and examine significant predictors for hospitalization for HIV patients in the US Veterans Health Administration (VHA) population

**METHODS:** Adult patients with ≥1 diagnosis for HIV (International Classification of Disease, 9th revision, Clinical Modification code 042; ICD-10-CM: B20) during the identification period (01OCT2014-30SEP2017) were included from the VHA population. The first HIV diagnosis was designated as the index date (case cohort). Patients without an HIV diagnosis but with the same age, sex, race, and index year as an HIV patient were identified as controls. The index date for control patients was randomly selected to minimize bias. Patients were required to have continuous enrollment for 12 month pre- and post- (follow-up) index date. Healthcare utilization and costs during the follow-up period were compared among case and control patients. Logistic regression was used to identify the predictors of hospitalization (covariates included age [ref: ≥65 years], race [ref: white], Charlson comorbidity index [CCI]) among case (HIV) patients. Odds ratios (ORs) and 95% confidence intervals (CIs) were reported.

**RESULTS:** A total of 51,774 patients were included in each cohort. The mean age was 56 years and 97% of patients were men. HIV patients had higher mean CCI scores (1.00 vs 0.79; $P<0.001$) than control patients. During follow-up, HIV patients had an over three times higher proportion of patients with ≥1 hospitalization (9.6% vs 2.9%; $P<0.001$) and incurred significantly higher inpatient ($4,028 vs $997), outpatient ($6,868 vs $2,188), pharmacy ($8,009 vs $477), and total healthcare costs ($18,906 vs $3,662) compared to controls. Higher CCI score (OR: 1.24, 95% CI: 1.21-1.27), age ([18-25 years: OR: 1.25; 95% CI: 0.62-2.48]; [26-34 years: OR: 1.47; 95% CI: 1.19-1.43]; [35-54 years: OR: 1.23; 95% CI: 1.09-1.39]; [55-64 years: OR: 1.28; 95% CI: 1.15-1.44]), and race (black: OR: 1.30, 95% CI: 1.19-1.43) were the significant predictors of hospitalization among HIV case patients.

**CONCLUSIONS:** Patients diagnosed with HIV had significantly higher economic burden and hospitalization than those without HIV during the follow-up. Higher CCI score and age and black race were significant predictors of hospitalization.

**SPONSORSHIP:** None

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

### C1 Examination of Financial Toxicity on Catastrophic Outcomes, Utilization, and Quality of Life in Cancer Patients in a United States Representative Database

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**BACKGROUND:** Cancer patients carry a burden of paying higher out of pocket costs for their care than those without cancer. In the US, medical costs of cancer have skyrocketed from $27 billion in 1990 to $80.2 billion in 2015. 25% of insured adults with cancer reported using all or most of their savings during treatment in 2006.

**OBJECTIVE:** Goals of this study were to quantify the relationship between indicators of patient financial strain (commonly known as "financial toxicity") and health utilization and quality of life (QOL) in subjects ever diagnosed with cancer.

**METHODS:** This was a 2016 retrospective cohort study investigating financial toxicity of cancer patients using the Medical Expenditure Panel Survey (MEPS). The analysis focused on MEPS participants who indicated cancer history on the validated Cancer Self-Administered Questionnaire. Survey multiple logistic regression quantified the relationship via odds ratios between two exposures related to financial toxicity ("Were you worried about income stability?" and "Did you have to sacrifice your living situation?") and the separate outcomes of (1) one or more hospitalization, (2) one or more emergency department (ED) visit, (3) total health spend of $20,000 or more, (4) death, (5) poor QOL. Analysis was adjusted for age, race, gender, marital status, and census region. All analyses were conducted in RStudio (Boston, MA) with an $\alpha$-level $<0.05$ for all tests.

**RESULTS:** The weighted sample size was 26,004,707 lives with 40% males, 60% females. Mean subject age was 65. For the exposure of "sacrificed living situation" and the 2016 outcomes of hospitalizations, ED visits, total health spend of $20,000 or more, death, and poor QOL, the ORs were 2.53 [95% Confidence Interval (CI), 1.0, 6.2], 2.33 [95% CI, 1.1, 5.1], 7.1 [95% CI, 1.7, 29.6], 11.24 [95% CI, 2.8, 44.4], 3.97 [95% CI, 1.3, 12.2], respectively. For the exposure of "worry about income stability" and the 2016 outcomes of hospitalizations, ED visits, total health spend of $20,000 or more, death, and poor QOL, the ORs were 2.7 [95% CI, 1.5, 5.1], 1.45 [95% CI, 0.8, 2.5], 1.88 [95% CI, 0.7, 5.0], 2.31 [95% CI, 0.9, 5.9], 1.59 [95% CI, 0.4,5.3], respectively.

**CONCLUSIONS:** In a nationwide, validated US representative sample, cancer patients suffering from financial duress are more likely to utilize health care resources, incur high total costs, face poor quality of life, and likelihood of death. Given rapidly increasing costs of oncology therapies, these trends are likely to exacerbate. Policy development is necessary to reduce the cost burden linked to poor patient outcomes.

**SPONSORSHIP:** None

### C2 Productivity Loss Costs Among Hepatocellular Carcinoma Patients and Caregivers in a Commercially Insured Population in the United States

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**BACKGROUND:** In the US, there are 42,030 new liver cancer cases in 2019. Hepatocellular carcinoma (HCC) represents 80% of liver cancer cases. The median age at HCC diagnosis is 62 years, indicating that >50% of patients are likely members of the workforce. Working patients with HCC, and their caregivers, need time for medical care and recovery resulting in indirect costs to their employers due to lost productivity.

**OBJECTIVE:** This study examined productivity time loss and costs associated with absenteeism (ABS), short-term disability (SD), and long-term disability (LD) among HCC patients and their caregivers.

**METHODS:** The MarketScan database was used to identify HCC patients (ICD-9 155.0, ICD-10 C22.0, C22.8) from 1/1/2011-6/30/2018 continuously enrolled for ≥6 months prior and ≥1 month post HCC diagnosis (index). The final sample consisted of newly diagnosed HCC patients who were full time workers who had ABS, SD or LD eligibility. Those who were pregnant, had prior liver transplant, prior metastasis, or clinical trial participation during the study period were excluded. Adult caregivers, also full-time workers, among eligible HCC patients were identified and required to be continuously enrolled for ≥6 months prior and ≥1 month post index. Caregivers were identified in MarketScan by a key indicating the relationship of the patient to primary enrollee. Productivity time loss and costs (indirect cost)

associated with ABS, SD and LD were examined during follow-up; lost wages were calculated based on the US Bureau of Labor Statistics 2017 report. Productivity time loss and cost were reported as per-patient-per-month (PPPM).

**RESULTS:** The final sample included 554 patients (80% male, mean age 55.6 years, median follow up, 12.7 months) and 413 caregivers (75% female, mean age 53.1 years, median follow up 28.5 months). Demographics were similar across ABS, SD and LD cohorts for patients and caregivers. Use of ABS and SD was more common than LD among patients (78.5%, 47.7% and 11.8%) and caregivers (87.5%, 17% and 2.1%), respectively. Indirect cost was higher for those with an ABS claim (44.7 hours, $1,424 PPPM) than an SD claim (4.1 days, $700 PPPM) or LD claim (1.1 days, $192 PPPM) among patients. Similar results were observed among caregivers: (ABS: 23.4 hours, $641 PPPM), (SD: 0.4 days, $61 PPPM) and (LD: 0.1 days, $8 PPPM).

**CONCLUSIONS:** HCC patients and their caregivers incur a substantial indirect cost. Novel agents are needed to lessen the time burden on patients with HCC and their caregivers.

**SPONSORSHIP:** AstraZeneca

## C3 Epidemiology, Economic Burden, and Humanistic Burden Among Patients with Hepatocellular Carcinoma in the United States: A Systematic Literature Review

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**BACKGROUND:** Despite recent declines in incidence and deaths from all cancer in the United States (US), liver cancer incidence and mortality is rising. Hepatocellular carcinoma (HCC) represents ~80% of all liver cancers, but the current burden is unclear.

**OBJECTIVE:** To describe the epidemiological, economic, and humanistic burden among patients with any stage of HCC in the US who are not eligible for liver transplant.

**METHODS:** MEDLINE-indexed articles and Embase-indexed conference abstracts published from 2008-2018 and describing observational evidence of patients with HCC in the US were considered for this review. Epidemiology and economic information was limited to studies using sources with national coverage; epidemiology was further limited to studies from the past 5 years. Study design, patient characteristics, and outcomes data were extracted and compiled.

**RESULTS:** From 9795 total citations screened, 99 citations were included. On average, patients were ~64 years old and 74% were male; payers included Medicare (41%), commercial insurance (32%), Medicaid (17%), self-pay (4%), and others/none (6%). Incidence was 9.5 per 100,000 person-years (PY) in the general population but was higher in Medicare and Veterans Affairs (22.3 and 45 per 100,000 PY, respectively). HCC incidence among patients with cirrhosis from any cause, infection with hepatitis B/C, or alcoholism was ~100-times higher than the general population; as a result, a high proportion of patients with HCC had these risk characteristics. Treatment patterns and median overall survival (months) depended on disease stage at diagnosis: resection (8%, 20.2-47.1), liver-directed (16%, 11.5-25.6), radiation (4%, 5.2-15.3), chemotherapy (8%, 6.4-10.4), and no treatment (59%, 3.1-6.4). Total payer+patient monthly costs ranged from $11,913 to $16,947 depending on treatment modality; 3-year payer costs were $154,688 versus $69,010 in non-cancer patients with cirrhosis. Employees with HCC miss on average 22 days of work in the 6 months following diagnosis, which translates to a $3594 cost per patient to employers versus 3.4 days and $652 cost in healthy controls. Limited humanistic burden evidence indicated significant symptom burden and poor quality of life.

**CONCLUSIONS:** The incidence and costs of HCC represent a major burden to patients, caregivers, and the health care system in the US. Patients with intermediate or advanced HCC may elect to forgo treatment due to high costs and limited survival benefits of existing therapies.

**SPONSORSHIP:** AstraZeneca

## C4 Comparing Total Cost of Care for Medicare Fee-for-Service Patients with Metastatic Pancreatic Cancer by Chemotherapy Regimen

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**BACKGROUND:** There is currently limited real-world evidence on treatment costs for metastatic pancreatic cancer patients with Medicare.

**OBJECTIVE:** To analyze total cost of care for patients with metastatic pancreatic cancer (m-PANC) by FDA-Approved/NCCN Category 1 therapeutic regimen.

**METHODS:** We identified patients with m-PANC using ICD-9/10 diagnosis codes in the 2014-2017 Medicare 100% Research Identifiable Claims Files, which included all Medicare Part A, B, and D paid claims for 42.5 million fee-for-service (FFS) beneficiaries. We studied total costs of care by therapy regimen. Patients in our study had two or more claims with a pancreatic cancer (PANC) diagnosis more than 30 days apart and one or more claim with a secondary malignancy (metastasis) diagnosis on or after the first PANC diagnosis date. We defined index date as the earliest metastasis diagnosis date. We excluded patients with pre-index non-PANC malignancies and those without six-month pre-index and three-month (or until death, if earlier) post-index Medicare FFS enrollment. A therapy regimen was defined as ending the day before a new chemotherapy began, 28 days after the last chemotherapy (if no new chemotherapy), or upon death.

**RESULTS:** We identified 28,063 m-PANC patients (mean age at index: 74.5 years; mean Charlson comorbidity index score: 3.4). FDA-Approved/NCCN Category 1 regimens studied include gemcitabine/nab-paclitaxel (gem-nab: 18% of regimens), FOLFIRINOX (FFX: 5%), and liposomal irinotecan (nal-IRI: 2%). Total cost of care for m-PANC patients was similar across regimens: $39,497 for gem-nab, $39,470 for FFX, and $39,909 for nal-IRI. The main cost drivers across all regimens were Part B chemotherapy, Part B growth factor and inpatient services (intensive care unit –ICU-, radiotherapy, and surgery). Part B Chemotherapy costs were 36% of total costs for gem-nab, 3% for FFX, and 46% for nal-IRI. Part B Growth Factor costs were 5% of total costs for gem-nab, 29% for FFX, and 10% for nal-IRI. Inpatient service costs were 22% of total costs for gem-nab, 20% for FFX, and 13% for nal-IRI.

**CONCLUSIONS:** The mean total Part A, B, and D costs for the three FDA-Approved/NCCN Category 1 regimens studied were similar, however, the drivers of cost differed. Although nal-IRI had the highest Part B Chemotherapy costs among the regimens studied (46%), it also had the lowest inpatient services costs (13%). FFX had the lowest Part B Chemotherapy costs (3%), but the highest Part B Growth Factor costs (29%). Gem-nab had the lowest Part B Growth Factor costs (5%).

**SPONSORSHIP:** Ipsen Biopharmaceuticals

## C7 Treatment Patterns, Healthcare Resource Utilization, and Costs of Care in Patients with Extensive Stage Small Cell Lung Cancer

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**BACKGROUND:** Limited data exist on treatment patterns and costs in patients with extensive stage small cell lung cancer (ES-SCLC) since the introduction of immune-oncology (IO) agents.

**OBJECTIVE:** This study evaluated treatment patterns, healthcare resource utilization (HCRU) and costs in patients with ES-SCLC in the US prior to the introduction of IO as a first-line (1L) treatment option.

**METHODS:** A retrospective cohort study was performed using the IBM Watson Health MarketScan Commercial and Medicare databases to identify patients with an index lung cancer diagnosis in Jan-Dec 2017 and drug codes for SCLC-specific therapies including irinotecan, topotecan, temozolomide, bendamustine, and etoposide with ≤3 day infusions. Patients were ≥18 years of age and had continuous health plan enrollment from 12-months pre-index diagnosis date through the start of 1L treatment. Treatment patterns in 1L and second-line (2L) are reported. Per patient per month (PPPM) HCRU and costs (payer-paid and patient out-of-pocket [OOP], USD 2018) were measured from the index diagnosis date to the end of follow-up.

**RESULTS:** In 2017, 225 patients meeting the inclusion criteria received 1L chemo. Their mean age (SD) was 64.8 (9.7) years, with 56.4% female. The mean (SD) time from diagnosis to 1L treatment start was 28.4 days (18.5). The mean 1L treatment duration was 95.8 days, consistent with 4-5 cycles of chemotherapy. The mean treatment-free interval after 1L chemotherapy among the 72 patients receiving 2L therapy was approximately 2.5 months (70 days). Among 2L patients, 51.4% (n=37) received chemo and 48.6% (n=35) received IO monotherapy. During follow up of the 225 patients, 75.6% had an inpatient stay (average length = 6.4 days), 65.8% had an emergency room visit, and patients averaged 7.2 outpatient visits per month. The total cost PPPM was $15,811 (SD=$15,725) of which payers paid 97% ($15,386) and patients (OOP) paid 3% ($425). Mean (SD) inpatient and outpatient PPPM costs were $6,311 ($13,285) and $9,150 ($6,622), respectively. The PPPM cost for visits associated with lung cancer drug therapy was $3,214 (the cost of drug and supplemental therapies, drug administration, provider visits and additional procedures).

**CONCLUSIONS:** In 2017, only about a third of ES-SCLC patients treated with 1L chemo went on to receive 2L therapy, consistent with the aggressive nature and poor prognosis of this disease and indicating a high unmet need for improved 1L treatments. Monthly costs per patient were considerable, averaging $15,000 to payers and $400 to patients.

**SPONSORSHIP:** AstraZeneca

## C8 Treatment Patterns and Overall Survival in Patients with Extensive Stage Small Cell Lung Cancer from US Community-Based Oncology Practices

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**BACKGROUND:** Limited data exist on outcomes in extensive stage small-cell lung cancer (ES-SCLC) since the introduction of first-line (1L) immune-oncology (IO) treatment.

**OBJECTIVE:** To evaluate treatment patterns and overall survival (OS) among patients with ES-SCLC treated with chemotherapy (chemo) or IO therapy in 1L.

**METHODS:** A retrospective cohort study was performed using structured data from a US community-based oncology electronic medical record database. Patients with ES-SCLC, ≥18 years old, initiating 1L with chemo or IO agents Jan 2017-May 2019 were classified into 3 groups: chemo alone, IO alone, or chemo+IO. Treatment patterns in 1L and second line (2L) are reported. Changes in 1L IO use following chemo+IO approval in 1L were evaluated by the treatment distribution for patients initiating 1L pre-Dec 2018 and post-Dec 2018. Time to next treatment (TTNT), used as a proxy for progression-free survival, was computed as the time from start of first treatment until the start of 2L treatment or the earliest of death or end of follow-up for those who did not start 2L. TTNT and OS were calculated using the Kaplan-Meier estimator.

**RESULTS:** 366 patients met study criteria initiating 1L therapy Jan 2017-May 2019 with chemo alone (82%, n=301), IO alone (4%, n=13), or chemo+IO (14%, n=52). Mean age (SD) was 67.7 (9.1) years, with 51.6% female. 1L treatment distribution pre-Dec 2018 vs post-Dec 2018 was 92% vs 39% chemo alone, 4% vs 3% IO alone, and 5% vs 58% chemo+IO. Of the 301 chemo alone patients, carboplatin+etoposide was the most common 1L regimen (85%), and almost all patients (98%) in the chemo+IO group used atezolizumab in combination with etoposide+a platinum agent. Of the 366 1L patients, 44% (n=160) moved on to 2L after a mean treatment-free interval of 66 days. The median TTNT was 171, 145, and 162 days, with percent of patients who died or received 2L at 6 months being 52.7%, 55.0%, and 51.3% for the chemo alone, IO alone and chemo+IO groups, respectively. Median (95% CI) OS was 8.8 (7.9-9.9) months in the chemo alone group, and was not reached due to censoring in the IO alone and chemo+IO groups primarily as a function of shorter follow-up time for patients receiving IO or chemo+IO in 1L (mean days=212, 184 and 112, respectively).

**CONCLUSIONS:** 1L IO use in ES-SCLC increased to approximately 60% of study patients primarily in combination with chemotherapy by mid-2019. Assessment of OS and TTNT are limited by <6 months of follow-up time for the IO therapy groups indicating a need for additional research.

**SPONSORSHIP:** AstraZeneca

## C9 A Budget Impact Analysis on the Prophylactic Use of Biosimilar Pegfilgrastim in Non-Myeloid Cancer Patients at Risk of Chemotherapy-Induced Febrile Neutropenia and Its Expanded Use to Intermediate-Risk Patients

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**BACKGROUND:** Febrile Neutropenia (FN) remains one of the most serious and costly, yet one of the most preventable complications of chemotherapy. Current practice guidelines recommend routine primary prophylaxis (PP) with a granulocyte-colony stimulating factor (G-CSF) in patients at high-risk of FN, but not for lower-risk settings (i.e., intermediate risk) owing to cost concerns. However, biosimilar G-CSFs (e.g. with pegfilgrastim-bmez) may help reduce drug costs while expanding access to G-CSF PP for patients at intermediate risk of FN.

**OBJECTIVE:** To quantify the budget impact (BI) of converting patients from reference pegfilgrastim to biosimilar pegfilgrastim-bmez, and expanding its use to patients at intermediate risk of FN from a mixed US commercial and Medicare payer perspective.

**METHODS:** BI analyses were conducted in a hypothetical one-million-member health plan over a 5-year time horizon and evaluated the total costs of PP (drug and FN-related healthcare resource utilization [HCRU]) with G-CSF (six cycles in a year) in non-myeloid cancer patients. The rates of high, intermediate, and low FN-risk patients receiving G-CSF prophylaxis were obtained from the literature. The first scenario assessed the BI of converting patients from reference pegfilgrastim to pegfilgrastim-bmez (10% utilization in year 1 to 60% by year 5), keeping the number of G-CSF eligible patients constant. The second scenario assessed the BI of expanding the use of PP with

pegfilgrastim-bmez to 10% more patients at intermediate FN-risk. Costs for G-CSF utilization and FN-related HCRU were estimated from publicly available data and literature. Cost for pegfilgrastim-bmez was assumed to be 63% of the wholesale acquisition cost of reference pegfilgrastim.

**RESULTS:** Assuming increase from 3,432 to 3,518 G-CSF eligible patients from Year 1 to Year 5, converting patients from reference pegfilgrastim to pegfilgrastim-bmez would result in $92M savings ($37M for Medicare and $55M for Commercial) over 5 years. Expanding the use of G-CSF with pegfilgrastim-bmez to patients at intermediate risk of FN (n = 700 in Year 1 and n = 717 in Year 5) would result in an additional $16M ($6.6M in Medicare and $9.5M in Commercial) 5-year cumulative savings.

**CONCLUSIONS:** Converting patients at risk of FN from reference pegfilgrastim to pegfilgrastim-bmez is a cost-saving strategy. In addition, expanding the use of PP with pegfilgrastim-bmez to patients at intermediate risk of FN is also cost saving, generating offsets associated with a lower rate of FN-related complications and improving patients outcomes.

**SPONSORSHIP:** Sandoz

## C13 The Cost Impact of Increased Molecular Testing Rates for the Treatment of Patients with Gastrointestinal Stromal Tumors

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**BACKGROUND:** The effectiveness of approved therapies used to treat gastrointestinal stromal tumors (GIST) varies by type of cancer driver mutation. Because adherence to guideline-recommended molecular testing of patients with GIST is limited, measuring the costs associated with increased testing is relevant for healthcare decision makers.

**OBJECTIVE:** To estimate the cost impact associated with an increase in molecular testing rates of *PDGFRA* exon 18 and *KIT* exon 9 for US GIST patients, including the effects of treatment allocation decisions and adverse events (AEs).

**METHODS:** A cost impact model was developed in Microsoft Excel with a US health plan perspective on a 12-month incidence basis, and included both adjuvant and advanced/metastatic patients. The model compared costs based on current testing rates at diagnosis: 49% for *PDGFRA* exon 18 and 60% for *KIT* exon 9, to a scenario where 100% of patients are tested. The model incorporated testing costs assuming PCR-based tests. Un-tested patients or those with other mutations were assumed to receive treatment with standard generic imatinib 400 mg, while *KIT* exon 9+ patients were assumed to receive imatinib 800 mg. *PDGFRA* exon 18 patients received best supportive care, based on the lack of response observed for any treatment in patients with the exon 18 D842V mutation, the majority of exon 18 patients. Duration of treatment in the adjuvant setting was a standard 36-month period, and duration in the advanced/metastatic setting was based on median progression free survival from clinical trials in patients with each mutation type.

**RESULTS:** The base case of the model used a mixed 69% commercial, 22% Medicare, and 9% Medicaid plan, and a GIST incidence rate of 11 per million members. The number of additional patients needed to test for one patient to receive optimized treatment was 10. An increase in testing rates to 100% for both mutation types was associated with a total annual cost increase of $15,213 per million members, or $0.015 per member per year (PMPY). Testing costs were $2,748 higher, AE costs were $293 lower, and pharmacy costs increased by $12,758, driven by increased dosing and longer progression free survival in KIT exon 9 patients. If only PDGFRA exon 18 testing is included, the result is a cost savings of $0.008 PMPY, due to lower pharmacy costs. The magnitude of the cost impact associated with increased testing remained small across all plan types.

**CONCLUSIONS:** Increased molecular testing in GIST is associated with minimal additional cost and a meaningful increase in the number of patients receiving optimized treatment.

**SPONSORSHIP:** Blueprint Medicines Corporation

## C14 Does Breast Cancer Staging Affect Achievement of Target Price Under the Oncology Care Model?

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**BACKGROUND:** The Oncology Care Model (OCM) is an episode-based alternative payment model developed by the Center for Medicare and Medicaid's Innovation Center to improve quality of care while reducing total cost of care. OCM participants can achieve shared savings if aggregate episode expenditures fall below set target prices. Currently cancer staging, which represents disease burden and prognosis, is not included in the target price calculation and could lead to unrealistic target prices being set.

**OBJECTIVE:** To describe the characteristics of OCM breast cancer episodes and explore the difference between mean episode expenditure and target price among different levels of cancer progression.

**METHODS:** A retrospective cross-sectional study was conducted at Jefferson Health, an NCI-designated cancer center, using data from Jefferson's electronic medical record and OCM performance data for episodes initiated between 6/30/16 and 7/1/18. OCM episodes were included if they were classified as a breast cancer episode for which cancer stage information was available in the EMR and patient was alive at the time of data extraction. Episodes were divided into groups based on cancer staging (stages I-IV). Difference from target price was calculated by subtracting target price from adjusted total cost of care. Chi-square tests were used to analyze patient demographics and analysis of variance tests were used to compare mean differences from target price between multiple levels of staging.

**RESULTS:** Of the 501 breast cancer OCM episodes included, 45.1%, 24.6%, 6%, and 24.4% of episodes were identified as stage I-IV, respectively. The mean target price per-episode was $9,289, $12,681, $19,578, and $30,031 for stages I-IV, respectively, and mean difference between per-episode total cost of care and target price was -$2,311, $1,378, -$6,928, and $14,107 for stages I-IV, respectively. Per-episode mean difference from target price was found to be statistically significantly different between all groups ($P < 0.01$). Per-episode mean difference was also found to be statistically significant when comparing metastatic cancer against non-metastatic ($P < 0.01$), stage II against stage I ($P = 0.02$), and stage IV against stage I ($P < 0.01$).

**CONCLUSIONS:** Our results suggest a possible association between cancer staging and the difference of adjusted total cost of care and target price for breast cancer episodes in the OCM. These findings indicate there may be opportunities to further improve the OCM risk adjustment model by incorporating important patient-level clinical characteristics including cancer staging.

**SPONSORSHIP:** None

## C15 Evaluation of Treatment Patterns and Outcomes in Patients Diagnosed with Metastatic Solid Cancers with Linked Claims plus Prior Authorization Data

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**BACKGROUND:** Integration of clinical and claims data allows for the examination of outcomes and characteristics that are not available in a single database, and is essential for real world evidence generation. We describe utilization of an oncology clinical data program integrated with claims data to describe treatment patterns and outcomes in select solid cancers.

**OBJECTIVE:** Evaluate treatment patterns, resource utilization, and total costs of therapy for patients with newly diagnosed metastatic breast (B), pancreatic (P), melanoma (M), or colorectal (C) cancer, using linked clinical and claims database.

**METHODS:** 23,659 commercial patients with a solid cancer diagnosis, captured between February 2016 to May 2018 with both clinical information from a Prior Authorization (PA) tool (based on NCCN guidelines) and claims from the Optum Research Database were selected to be included in the analysis. Demographics, clinical information (metastatic status and line of therapy), treatment duration, resource utilization, and all-cause cost were collected, and uploaded to a dynamic web-based Tableau® dashboard. Analysis was conducted for 1st line therapy in metastatic setting, based on the 1st observed episode; drug additions or switches incremented line of therapy, while single drug discontinuations did not increment. All cost data were adjusted to 2017 values.

**RESULTS:** 6,217 metastatic patients were identified; 1,861 B, 791 P, 413 M, and 3,152 C; 3,575 were in their 1st line of therapy. 54.2% of the population was at least 55 years in age and 41.4% were male. The top regimen in 1st line for each cancer type were: cyclophosphamide + doxorubicin (B), fluorouracil + irinotecan + oxaliplatin (P), ipilimumab + nivolumab + followed by monotherapy of nivolumab (if administered) (M), and fluorouracil + bevacizumab + oxaliplatin (C) respectively. The median duration of 1st line treatment for each cancer type ranged from 76(B) to 99(C) days. The highest rate of inpatient admissions (among regimens with > 100 patients) were observed in patients with melanoma cancer on regimen of ipilimumab + nivolumab: 41.44% (n = 46/111). Of the four cancers, M was the most expensive in the metastatic 1st line setting with mean total costs of $212,056 (SD: $196,857) followed by B at $102,769 (SD: $145,537), and then C at $86,759 (SD: $102,351) and P at $81,073 (SD: $99,078).

**CONCLUSIONS:** Combination of clinical and claims data points are valuable to evaluate treatment outcomes in specific personalized subcohorts of patients and maybe one day used for treatment selection at point of care.

**SPONSORSHIP:** Optum and UHG

## C16 Budget Impact Model of Including Talazoparib on US Payer Formulary for the Treatment of Adult Patients with Germline BRCA1/2-Mutated, HER2-Locally Advanced, or Metastatic Breast Cancer

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**BACKGROUND:** Talazoparib, a poly (adenosine diphosphate-ribose) polymerase (PARP) inhibitor, demonstrated significant benefit in median progression-free survival (PFS) over standard chemotherapy (hazard ratio 0.54; 95% confidence interval, 0.41-0.71; $P < 0.001$; median 8.6 vs 5.6 months) based on the Phase 3 EMBRACA clinical trial (NCT01945775).

**OBJECTIVE:** This study estimates the incremental budget impact of including talazoparib on a health plan formulary for the treatment of adult patients with germline *breast cancer susceptibility gene 1* or 2-mutated (g*BRCA1/2*mut) human epidermal growth factor receptor 2-negative (HER2-) locally advanced or metastatic breast cancer from a US commercial health plan perspective.

**METHODS:** The model estimated the incremental cost of introducing talazoparib to a health plan formulary over a 3-year time horizon for its FDA-approved indication. The model compared two scenarios; treatments with current real-world standard of care with and without talazoparib. Treatment utilization rates for the non-PARP inhibitors basket of treatments were derived based on real-world data. It was assumed that the PARP inhibitor olaparib had a 20% utilization rate. In the scenario containing talazoparib, it was assumed that a proportion of patients will start on talazoparib in lieu of olaparib. Treatment duration was based on the median duration of therapy or median PFS if the duration of therapy was not reported. The model considered drug acquisition, drug administration, subsequent therapy and adverse event management costs.

**RESULTS:** After adding talazoparib to a US commercial health plan with one million members, half of the patients started talazoparib in lieu of olaparib resulting in a decrease of treatment costs by $35,658 and an increase in adverse event management costs by $5,239. This corresponds to potential incremental cost-savings of $242 per treated member per month.

**CONCLUSIONS:** Talazoparib may represent a cost-saving treatment option versus olaparib for patients with g*BRCA1/2*mut HER2– advanced breast cancer from a US payer perspective. Future studies are warranted to validate these results using real-world US health plans' data.

**SPONSORSHIP:** Pfizer

## C17 Patient-Reported Outcomes in Patients with HER2-Negative Advanced Breast Cancer and Germline BRCA1/2 Mutation Receiving Talazoparib Versus Physician's Choice of Chemotherapy in EMBRACA: Analysis of Patients Who Did/Did Not Experience Hospitalization

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**BACKGROUND:** EMBRACA, a 2:1 randomized open-label Phase 3 study (NCT01945775), showed improved progression-free survival with talazoparib (TALA) vs physician's choice of chemotherapy (PCT) (HR [95%CI] = 0.54 [0.41-0.71] $P < 0.001$) in patients (pts) with germline *BRCA1/2* mutation (gBRCAmut) HER2– advanced breast cancer (ABC).

**OBJECTIVE:** These post hoc analyses evaluated patient-reported outcomes (PRO) in subgroups of pts who did/did not experience serious adverse event-associated hospitalization.

**METHODS:** PRO were assessed at baseline, start of each treatment cycle (3 wks), 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 in pts who did/did not experience hospitalization 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 difference in overall change from baseline in GHS/QoL favored TALA vs PCT for both pts who did (7.6 [95%CI, 0.4-14.9]

P=0.04)/did not (9.0 [95%CI, 5.3-12.7] *P*<0.001) experience hospitalization. A statistically significant difference in overall change from baseline in pain symptoms favored TALA vs PCT for pts who did (-15.7 [95%CI, -26.5, -4.9] *P*=0.005)/did not (-11.1 [95%CI, -15.9, -6.3] P< 0.001) experience hospitalization. A delay in TTD favoring TALA was observed in GHS/QoL for pts who did (median: 12.6 vs 5.5 mos, HR=0.49 [95%CI, 0.23-1.05] *P*=0.06)/did not [median: NR vs 10.3 mos, HR=0.33 [95%CI, 0.21-0.53] P< 0.001) experience hospitalization. A statistically significant delay in TTD favoring TALA was observed in pain symptoms for pts who did (median: 11.6 vs 5.5 mos, HR=0.36 [95%CI, 0.17-0.77] *P*=0.006)/did not (median: 18.3 vs 10.3 mos, HR=0.36 [95%CI, 0.22-0.59] *P*<0.001) experience hospitalization. When comparing between arms, no analyses in either subgroup yielded statistically significant PRO results favoring PCT.

**CONCLUSIONS:** In pts with g*BRCA*mut HER2– ABC, TALA (vs PCT) resulted in delayed TTD and significantly better change from baseline in GHS/QoL and in patient-reported pain symptoms in both subgroups of pts who did/did not experience hospitalization during the study; none of the analyses significantly favored PCT; these results further support the positive benefit-risk profile of TALA vs PCT.

**SPONSORSHIP:** Pfizer (Medivation)

## C18 Treatment Patterns and Costs After Trastuzumab Emtansine Therapy in US Patients with Advanced Breast Cancer

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**BACKGROUND:** Evidence-based guidelines recommended the use of trastuzumab, pertuzumab and taxane for first-line treatment and trastuzumab emtansine (T-DM1) for second-line treatment in patients with HER2-positive advanced breast cancer. However, treatment choice in the third-line setting is not standardized and is often at clinical discretion.

**OBJECTIVE:** The objective of this study was to characterize treatment patterns and costs in US advanced breast cancer patients following T-DM1 therapy in real world setting.

**METHODS:** A retrospective analysis was performed using the IQVIA Health Plan Claims Database-US. Patients were eligible if they received T-DM1 from Dec 2013 to Dec 2018, had at least one claim associated with breast cancer diagnosis identified by ICD-9 or ICD-10 code within 1 year before the last T-DM1 claim, continuously enrolled for at least 90 days before and after the last T-DM1 claim, and received no breast surgeries within 90 days of first T-DM1 claim. Treatment regimens subsequent to T-DM1 were defined by medical and pharmacy claims in the 90 days after the last T-DM1 claim. Per-patient-per-month (PPPM) all-cause health care costs after T-DM1 discontinuation were examined.

**RESULTS:** A total of 947 patients were included in the analysis (98% female, mean age=54). Within 90 days post T-DM1 discontinuation, 535 (56.5%) patients received anti-HER2 therapies (with or without chemotherapy or hormonal therapy), 97 (10.2%) received chemotherapy (with or without hormonal therapy), 58 (6.1%) received hormonal therapy alone, and 257 (27.1%) did not receive systemic therapy. Among patients who received systemic therapy (n=690), the most common anti-HER2 therapy received was trastuzumab (T) (n=313; 45.4%), followed by trastuzumab plus pertuzumab (T+P) (n=112; 16.2%) and lapatinib (Lap) (n=110; 15.9%). Mean duration of therapy was 9.7 months for T, 7.4 months for T+P and 4.9 months for Lap. With the median follow-up of 10 months, mean (SD) PPPM cost for the overall sample was $14,841 (11,529). PPPM cost was highest among patients receiving anti-HER2 therapies [$22,052 (11,742) for P+T; $17,056 (9,454) for T; $16,939 (11,622) for Lap], followed by chemotherapy (with or without hormonal therapy [$15,313 (12,904)], hormonal therapy alone [$10,486 (11,207)], and lowest for patients who did not receive subsequent treatment [$8,906 (10,206)].

**CONCLUSIONS:** Anti-HER2 therapy was commonly used after T-DM1 discontinuation. The economic burden among patients who failed T-DM1 remained high.

**SPONSORSHIP:** Daiichi Sankyo

## C19 Early Real-World Experience on Characteristics and Treatment Patterns Among Patients with Metastatic HR+/HER2- Breast Cancer Treated with Ribociclib

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**BACKGROUND:** Ribociclib is a cyclin dependent kinase 4 and 6 (CDK4/6) inhibitor FDA approved in 2017 for the treatment of women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer (mBC).

**OBJECTIVE:** To describe the characteristics and treatment patterns (persistence and adherence) of patients (pts) treated with ribociclib in real-world clinical practice.

**METHODS:** Adult women with HR+/HER2- advanced or mBC who initiated treatment with ribociclib as first CDK4/6 inhibitor, regardless of line of therapy, were identified from IBM MarketScan Data (Q1 2000 - Q3 2018), a large US commercial claims database. Previously published claims-based algorithms were used to identify HR+/HER2- and menopausal status. The index date was defined as date of ribociclib initiation, and at least 2 prescription fills for ribociclib were required. Treatment persistence was analyzed using Kaplan-Meier (KM) as time from index date to discontinuation, defined as an interruption of at least 90 consecutive days of the index treatment. Adherence was measured by proportion of days covered (PDC), taking into account the recommended administration schedule of 21 days on treatment followed by 7 days off treatment.

**RESULTS:** 81 pts were included: median age was 58 years and 62 (76.5%) were postmenopausal. At baseline, median Charlson Comorbidity Index was 6.0 (mean: 6.7). 34 pts (42.0%) received ribociclib as first-line therapy for mBC, 16 (19.8%) as second-line, and 12 (14.8%) as third-line; 53 pts (65.4%) initiated ribociclib in 2017, and 28 pts (34.6%) initiated in 2018. Median time from first mBC diagnosis to index date was 6.6 months (mean: 22.3 months; IQR 2.0-37.3 months). Common metastatic sites as recorded by diagnostic codes included bone and bone marrow (54 pts; 66.7%) and visceral (34 pts; 42.0%), most commonly liver (17 pts; 21.0%) and lung (13 pts; 16.0%). Median duration of follow-up was 8.6 months (mean: 9.4). KM proportions of persistence were 78.6% at 6 months, and 71.8% at 9 months. Mean PDC was 0.90, and 74.1% of patients had PDC≥0.85.

**CONCLUSIONS:** This study is the first US study demonstrating early real-world treatment patterns among pts treated with ribociclib. Both persistence and adherence to ribociclib were found to be high. More real-world studies are warranted to determine long term treatment patterns and outcomes.

**SPONSORSHIP:** Novartis Pharmaceuticals

## C20 Epidemiology of Human Epidermal Growth Factor Receptor 2-Positive Metastatic Breast Cancer in the United States in 2019

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**BACKGROUND:** The incidence of metastatic breast cancer (MBC) in the United States (US) is gathered via population-based cancer registries, but because these registries do not collect progression data, incident MBC is underestimated. This gap in knowledge poses challenges for researchers and policy makers, who rely on these data for decision-making, and is particularly important for HER2+ breast cancer (BC) which is more aggressive than HER2- BC.

**OBJECTIVE:** To estimate the incidence of HER2+ MBC in the US in 2019, accounting for both de novo cases of HER2+ MBC and patients progressing to HER2+ MBC.

**METHODS:** A patient flow model was developed using data from a targeted literature review and the Surveillance, Epidemiology, and End Results (SEER) Program. We extracted estimates of BC incidence, proportions of incident BC cases that are metastatic and/or HER2+, and progression rates from early-stage BC to MBC from studies published since 2010 that met quality criteria and were generalizable to the US population. Data were included in the model based on inclusion/exclusion criteria, sample size/data source, time period, and study methodology. A sensitivity analysis was conducted to evaluate the uncertainty and influence of each parameter on the overall estimate. A primary analysis of SEER using SEER*Stat was also undertaken to estimate new cases of HER2+ MBC by calculating trends in incidence from 2010 to 2015 and applying those trends to subsequent years.

**RESULTS:** Using the best published data from the literature, the model estimates that of 268,600 patients with incident BC in 2019 (SEER), 15,042 (5.6%) will have MBC at diagnosis, of whom 3,946 (26.2%) will be HER2+. Among patients with non-metastatic BC at diagnosis (n=253,558), it is estimated that 38,034 (15.0%) will be HER2+ and that 4,944 patients will progress to HER2+ MBC during 2019 (13.0% 5-year progression rate, assumed to apply at 2.6% per year over 5 years from the time of diagnosis). Combining these estimates, 8,890 individuals will have been newly diagnosed with metastatic disease (n=3,946) or progressed to HER2+ MBC (n=4,944) in 2019 in the US. In sensitivity analyses, using the highest and lowest published values, the estimates ranged from 6,044 to 9,474 persons. Using trends from SEER data, the estimated number of new HER2+ MBC cases was 8,380.

**CONCLUSIONS:** This model provides a robust, evidence-based approach to estimate the number of new cases of HER2+ MBC in the US in 2019, in order to inform healthcare decision-making. Future research could incorporate patient survival in order to estimate the full prevalence of HER2+ MBC.

**SPONSORSHIP:** Seattle Genetics

## C21 The Long-Awaited Launch of Oncology Biosimilars: Evaluating the Impact of Payer and Provider Strategies on Early Adoption

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**BACKGROUND:** Nine years have elapsed from the establishment of the US biosimilar approval pathway (351k) to the launch of the first therapeutic oncology biosimilar agent in the US. Biosimilars for bevacizumab and trastuzumab launched in July 2019, followed by the launch of a rituximab biosimilar in November. Now that biosimilars are available, the question remains as to how payers should manage, or even encourage, uptake in their use compared to the reference products.

**OBJECTIVE:** Evaluate potential payer strategies for managing emerging oncology biosimilars.

**METHODS:** In late 2018, Magellan Rx (MRx) created an oncology biosimilar strategy team to examine clinical and business aspects related to therapeutic oncology biosimilars and advise payers on a proactive management approach. Key areas of focus included indication similarities, interchangeability issues, projected cost savings, input from key opinion leaders, and manufacturer access. MRx also created educational webinars for key oncology providers within payer networks. Biosimilar utilization management (UM) policies were drafted for payers' internal P&T committees to review prior to market launch. One additional, elective strategy included step therapy (ST) requirements for patients not previously treated with the reference product. Conversely, payers could manage oncology biosimilars at parity with the reference products. MRx retrospectively analyzed determinations data from 9/1/2019-11/25/2019 for 7 regional health plans with over 7 million covered lives combined. Inclusion criteria were patients with an authorization for the reference product or biosimilar for bevacizumab or trastuzumab within the measurement period.

**RESULTS:** In clients who opted for ST requirements, authorizations for biosimilars made up 47.6% of approvals. By comparison, 15.7% of approvals among clients without ST requirements were for biosimilars. This increase was observed for each individual biosimilar. Patterns also emerged showing providers voluntarily switching patients from reference products to the corresponding biosimilar.

**CONCLUSIONS:** Payers equipped with proactive UM strategies for oncology biosimilars were able to capitalize on early cost savings. Specifically, ST requirements increased use of biosimilars, and were implemented successfully with minimal disruption. Data also indicates that some providers are proactively switching patients to oncology biosimilars. Longer follow-up may provide further insights on the true uptake in biosimilar use. Nevertheless, the observed association supports the impact of UM to facilitate biosimilar usage.

**SPONSORSHIP:** Magellan Rx Management

## C22 Incidence of Febrile Neutropenia in Chemotherapy Cycles with Pegfilgrastim Receipt Via On-Body Injector Versus Pre-Filled Syringe

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**BACKGROUND:** Febrile neutropenia (FN) is a potentially life-threatening side effect of myelosuppressive chemotherapy (CTX), resulting in considerable healthcare utilization and costs. Prophylaxis with a long acting granulocyte colony-stimulating factor, such as pegfilgrastim (Neulasta®), is recommended. An on-body injector (OBI) (Onpro) administers pegfilgrastim 27 hours after its application on the last day of each CTX cycle, whereas a pre-filled syringe (PFS) may require a return visit.

**OBJECTIVE:** To examine the incidence of FN with pegfilgrastim receipt stratified by Onpro vs. PFS after an Onpro-specific CPT code was implemented in claims.

**METHODS:** Adult patients with Commercial or Medicare supplemental insurance initiating new CTX with pegfilgrastim between 1/1/2017 and 5/31/2018 were identified retrospectively from the IBM MarketScan databases. Pegfilgrastim receipt was identified as Onpro or PFS (which included PFS and pegfilgrastim with unknown administration route) from date of completion of CTX in up to six cycles. Unadjusted FN incidence was measured in each cycle and defined as inpatient admission with diagnoses of neutropenia and either fever or infection, or outpatient encounter with diagnoses of neutropenia and either fever or infection with receipt of IV antimicrobial therapy.

**RESULTS:** Among 10,854 eligible patients, mean age was 55.4 years, 75.6% were female, 47.2% had breast cancer, and 42.6% had a

secondary malignancy. Of 36,421 pegfilgrastim cycles, a majority were identified as PFS (73.9%). Onpro was primarily identified on CTX end date (98.5%), corresponding to its timed-release on day after. PFS was identified on CTX end date (58.4%), day after (27.3%), and 2-5 days after (14.3%). A majority of cycles were classified as high FN risk level (64.6%), with greater high risk among Onpro (72.7%) vs. PFS (61.7%) cycles. Incidence of FN among all cycles was 1.6%. Incidence of FN was significantly lower among Onpro vs. PFS cycles (1.3% vs. 1.7%, $P=0.01$). Similar results were present with different FN definitions.

**CONCLUSIONS:** Among this real-world sample of patients initiating CTX, FN rates with Onpro were almost a third lower than with PFS. Timely receipt of pegfilgrastim through Onpro was achieved in a majority of cycles but PFS pegfilgrastrim was received less than a third of the time on the day following CTX. Overall, receipt of pegfilgrastim via an OBI facilitated better adherence, likely contributing to subsequent reduced FN incidence, which could provide a positive impact on healthcare utilization and costs.

**SPONSORSHIP:** Amgen

## C23 Real-World Treatment Patterns and Safety Outcomes Among Patients with HER2 Negative Advanced Breast Cancer and BRCA1/2 Mutations: Evidence from a Retrospective Medical Record Review Study in the United States

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**BACKGROUND:** Germline breast cancer susceptibility gene 1/2-(g*BRCA1/2*) mutated breast cancer (BC) represents ~5% of all BC. Historically, chemotherapy (CT) and endocrine-based therapy (EBT) have been commonly used in HER2- advanced BC (ABC) patients (pts) with *BRCA1/2* mutations (*BRCA1/2*mut). Between 2015-2018, cyclin-dependent kinase 4/6 inhibitors and poly ADP-ribose polymerases inhibitors (PARPi) became available as targeted therapy for some pts with ABC, including HER2- g*BRCA1/2* ABC. With the changing landscape, understanding treatment patterns and associated adverse events (AEs) may inform treatment choices.

**OBJECTIVE:** To assess real-world treatment patterns and associated AEs in US pts with HER2- ABC and *BRCA1/2*mut.

**METHODS:** Oncologists retrospectively reviewed charts (July-Oct 2019) of randomly selected pts ≥ 18 y, with HER2- ABC and *BRCA1/2*mut (i.e., g*BRCA1/2*mut, somatic [sBRCA1/2mut], or s*BRCA1/2*mut with an unknown g*BRCA1/2* status) who received ≥ 1 cytotoxic CT regimen(s) for ABC between Jan 2013-April 2018. AEs between different regimens were compared using $\chi^2$ or Fisher's Exact test.

**RESULTS:** 203 pts were included: 99.5% were female and 76.4% were white. Median age was 58.0 y. 87.2% had gBRCA1/2mut, 8.4% had sBRCA1/2mut, and 4.4% had s*BRCA1/2*mut and unknown g*BRCA1/2* status. 62.6% had advanced triple negative BC (TNBC), and 37.4% had hormone receptor (HR)+/HER2– ABC. In TNBC pts (n = 127), 1st line therapies included non-platinum-based CT (58.3%) and platinum-based CT (41.7%). Hematologic AE's occurred at higher rates in TNBC pts receiving platinum-based CT vs non-platinum-based CT (anemia, 41.5% vs 17.8%, $P<0.01$; neutropenia, 22.6% vs 9.6%, $P=0.04$; thrombocytopenia, 22.6% vs 11.0%, $P=0.08$). In HR+/HER2- pts (n = 76), CT (73.7%) or EBT (25.0%) were the most common 1st line therapies. Hematologic AE's were reported in more pts receiving CT vs EBT (anemia, 28.6% vs 0.0%, $P=0.01$; neutropenia, 12.5% vs 5.3%, $P=0.67$; thrombocytopenia, 12.5% vs 5.3%, $P=0.67$).

**CONCLUSIONS:** In this analysis of HER2- *BRCA1/2*mut ABC pts, CT was most frequently used in the 1st line setting. Pts with advanced TNBC and *BRCA1/2*mut had more hematologic AEs reported in those receiving platinum-based CT vs non-platinum-based CT. Pts with HR+/HER2- ABC and BRCA1/2mut, as expected, had more hematologic AE's in those receiving CT than those treated with EBT. Consideration of a regimen's toxicity profile may help guide pts and providers in selection of their therapy regimen, including targeted treatments such as the newly approved *BRCA1/2*-targeted therapies, PARPi.

**SPONSORSHIP:** Pfizer

## C24 Evaluating the Cost-Effectiveness of Adding Ribociclib to Endocrine Therapy for Patients with HR-Positive, HER2-Negative Advanced Breast Cancer Among Premenopausal or Perimenopausal Women

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**BACKGROUND:** The FDA has approved ribociclib for use in combination with an aromatase inhibitor for the first-line treatment of pre/perimenopausal women with HR-positive, HER2-negative advanced breast cancer. The regulatory decision was based on MONALEESA-7 clinical trial results. An economic evaluation of ribociclib treatment in this patient population is lacking.

**OBJECTIVE:** To evaluate the cost-effectiveness of ribociclib for pre/perimenopausal women with HR-positive, HER2-negative advanced breast cancer.

**METHODS:** A cost-utility analysis was conducted from a US payer perspective using a partitioned survival model with three health states (progression-free (PF), progressed disease (PD), and death) over a 20-year time horizon. Weibull survival curves were fitted to parametrize and extrapolate Kaplan-Meier survival curves for both PF-survival and overall survival. Other clinical parameters, utilities, and disutilities were obtained from the RED BOOK, Medicare Clinical Laboratory Fee Schedule, Medicare Physician Fee Schedule, and the literature. All costs were measured in 2019 US Dollars, and a 3% annual discount rate was applied. Effectiveness was measured in quality-adjusted life-years (QALYs) by adjusting gained life years with health state utilities. The main outcome measure was the incremental cost-effectiveness ratio (ICER), expressed as the incremental cost per QALY gained. One-way deterministic sensitivity analysis and Monte Carlo probabilistic sensitivity analysis were conducted to explore the model uncertainty. All modeling and computations were conducted using Stata/MP 15.1 and TreeAge Pro 2019, R2 Software.

**RESULTS:** In the base case scenario, ribociclib plus endocrine therapy was associated with an average total cost of $433,958 and 4.09 QALYs as compared to the endocrine therapy alone of $44,795 and 2.69 QALYs. The ICER for ribociclib plus endocrine therapy compared to endocrine therapy alone was $279,534/QALY. One-way deterministic sensitivity analysis showed that ribociclib WAC price was a main model sensitive driver. Monte Carlo simulation of 10,000 iterations showed that at a willingness-to-pay threshold of $268,800, ribociclib plus endocrine therapy would surpass endocrine therapy alone as a cost-effective option.

**CONCLUSIONS:** Despite the significantly improved overall survival and progression-survival over endocrine therapy alone, ribociclib plus endocrine therapy for pre/perimenopausal patients with HR+, HER2- advanced breast cancer is not cost-effective at a willingness-to-pay threshold $100,000 or $150,000 per QALY in the United States.

**SPONSORSHIP:** None

## C25 Examining Ibrance (Palbociclib) + Anti-Estrogen Therapy Outcomes If Concomitantly Dispensed at a Specialty Pharmacy Versus Retail Pharmacy

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**BACKGROUND:** Palbociclib is FDA approved as first-line treatment for HR+ HER2- metastatic breast cancer. It is an oral capsule taken with letrozole or fulvestrant to reduce risk of disease progression and goal of progression-free survival. Currently, palbociclib has limited distribution that is only available at a specialty pharmacy (SP) while letrozole and fulvestrant are available at local chain pharmacies or administered in a provider office (non-SP) as well as SP.

**OBJECTIVE:** To determine whether receiving all medication therapy from a single pharmacy site positively impacts medication adherence and lengthens duration of therapy in patients who are taking palbociclib for the treatment of HR+, HER2- metastatic breast cancer.

**METHODS:** In a retrospective cohort study, we analyzed 1,202 patients with HR+, HER2- metastatic breast cancer concurrently taking palbociclib from Avella Specialty Pharmacy and letrozole or fulvestrant. between March 2016 to December 2017 (when palbociclib + fulvestrant received approval). 232 patients were excluded for not having chart notes to notate concomitant and/or previous therapy. Patients were divided into 2 groups characterized by those that filled both medications at Avella and those that only filled palbociclib at Avella and the other medication at another pharmacy (Non-SP). Primary objectives were to compare the median duration of therapy (in days) and adherence through proportion of days covered (PDC) between both arms. Baseline demographics and insurance payor type were also evaluated. Baseline characteristics and payor type data were compared using unpaired t-test and PDC and duration of therapy were compared using Mann-Whitney U test.

**RESULTS:** Data analysis was conducted among 971 patients, 144 in SP and 827 in Non-SP arm (mean age = 69.37; SD = 11.40). Concomitant therapy was higher for fulvestrant in non-SP group, which is appropriate since it is an injection billed and administered in the prescriber office. Median palbociclib duration of therapy was found to be almost 60 days longer in the SP arm (SP = 151 vs Non-SP = 113, $P = 0.32$). Median palbociclib PDC was found to be comparable between arms (SP = 99.7% vs. Non-SP = 100%, $P = 0.31$). Majority of patients in each arm utilized Medicare Part D insurance and comparison of payor type had no significant difference ($P = 0.13$).

**CONCLUSIONS:** Although not statistically significant, median persistence was 38 days longer, almost 2 additional cycles, in the SP arm. If goal of palbociclib therapy is progression free survival, dispensing both palbociclib and concomitant therapy together at a SP showed clinical significance and could help improve patient outcomes.

**SPONSORSHIP:** None

## C27 Health Care Resource Utilization and Costs Associated with Disease Progression in Ovarian Cancer

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**BACKGROUND:** Most women diagnosed with ovarian cancer have advanced stage disease which commonly results in progressing through multiple lines of systemic therapy. With the approval of the PARP inhibitor olaparib for first line maintenance therapy in women with BRCA-mutated advanced ovarian cancer, patients have the possibility of several years of progression free survival (PFS) (60% PFS at 3 years).

**OBJECTIVE:** Given the limited published data regarding the cost of progression after first line treatment, the goal of this study was to understand how long-term front line PFS influences the burden of disease by quantifying the healthcare resource utilization (HRU) and costs of ovarian cancer progression.

**METHODS:** A retrospective analysis of Optum commercial and Medicare Advantage claims data in the US was conducted. Patients were required to have an index ovarian cancer diagnosis and to have received systemic therapy between 2010-2018. Patients were further required to be treated after Dec 1, 2014, with no evidence of a PARP inhibitor at any time. Patients were followed until death, end of follow up, or end of the study period. Medical and pharmacy HRU and costs were assessed from adjudicated claims and reported using descriptive statistics.

**RESULTS:** 2,939 patients met all inclusion criteria, median age was 67 (range 18-89), and 47% were commercially insured. 1,304 patients received second line (2L), 681 received third line (3L), and 334 received fourth line (4L) therapy. Mean time from the start of 2L to the completion of 4L therapy was 419 days (range 107-1309, median 392). Patients spent a mean of 144 days (range 1-2075, median 119) in 2L therapy, 133 days (range 1-894, median 107) in 3L therapy, and 121 days (range 2-708, median 93) in 4L therapy. Mean total per person healthcare costs for 2L through the completion of 4L therapy was $151,849 (SD $134,522, median $113,763). These represented $54,802 (SD $65,048, median $34,684), $51,081 (SD $70,036, median $29,556), and $44,930 (SD $60,734, median $26,318) during 2L, 3L, and 4L respectively. The majority of these costs (72-78%) were related to ambulatory care. Patients had a mean of 27.7 (SD 23.6, median 22), 25.6 (SD 22.1, median 19), and 24.5 (SD 20.1, median 19) unique ambulatory care interactions during 2L, 3L, and 4L.

**CONCLUSIONS:** This study documented significant HRU and costs associated with progression beyond 1L therapy in ovarian cancer, which were largely driven by the high number of ambulatory care visits. Prolonging PFS in ovarian cancer patients has the opportunity to delay the treatment and economic burden associated with progression.

**SPONSORSHIP:** AstraZeneca

## C28 Estimating Adverse Drug Event Costs Associated with Life-Prolonging Treatments for Metastatic Castration-Resistant Prostate Cancer

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**BACKGROUND:** Treatment with survival-improving therapies for metastatic castration-resistant prostate cancer (mCRPC) may be associated with adverse drug events (ADEs) that should be considered when choosing treatments. Estimating the actual total costs of care, as a result, should include both the costs of treatment and the associated ADEs.

**OBJECTIVE:** This analysis estimates costs associated with known Grade 3+ ADEs of 5 life-prolonging mCRPC therapies.

**METHODS:** A payer-perspective budget impact model (BIM) was developed to estimate direct inpatient medical costs for ADEs for mCRPC patients treated with a first-line agent. Average ADE rates were based on control-group-adjusted incidence rates reported in clinical trials or drug labels. A 0% incidence was assumed if no or a negative adjusted ADE rate was determined. An ADE was identified by grouping similar ICD-10 codes, then averaging respective costs per patient over the full regimen in the first treatment year. Costs were based upon publicly available 2016 Healthcare Cost and Utilization Project (HCUP) inpatient (ICD-10) data adjusted to 2019 USD.

**RESULTS:** We identified 21 ADEs with per-patient costs > $6,000; 8 with costs ≥ $10,000 Infection (central line) cost per event was highest [$20,563]; hematuria was lowest at $6,627 per event. The

most prevalent ADE across treatments in the BIM was cardiovascular disorder (any). Total ADE costs by product were $2,933 for docetaxel, $1,485 for radium-223, $1,103 for abiraterone acetate, $929 for enzalutamide, and $576 for sipuleucel-T.

**CONCLUSIONS:** This assessment demonstrates that all mCRPC treatments are associated with ADEs costs. Treatment costs and their ADEs should be considered by clinicians and patients when weighing risks and benefits of a given treatment amongst the options for mCRPC.

**SPONSORSHIP:** Dendreon Pharmaceuticals

## C29 Budget-Impact of Adding Darolutamide to a United States Payer Formulary for Non-Metastatic Castration-Resistant Prostate Cancer

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**BACKGROUND:** Men with nonmetastatic castration-resistant prostate cancer (nmCRPC) have prostate cancer that has progressed despite castrate levels of serum testosterone and no evidence of metastases. Darolutamide, a recently approved structurally distinct androgen receptor inhibitor, has shown to significantly prolong metastases development with a lower incidence of treatment related adverse events (AEs).

**OBJECTIVE:** To estimate the projected budget impact of including darolutamide on a United States (US) payer formulary as a treatment option for men with nmCRPC.

**METHODS:** A budget-impact model was developed to evaluate darolutamide for nmCRPC for a hypothetical 1-million-member plan over a 5-year period. Costs (drug acquisition, drug administration, and treatment-related AEs) were estimated for two scenarios: with and without darolutamide treatment for nmCRPC. The budget impact of darolutamide was calculated as the difference in costs for these two scenarios. An analysis for high-risk nmCRPC also was conducted. The model included treatments recommended by the National Comprehensive Cancer Network (e.g., apalutamide and enzalutamide) and potential comparators that are used but are not specifically indicated for nmCRPC. All treatments were assumed to be administered in combination with a weighted-average androgen deprivation therapy comparator (consisting of luteinizing hormone-releasing hormone agonists [LHRH], LHRH antagonists, and first-generation anti-androgens). Market share estimates were derived from interviews with physicians treating men with nmCRPC. The model includes serious AEs and the rates were obtained from clinical trial data. Costs were taken from publicly available sources.

**RESULTS:** For a plan with 1 million lives, there were approximately 90 incident cases of nmCRPC (46 high risk) each year, with 336 (110 high risk) treatment-eligible cases by year 5. Darolutamide's market share increased from 3.6% in year 1 to 18% in year 5. Given the utilization of other agents, introducing darolutamide along with other targeted therapies was predicted to increase total budget by $160,316 ($0.0134 per member per month [PMPM]) in year 1, which decreased over time to a cost-savings of $150,817 ($0.0126 PMPM) by year 5. The scenario with darolutamide showed reduced AE costs each year. Similar results were observed for the high-risk nmCRPC population.

**CONCLUSIONS:** Adding darolutamide to a US payer formulary for the treatment of nmCRPC can result in a manageable increase in the budget that is partly offset by AE costs in the first 4 years, followed by a cost-savings by year 5.

**SPONSORSHIP:** Bayer Pharmaceuticals

## C30 Investigating Non-Protocol-Driven Hospitalizations to Assess Darolutamide Tolerability in Patients with Non-Metastatic Castration-Resistant Prostate Cancer

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**BACKGROUND:** ARAMIS was a Phase III randomized controlled trial investigating darolutamide versus placebo in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who were already receiving androgen-deprivation therapy (ADT). Darolutamide significantly improved median metastasis-free survival by 40.4 months vs 18.4 months for placebo (hazard ratio [HR] 0.41; 95% confidence interval [CI] 0.34-0.50, $P<0.001$) with minimal increase of adverse events.

**OBJECTIVE:** This post hoc analysis of ARAMIS supplements findings to investigate the tolerability of darolutamide versus placebo within the non-metastatic stage of disease.

**METHODS:** Tolerability was measured by the rate of, and time to first hospitalization (or prolongation of hospitalization) due to treatment-emergent adverse events. Only events and time at risk observed prior to metastases were included in these analyses, to ensure the tolerability of the treatments were compared fairly without influence from the effects of metastases. The rate of hospitalizations per treatment arm and rate ratios were calculated unadjusted, using Poisson regression and negative binomial regression (to control for a large number of patients with zero events). A Cox regression model was also used to estimate the hazard ratio between treatments for time to first hospitalization.

**RESULTS:** There were 883 darolutamide and 491 placebo patients included in the analyses. Zero hospitalizations were observed for 740 (83.8%) darolutamide and 432 (88.0%) placebo patients. There were 204 hospitalizations observed for darolutamide and 79 observed for placebo. Darolutamide patients contributed 1,200.4 years of time at risk and placebo patients contributed 482.5 years, which led to unadjusted rates of hospitalizations per year of 0.17 for darolutamide and 0.16 for placebo. The negative binomial regression model was the best fitting, and estimated a hospitalization rate ratio between darolutamide and placebo of 1.05 (95% CI 0.76-1.45; $P=0.781$). The Cox regression model for time to first hospitalization produced a HR estimate (darolutamide versus placebo) of 0.99 (95% CI 0.73-1.34; $P=0.938$).

**CONCLUSIONS:** The results from this post hoc randomized comparison show that within the non-metastatic stage, there is no meaningful difference between treatment with darolutamide (plus ADT) and placebo (ADT alone) with respect to risk of adverse event related hospitalization. This conclusion was confirmed through various statistical methods and supports that darolutamide is a well-tolerated treatment option when given in addition to ADT for patients with nmCRPC.

**SPONSORSHIP:** Bayer HealthCare

## C31 Darolutamide Versus Apalutamide and Enzalutamide in Non-Metastatic Castration-Resistant Prostate Cancer: Matching-Adjusted Indirect Comparisons

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**BACKGROUND:** There are no published prospective comparative randomized trials comparing darolutamide (DARO), apalutamide (APA) and enzalutamide (ENZA) for non-metastatic castration-resistant prostate cancer (nmCRPC) patients.

**OBJECTIVE:** We performed matching-adjusted indirect comparisons (MAICs) of DARO vs APA, matching on the same set of 7 covariates as a recent MAIC poster comparing nmCRPC-approved drugs (Chowdhury 2018), and of DARO vs ENZA, matching on clinically relevant covariates.

**METHODS:** The ARAMIS (DARO), SPARTAN (APA) and PROSPER (ENZA) trials were evaluated for inter-trial differences. The MAIC aims to minimize inter-trial differences by adjusting across a set of clinically relevant baseline covariates. The MAICs were performed on the shared primary endpoint of metastasis-free survival (MFS) across the three trials. The DARO vs APA MAIC matched on 7 baseline covariates (age, prostate-specific antigen [PSA] level and doubling time, Eastern Cooperative Oncology Group [ECOG] status, Gleason score, bone-sparing agent use and prior surgery). DARO vs ENZA were matched on age, region, PSA level and doubling time, ECOG status, Gleason score and bone-sparing agent use. Sensitivity analysis were conducted on: 1) all 12 covariates available for both the ARAMIS and SPARTAN trials, and 2) a different subset of the 12 covariates. For all comparisons, patients with prior seizure history or metastasis at baseline were excluded from the ARAMIS treatment arms for comparability with the SPARTAN and PROSPER trials.

**RESULTS:** For DARO vs APA, the effective sample sizes (ESS) of DARO and its placebo (PBO) arm were 604 and 391 after matching on the 7 covariates. The corresponding pre- and post-match MFS hazard ratios (HRs) were 1.29 ($P=0.10$) and 1.14 ($P=0.42$), respectively. Significant post-match differences remained between the two trial populations for race, region, local/regional nodal disease, serum testosterone level, and tumor stage at diagnosis. Matching on all 12 covariates for both trials addressed this concern, but resulted in low ESS (≤80) for DARO and its PBO arm. For DARO vs ENZA, the ESS of DARO and its PBO arm were 580 and 395 after matching on all available baseline characteristics reported in both trials. Pre-and post-match MFS HRs were 1.23 ($P=0.15$) and 1.20 ($P=0.27$), respectively.

**CONCLUSIONS:** No statistically significant differences in MFS were found between DARO and APA, or DARO and ENZA. Safety and tolerability profiles and their impact on the quality of the patients' survival become important considerations in risk-benefit assessment and associated treatment choices in nmCRPC.

**SPONSORSHIP:** Bayer U.S.

## C36 Impact of Increasing Sites of Care on the Economic Burden of Travel for Patients with Relapsed/Refractory Large B-Cell Lymphoma Receiving Chimeric Antigen Receptor T-Cell Therapy in the United States

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**BACKGROUND:** CAR T cell therapies have shown durable remissions in patients (pts) with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) with limited treatment options. However, many pts travel long distances to receive therapy, and the time and cost associated with traveling to an academic center of excellence (COE) may be prohibitively high. Cost burden may be reduced by offering chimeric antigen receptor (CAR) T cell therapies at additional sites of care (SOC).

**OBJECTIVE:** To estimate the economic impact of the travel burden on pts by increasing SOC options for CAR T cell therapy administration.

**METHODS:** We estimated the annual incidence of third-line (3L) R/R LBCL at the county level from the National Program of Cancer Registries. Geographic information system techniques determined the shortest travel distance and time between pts with LBCL and the nearest CAR T cell therapy administration site. We conducted 2 scenario analyses: 1) academic COE only (n = 141); and 2) all academic and community hospitals plus nonacademic specialty oncology centers (n = 262). Using distance and time inputs, we estimated direct costs (based on mileage reimbursement rates), indirect costs (estimated from hourly wages and included value of leisure), costs for flights (for pts residing > 5 hours to the nearest site), and lodging/meal costs for 35 days (including apheresis, possible bridging chemotherapy, scans/laboratory tests, lymphodepletion and CAR T administration, and monitoring) from government per-diem rates (included if pts traveled > 60 minutes). All pts were assumed to travel with a caregiver.

**RESULTS:** Total national annual estimated travel costs for the 3L R/R LBCL cohort (N = 3,922) were reduced by $5.2M by increasing access to all sites vs academic COE only ($15.9M vs $21.1M, respectively). The weighted mean cost per pt decreased by $1,315 ($4,048 vs $5,363; $P<0.0001$). For all settings vs academic COE only, respectively, costs were driven by lodging/meals (62.1% vs 68.4%), followed by indirect costs (25.6% vs 21.1%), direct costs (12.2% vs 10.2%), and flights (0.1% vs 0.3%). Annually, for all settings vs academic COE only, 51 fewer pts were estimated to fly, and 426 fewer pts required lodging with increased SOC access. Pts in rural counties ($6,009 vs $7191) and the West region ($3,859 vs $11,037) were more burdened by limited access and achieved greater benefit from improved SOC access.

**CONCLUSIONS:** Travel costs were significantly reduced by increasing SOC access to any specialized center. These findings highlight the importance of considering the travel burden imposed on patients that may be associated with limiting the SOC for CAR T cell administration.

**SPONSORSHIP:** Bristol-Myers Squibb

## D1 Landscape Assessment of Quality Measures, Indicators, Tools, and Initiatives for Healthcare Services for Women with Uterine Fibroids and Heavy Menstrual Bleeding

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**BACKGROUND:** Symptomatic uterine fibroids (UF) impose an epidemiological and economic burden on the US healthcare system. Heavy menstrual bleeding (HMB) is one of the most common and bothersome symptoms associated with UF. With increasing focus on value-based care and lack of published assessments, there is need to evaluate the quality landscape for women with UF and HMB.

**OBJECTIVE:** Identify and review existing quality measures, indicators, tools and initiatives for care of women with UF and HMB and identify opportunities to advance quality of UF care.

**METHODS:** Targeted searches of literature were conducted using PubMed and other readily available databases such as Google Scholar. Quality measures were identified using the National Quality Forum Quality Positioning System and the Avalere Quality Measures Navigator. Websites of relevant professional societies and government-sponsored agencies were also searched (e.g., American College of Obstetricians and Gynecologists, American Academy of Family Physicians, Agency for Healthcare Research and Quality, Patient-Centered Outcomes Research Institute). Search strings were used to identify existing measures, indicators, tools and initiatives for care in UF and HMB. Searches were made for the period of 2008 to 2019.

**RESULTS:** In the CMS programs that target women's health, 38 quality measures were identified, only one addressed treatment of symptomatic UF and was specific to a procedure. Identified quality initiatives either compared efficacy of current treatments for UF or offer innovative care models with integrative practice units and patient-centered care. All address shared decision-making to involve women in their treatment

options. Of seven symptom assessment questionnaires reviewed, six incorporated quality-of-life (QOL) items. However, these surveys were longer (more than 15 items) than practical for daily clinical use.

**CONCLUSIONS:** While ongoing quality initiatives have incorporated patient perspective for managing treatments, broader adoption of comprehensive care practices and shared decision- making tools may be beneficial. Incorporating QOL questionnaires in routine clinical use could further improve symptom management decisions. Attention to women with symptomatic UF requires a tailored approach. Refining preference-sensitive tools and care models may provide an opportunity for improvement in optimization of individualized care of women with UF and HMB.

**SPONSORSHIP:** AbbVie

## D2 Utilization and Trends of Multi-Gene Panel Testing in Oncology

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**BACKGROUND:** New tumor agonist therapies are available which utilize multi-gene panel testing (MGPT) for identification of patients who may benefit from certain treatments; however, there is limited information regarding historical utilization of these tests across tumors.

**OBJECTIVE:** Assess real-world historical trends and utilization patterns of MGPT and its impact on treatment decisions.

**METHODS:** The Humana Research Database was used to identify individuals age 18-89 with incident diagnosis of solid tumor cancer between 1/1/2016 to 12/31/2018 (≥2 claims with a diagnosis (dx) of the same cancer within 7-90 days, and no dx of the same cancer preceding the first cancer dx). Identification of large panel (LP) (≥50 genes) and medium/small panel (MSP) (2-50 genes) tests were based on a novel algorithm using tax ID numbers to identify specific laboratories and CPT codes to identify the type of testing conducted based on that labs available tests. Total and proportions of patients with testing were reported by quarter/year and tumor type. Unadjusted outcomes examined in advanced non-small cell lung cancer (NSCLC) included time from dx to testing, proportion of patients receiving a new anti-cancer agent and genetic test costs (based on Centers for Medicare & Medicaid fee schedule).

**RESULTS:** We identified 121,675 patients with an incident solid tumor of which 5,457 received a panel test (4.5%). While the total number of panel tests increased over time from 238 in Q1 2016 to 755 in Q4 2018, the percent of diagnosed patients in a given quarter/year utilizing any panel test remained relatively stable at 4-5% per quarter/year. Lung comprised the greatest proportion of patients with cancer utilizing a panel test per year (12-18%), followed by gastrointestinal (5-9%) and female reproductive (2-3%). Among those tested, utilization of LP tests increased from 20% in Q1 2016 to 46% in Q4 2018. Patients with advanced NSCLC (n=1,010) utilizing LPs vs. MSP were observed to have a longer time from dx to panel test (mean days: 61.4 vs. 45.9) and a greater proportion receiving treatment prior to panel test (37.3% vs. 25%). Use of a targeted or cancer immunotherapy agent within 90 days after the test was slightly higher in the LP group (18.9% vs. 15.6%). The estimated cost of the MSP was less than the LP in advanced NSCLC.

**CONCLUSIONS:** Historical utilization of panel tests were low and mostly utilized in advanced NSCLC, which resulted in receipt of targeted therapy for some. Further research is needed to understand the possible impact of recent policy changes on future MGPT utilization.

**SPONSORSHIP:** Genentech

## D3 Quality of Life and Adherence of Patients to Oral Oncology Specialty Medications Provided by a Specialty Pharmacy

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**BACKGROUND:** Specialty pharmacy drugs (SP-D) are high-cost medications that treat complex conditions. Improving adherence and quality of life (QoL) contribute to desired treatment outcomes. SP Medication Therapy Management (SPMTM) contributes to optimization of QoL and better adherence.

**OBJECTIVE:** Measure adherence to oral oncology SP-D and compare quality of life (QoL) of patients in SPMTM before and after Start of Care (SOC).

**METHODS:** From 01/01/19-6/30/19 a retrospective, observational study of n=83 unique cancer patients' reported outcomes (PRO) was conducted on those taking oral oncology SP-D. Patient assessments (PA) occurred at SOC and 7 days before refill. PA included EQ-5D-5L QoL PRO instrument which has 5 dimensions with Likert scales (5-point and a visual analog scale (VAS)100). Dimensions summarized: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Likert scales summarized: None, Slight, Moderate, Severe, and Extreme plus VAS100 for Overall Health Care Status. Dimensional means were calculated before and after starting SP-D, then compared for differences, representing patient perception of improved or diminished QoL. The mean Proportion of Days Covered (PDC) was calculated on the F-U group. ≥3 therapy-days per month (TxDM) of reported missed/skipped (M/S) SP-D resulted in intervention (reason doses missed; patient re-education; and informing the oncologist).

**RESULTS:** Mean number of dispenses per patient was 3.7. The number of PA was 182 (51 SOC and 131 F-U) with 32 (38.6%) declining to participate. 51 (61.4%) completed both SOC and F-U PA. The mean PDC was 0.95. Of 131 F-U PA completed, 66 (50.4%) indicated ≥1 TxDM were M/S, and Intervention occurred on 32 (24.4%) of the 66 due to ≥3 TxDM M/S. The differences between means before and after SP-D start were: Mobility -0.04 (4%), Self-Care -0.085 (8.5%), Usual Activities -0.27 (27%), Pain/Discomfort -0.29 (29%), Anxiety/Depression +0.02 (2%), Overall Health State +6.08 (6.08%). ("-" difference=improvement in Dimensions 1-5; "+" difference = improvement in overall health state. Percentages=absolute values.)

**CONCLUSIONS:** PDC was 0.95-18.75% higher than industry standard of 0.8. On average, across all EQ-5D-5L Dimensions (except Anxiety/Depression), patients reported QoL improvements after starting on oral oncology SP-D plus SPMTM compared to before starting the SP-D. 24% reported having M/S≥3 TxDM of oral oncology therapy in F-U PA, resulting in interventions. Further study with larger n size with similar patient population is suggested to better explain medication non-adherence and determine any impact on Anxiety/Depression dimension rating.

**SPONSORSHIP:** None

## D4 Economic Burden of End Organ Damage Among Patients with Sickle Cell Disease on Commercial Insurance in the US

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**BACKGROUND:** Sickle cell disease (SCD) is an inherited disorder in which pathology is driven by hemoglobin polymerization and red blood cell sickling, leading to chronic anemia, hemolysis, and episodic vaso-occlusion. Anemia is associated with stroke, chronic kidney disease (CKD), end-stage renal disease (ESRD), pulmonary hypertension (PH), and mortality.

**OBJECTIVE:** To quantify the economic burden of end organ damage among patients with SCD on commercial insurance.

**METHODS:** Patients with ≥3 nondiagnostic SCD ICD-9/ICD-10 codes within 5 years (Jan 1, 2013 to Mar 30, 2018) were identified in the MarketScan Commercial claims database. Each patient's follow-up period was divided into 3-month intervals. The entire available claims history was checked for each interval to identify 4 types of end organ damage experienced by patients with SCD: stroke (within 1 year and >1 year after an acute stroke event), CKD, ESRD, and PH. Patient characteristics, healthcare resource utilization, and costs were summarized descriptively by type of end organ damage. Three multivariate generalized linear models with log link function and gamma error distribution were used to estimate the relative ratios of total costs, inpatient days, and number of emergency department (ED) visits of patients with versus without end organ damage, controlling for patients' demographic and clinical characteristics.

**RESULTS:** A total of 6410 patients with SCD on commercial insurance were identified, contributing 65,607 intervals (mean follow up: 2.4 years; age ≥18 years: 68.2%; female: 58.5%; urban: 93.1%). Patients with end organ damage had more days in hospital, ED visits, outpatient visits, lab tests, and outpatient pharmacy claims per month than patients without organ damage. After controlling for demographic and clinical characteristics, patients with end organ damage had significantly higher costs, more days in hospital, and ED visits than those without these conditions. Costs in the first year after stroke were 7.57 times the costs for patients without any organ damage (1.98 times if >1 year after stroke; 2.17 times for CKD; 5.83 times for ESRD; 2.05 times for PH; $P<0.0001$ for all comparisons). Patients with other SCD complications (eg, avascular necrosis, leg ulcers) had significantly greater total costs compared with patients without organ damage ($P<0.0001$).

**CONCLUSIONS:** The economic burden of SCD is significantly elevated when patients experience stroke, renal dysfunction, or cardiopulmonary conditions. SCD management strategies that potentially reduce the risks of end organ damage offer both clinical and economic value to patients and society.

**SPONSORSHIP:** Global Blood Therapeutics

## D5 Vaso-Occlusive Crises and Costs of Sickle Cell Disease in Medicaid and Medicare Beneficiaries: The Perspective of Public Payers

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**BACKGROUND:** The economic burden of sickle cell disease (SCD) is substantial given patients' (pts) recurrent inpatient (IP) hospitalizations due to complications, notably painful vaso-occlusive crises (VOCs).

**OBJECTIVE:** To characterize VOCs and assess SCD costs of Medicaid and Medicare pts using an Excel-based model.

**METHODS:** Pts with SCD aged ≥16 years from all US states, with ≥24 months of continuous coverage (medical and pharmacy), with no dual eligibility or stem cell transplant, were identified in the Medicaid Analytic eXtract (2008-2014) and Medicare Research Identifiable Files (2012-2016) databases, separately. Data was entered into an Excel-based model; the key model inputs were VOC episodes requiring healthcare visits and healthcare costs.

**RESULTS:** 18,287 Medicaid pts (mean age 28.5 years, 58.2% female, 50.2% with a Fee-for-service plan) and 15,431 Medicare pts (mean age 48.2 years, 59.6% female, 77.4% with disability status) were included. In Medicaid, annually, 36.1% of pts had 0 VOC episodes, 17.0% had 1 VOC, and 46.8% had ≥2 VOCs (mean VOC episodes: 3.1 [median: 1.0]); 46.1% of VOC episodes were in an IP, 35.0% in an emergency room (ER), and 19.0% in an outpatient (OP) setting. Mean annual total all-cause healthcare costs were $16,750, $29,880, and $64,566 for pts with 0, 1, and ≥2 VOCs, respectively. Mean annual IP costs accounted for 37.2%, 64.3%, and 72.9% of total all-cause healthcare costs in pts with 0, 1, and ≥2 VOCs, respectively. Mean annual SCD-related healthcare costs accounted for 60.9%, 73.9%, and 92.3% of total all-cause healthcare costs in pts with 0, 1, and ≥2 VOCs, respectively. In Medicare, annually, 44.9% of pts had 0 VOC episodes, 11.4% had 1 VOC, and 43.7% had ≥2 VOCs (mean VOC episodes: 3.4 [median: 1.0]); 37.7% of VOC episodes were in an IP, 30.1% in an ER, and 32.2% in an OP setting. Mean annual total all-cause healthcare costs were $21,877, $29,250, and $58,308 for pts with 0, 1, and ≥2 VOCs, respectively. Mean annual IP costs accounted for 47.9%, 54.9%, and 67.5% of total all-cause healthcare costs for pts with 0, 1, and ≥2 VOCs, respectively. Mean annual SCD-related healthcare costs accounted for 74.9%, 84.4%, and 95.4% of the total all-cause healthcare costs among pts with 0, 1, and ≥2 VOCs, respectively.

**CONCLUSIONS:** Over 75% of Medicare pts with SCD had disability status, indicating a high disease burden. Among Medicaid and Medicare pts with SCD, the model showed that the contribution of SCD-related costs and IP costs to annual total all-cause healthcare costs accounted for a significant proportion and increased with the number of VOCs.

**SPONSORSHIP:** Novartis

## D10 Health Care Costs and Utilization Among Adult Patients with Immune Thrombocytopenia Enrolled in Texas Medicaid

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**BACKGROUND:** Our previous analysis reported that the average annual prevalence of immune thrombocytopenia (ITP) was 21.5 per 100,000 persons among Texas Medicaid beneficiaries. No known studies have estimated the economic burden of ITP in this population.

**OBJECTIVE:** To estimate the costs and health care utilization among adult patients with ITP enrolled in Texas Medicaid.

**METHODS:** A retrospective analysis was conducted using Texas Medicaid claims for calendar years 2012-2015. ITP patients aged from 19 to 63 years were identified using ICD-CM-9 code 287.31 and ICD-CM-10 code D69.3, with a requirement of two claims for ITP separated by at least 30 days. The index date was the first date with claims for ITP in the dataset. Patients were required to have continuous enrollment for 6 months before and 12 months after the index date. Patients with concurrent diagnoses that made ITP unlikely or secondary to other diseases were excluded. Outcomes included all-cause and ITP-related costs, costs attributed to different types of services, types of therapies used, emergency department (ED) visits and hospitalizations during the 12-month follow-up.

**RESULTS:** A total of 154 adult ITP patients (70 % female) with a mean age of 40.8 years were included in the analyses. The average all-cause costs for 12 months were $27,041 (SD = $35,247) per person, including

$7,184 drug costs and $19,857 non-drug medical costs. ITP-related costs were $6,501 (SD = $13,749), including $2,447 (38%) drug costs and $4,054 (62%) non-drug medical costs. More than half (65%) of non-drug medical costs were attributed to hospitalization, followed by office visits (31%) and outpatient visits (3%). One-half of drug costs were attributed to thrombopoietin receptor agonists (TPO-RAs), followed by IVIG (29%) and rituximab (19%). ITP-related costs were relatively higher in the first two months after initial diagnosis, with average costs of $ 2,770 and $890 in the first and second month respectively. A total of 68 (44%) patients received first-line therapies for ITP, including corticosteroids and IVIG; 17 (11%) patients received second-line therapies, including rituximab, TPO-RAs, immunosuppressants and splenectomies. 90 (58%) patients had at least one hospitalization, of which 50 were ITP-related; 103 (67%) had at least one ED visit, of which only four were ITP-related.

**CONCLUSIONS:** There was a large variation in health care costs among adult ITP patients in Texas Medicaid. Hospitalization and drug therapies were major contributions to ITP-related costs. ITP- related ER visits were rare in adult patients.

**SPONSORSHIP:** None

## D11 Severe Hemophilia A Patients Receiving Prophylactic Factor VIII in US Claims Data: Identification, Resource Use, and Costs

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**BACKGROUND:** Hemophilia A is a rare X-linked hereditary bleeding disorder marked by a deficiency or absence of coagulation factor VIII (FVIII). There is a wide distribution of overall treatment costs.

**OBJECTIVE:** This research identifies severe hemophilia A patients, categorizes them based on patterns of factor VIII use, and estimates resource use and costs borne by large commercial insurers in the US.

**METHODS:** Adult male severe hemophilia A patients were identified in the OptumHealth Care Solutions Claims database (1999-2017). Timing of claims was examined to develop criteria for identifying probable FVIII prophylaxis use; 3 groups were defined: (1) ≥4 and (2) ≥6 Factor VIII non-IP or non-ED claims per year and (3) no gaps >60 days in supply of FVIII over the last 12-month period. Healthcare resource use and costs were assessed during the most recent 12 months of insurance coverage. Outcomes (USD, amounts paid) included total medical and pharmacy costs, medical costs by place of service, and medical and pharmacy FVIII costs—including and excluding inpatient (IP) and emergency department (ED) FVIII costs.

**RESULTS:** 189 patients met criteria for sample selection; 3 groups with prophylaxis use were identified with (1) 118, (2) 94, and (3) 61 patients, respectively. Total healthcare costs were high (mean: $287,055) and variable (SD: $306,933); 91.3% were from non-IP/non-ED FVIII costs. Similarly, the majority of total costs in each of the 3 prophylaxis groups were non-IP/non-ED: 94%, Group 1 ($383,389/$407,752); 93.8%, Group 2 ($432,136/$460,576); and 96.2%, Group 3 ($529,864/$551,645). FVIII pharmacy costs were 3 times higher than FVIII medical costs (mean ± SD: $193,875 ± $283,739 vs. $68,113 ± $173,486) for all and for each prophylaxis group. Mean exceeded median costs, reflecting high-cost outlier patients; median FVIII costs in each group were still substantial. Nearly all (98%) had ≥1 outpatient (OP) visit, and 52% had ≥1 home health claim. However, among probable prophylaxis users, fewer had home health claims (Group 1: 31%; Group 2: 33%; Group 3: 28%). Home health agency (HHA) claims (which may include payment for FVIII) accounted for the highest proportion of medical costs compared to IP, ED, OP, and other costs.

**CONCLUSIONS:** Healthcare costs for severe hemophilia A patients enrolled in large commercial insurers are high and variable, with non-IP/non-ED FVIII claims accounting for over 90% of total healthcare costs. Within a group of patients with continuous prophylactic use of FVIII, total healthcare spending exceeds $500,000 per patient per year.

**SPONSORSHIP:** BioMarin Pharmaceutical

## D12 Real-World Factor Consumption, Healthcare Resource Utilization, and Costs Among People with Severe Hemophilia B in the US Treated with Prophylactic Factor IX Replacement Therapy

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**BACKGROUND:** Prophylactic treatment with factor IX (FIX) is broadly administered in people with severe hemophilia B (HB) across the US, primarily to reduce the frequency of spontaneous bleeding and joint deterioration. Healthcare system costs of severe HB in the US are disproportionately (>90%) associated with FIX prophylaxis. Moreover, hospitalizations, breakthrough bleed events, and joint degradation continue to occur despite FIX prophylaxis.

**OBJECTIVE:** To examine real-world factor consumption, costs and healthcare resource utilization among patients with severe HB in CHESS US+ receiving prophylactic FIX replacement therapy.

**METHODS:** This analysis draws on patients with severe HB receiving prophylactic FIX replacement in the 'CHESS US+' study (Cost of Hemophilia Across the United States: A Socioeconomic Survey+), a cross-sectional study of adults with severe hemophilia (<1% IU/dL) in the US. A patient-completed questionnaire gathered data on clinical, economic, and humanistic outcomes. Data on annual FIX consumption (in international units [IU]), including FIX prophylaxis and additional FIX required in response to a bleed and during surgical procedures, were reported. The annual cost of treatment was calculated using product-specific unit prices. Results were presented as mean (± standard deviation) or N (%).

**RESULTS:** Of 356 patients profiled in the study, 97 (27%) had severe HB. Patients on FIX prophylaxis (N = 57) had a mean age and weight (kg) of 35.84 (± 12.69) and 85.57 (± 21.15), respectively. Standard half-life (SHL) FIX was prescribed in 22 patients and extended half-life (EHL) FIX in 35 patients. Mean annual consumption and cost of FIX was 339,966 IU (± 199,337) and $895,445 (± $563,870). Among patients treated with SHL FIX, annual consumption and cost of FIX was 409,628 IU (± 227,055) and $665,800 (± $343,279), while patients treated with EHL FIX reported annual FIX consumption and cost of 294,891 IU (± 167,601) and $1,044,039 (± $630,094). Patients reported 12-month resource use as [mean (± SD)]: hematologist consultations [2.63 (± 4.25)]; hemophilia nurse consultations [2.09 (± 4.00)]; physical therapist consultations [2.14 (± 4.93)]; orthopedist consultations [0.60 (± 1.10)]. Furthermore, two patients (4%) underwent a major joint procedure and 19% were admitted to hospital due to a bleed event.

**CONCLUSIONS:** Data from the CHESS US+ study reported substantial economic burden to the US healthcare system among severe HB patients receiving FIX prophylaxis. Such significant burden highlights that unmet needs remain in HB management in the US.

**SPONSORSHIP:** uniQure

## D13 An Early View Analysis of Characteristics of Persons with Hemophilia A Treated with Emicizumab Using Secondary Claims Data

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**BACKGROUND:** Emicizumab (EMI) is indicated for routine prophylaxis in hemophilia A (HA) with/without factor VIII (FVIII) inhibitors.

**OBJECTIVE:** Early view of the characteristics of patients treated with EMI.

**METHODS:** This retrospective cohort study used commercial claims data from MarketScan Commercial Research (11/16-12/18) and PharMetrics Plus (11/16-3/19) Databases. Patients with ≥1 EMI claims from 11/17-3/19 and ≥12 months of continuous enrollment prior to the index date (pre-EMI year) were identified. Index date was the date of first EMI claim. Demographics, clinical characteristics (major bleeds, arthropathy and pain), healthcare resource use, and costs were examined in the pre-EMI year. Major bleeds were defined using an algorithm by Shrestha et al. (2017); arthropathy and pain were identified using ICD-9-CM/ICD-10-CM diagnosis codes. NDC or HCPCS codes were used to identify EMI, FVIII and bypassing agents (BPA).

**RESULTS:** A total of 107 patients with ≥1 EMI claims were identified. All patients were males (100%); majority were covered with Preferred Provider Organization plans (72%, n=77). Mean age was 24.1 (SD±17.6) years (y) (range=1-62 y) with 16.8% (n=18) aged ≤5 y. In the pre-EMI year, 28% (n=30) had evidence of major bleeds, with a mean of 2.2 (SD±1.9) bleeds (range=1-8) among those with ≥1 major bleed; 17% (n=18) had evidence of arthropathy and related disorders, and 12% (n=13) had any pain diagnosis. Overall, 35% (n=37) had ≥1 emergency room visit (mean±SD=0.7±1.4); 14% (n=15) had ≥1 inpatient stay with mean length of stay of 1.1 (SD±3.5) days; 82% (n=88) had ≥1 outpatient hospital visit (mean±SD=4.1±9.7); and 88% (n=94) had ≥1 office visit (mean±SD=8.0±9.7). A total of 79% (n=85) had evidence of FVIII use and 17% (n=18) had a BPA claim (evidence of inhibitors) with an average of 10.3 (SD±12.3) and 8.6 (SD±7.9) prescriptions, respectively. The average HA-related cost in the pre-EMI year was estimated at $718,957 (SD±1,269,973) (median=$316,646) of which, 93% was attributed to FVIII/BPA drug costs. For patients with ≥1 FVIII or BPA claim, the mean drug costs in the pre-EMI year were $590,847 (SD±996,264) and $1,171,439 (SD±1,390,883), respectively.

**CONCLUSIONS:** To our knowledge, this is the first real-world claims study that describes the characteristics of patients initiating EMI, and underscores their disease and treatment burden. Results show utilization of EMI in patients with different clinical characteristics and across various age groups. Longer follow-up data will help to further examine these real-world outcomes.

**SPONSORSHIP:** Genentech

## D14 A Cost Minimization Analysis of Eltrombopag and Romiplostim for the Treatment of Adult Patient with Chronic Immune Thrombocytopenia

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**BACKGROUND:** Promacta (eltrombopag) and Nplate (romiplostim) have not been compared in head to head trials for treatment of chronic immune thrombocytopenia (cITP), however indirect treatment comparisons have indicated similar efficacy and safety outcomes, and the drugs are generally accepted as therapeutic alternatives.

**OBJECTIVE:** To determine which of the two therapies would result in the lowest overall cost from a US health plan perspective, under the assumption of equivalent clinical efficacy and safety.

**METHODS:** A cost minimization model was developed in Microsoft Excel. The model incorporated only costs which differ between the treatments, including drug acquisition, administration, and monitoring costs, over a 52 week horizon. Average dosing for eltrombopag (EPAG) and romiplostim (ROMI) was taken from the long-term EXTEND trial and from a published meta-analysis of 14 clinical trials respectively. As ROMI is injectable while EPAG is oral, only ROMI had administration costs. EPAG pricing was based on Wholesale Acquisition Cost (WAC), ROMI pricing was based on Average Sales Price (ASP), and the model assumed patients used 25 mg EPAG tablets and the 250 µg vial size of ROMI. ROMI vial wastage was included in drug acquisition costs by rounding up average dose to the nearest whole vial. Monitoring requirements were determined from prescribing information, with platelet monitoring assumed equal, and hepatic panel testing every 4 weeks for EPAG. The model was adjustable to commercial, Medicare and Medicaid plan perspectives, with optional inclusion of vial wastage, monitoring or administration costs.

**RESULTS:** The base case used a commercial plan perspective, with average dosing of 51.5 mg/day for EPAG and 4.20 µg/kg/week for ROMI. The analysis found an annual cost difference per treated patient of $64,770 in favor of EPAG. Breakdown by unique costs for EPAG: drug acquisition cost $123,135; monitoring cost $705. Breakdown by unique costs for ROMI: drug acquisition cost $183,234, of which wastage $63,179; administration cost $5,377. Based on a hypothetical commercial plan with 1 million members and an estimated 15 cITP patients receiving ROMI, potential annual savings for switching all patients from ROMI to EPAG is $971,554 or $0.08 per member per month. EPAG remained the less costly option for all plan types and assumptions. A sensitivity analysis found that the result was most sensitive to drug pricing and vial wastage inputs.

**CONCLUSIONS:** Because of lower drug acquisition, drug wastage and administration costs, treatment of cITP with eltrombopag is associated with a lower net cost per patient than romiplostim.

**SPONSORSHIP:** Novartis Pharmaceuticals

## D15 Uptake of Emicizumab-kxwh (Hemlibra) in the MO HealthNet Population and Impact on Medical and Pharmacy Cost and Utilization

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**BACKGROUND:** Patients with severe hemophilia (HEM) A need regular infusions of Factor VIII (FVIII) to avoid bleeding. About 25% develop a FVIII inhibitor that interferes with the effectiveness of FVIII, making it difficult to control bleeding without using high doses of FVIII or a bypassing agent. In November 2017, emicizumab-kxwh (EMC) was approved to prevent or reduce the frequency of bleeding episodes in patients with HEM A with FVIII inhibitors. In November 2018, the FDA expanded EMC's indication to include all patients with HEM A. This study was designed to determine uptake of EMC and its impact on medical and pharmacy cost and utilization.

**OBJECTIVE:** To describe EMC adoption rates, user demographics and changes in cost and utilization before and after EMC initiation.

**METHODS:** Using the MO HealthNet claims database, enrollees with a diagnosis of HEM A who started EMC between January 2018 and June 2019 were identified as the EMC population. Each EMC recipient was matched to a control recipient with a diagnosis of HEM A and a date of birth within one month of the EMC recipient. All recipients were

continuously enrolled during the analysis period, which was six months before and six months after EMC initiation. Recipient demographics and EMC adoption rates and adherence were determined. Utilization and cost per utilizer per month (PUPM) for medical services and pharmacy cost were determined from claims data and compared to the matched controls.

**RESULTS:** Of 81 enrollees with HEM A, 18 (22%) started EMC during the study period with the highest number (12) in the 5 to 17 year old age group. The average age of the EMC group was 12.2 years compared to 12.7 years in the control group. Adherence to EMC therapy ranged from 33% to 100% with an overall adherence of 95%. Six months prior to EMC initiation, pharmacy cost PUPM ($45,209 EMC and $42,283 control), medical cost PUPM ($2,351 and $2,015) and medical utilization PUPM (1.46 and 1.41) were similar between the two groups. Six months after EMC initiation, pharmacy cost PUPM decreased $8,122 (18.0%) in the EMC group, compared to $1,000 (2.4%) in the control group, driven by decreases in HEM drug cost ($8,179 and $1,015, respectively). Medical cost and utilization PUPMs also decreased to a greater extent in the EMC group compared to the control group ($1,059 [45.1%] and $49 [2.4%]; 0.43 [29.3%] and 0.07 [5.2%], respectively).

**CONCLUSIONS:** In this analysis, EMC therapy was associated with a decrease in the cost of HEM medications and cost and utilization of medical services.

**SPONSORSHIP:** Conduent

## D17 Real-World Retrospective Data on the Uptake of Neulasta Biosimilars Without Preferred Status on Medicare Part B in a Multi-State Regional Health Plan

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**BACKGROUND:** Biosimilar products are entering the market at an ever increasing rate and represent the potential for significant cost savings. For predicted cost savings to materialize, providers need to demonstrate a willingness to prescribe the new biosimilar products. There is variation in professional opinions regarding whether health plans should actively steer providers towards the biosimilar products or wait for provider prescribing habits to change.

**OBJECTIVE:** To compare utilization of Neulasta (pegfilgrastim) with the biosimilar products Fulphila (pegfilgrastim-jmdb) and Udenyca (pegfilgrastim-cbqv) in Medicare Advantage members over the course of a single year when utilization requirements do not favor any particular formulation.

**METHODS:** A retrospective analysis was done utilizing regional health plan claims records for Medicare Advantage members. Claims for pegfilgrastim, pegfilgrastim-jmdb, and pegfilgrastim-cbqv during the timeframe from August 1, 2018 through August 1, 2019 were included in the analysis to encompass the market availability of all three products. The utilization management of all products at this time was a preauthorization with documentation supporting a Food and Drug Administration (FDA) labeled indication and did not prefer a specific formulation via contracting, reimbursement, or formulary placement.

**RESULTS:** In the allotted time frame, pegfilgrastim, pegfilgrastim-jmdb, and pegfilgrastim-cbqv accounted for 302 claims for 61 unique Medicare advantage members from a total population of 32,700. The originator product represented 73% (221) of total claims. Based on average wholesale price, the total cost represented $1,652,417 in claims. If the originator had been replaced with either biosimilar product the equivalent cost would have been $1,107,210, representing a missed savings of 32% or $545,207.

**CONCLUSIONS:** Providers within this region heavily favored the originator product when given the choice between the three products. In order to achieve the cost savings intended with the launch of biosimilars additional work is needed such as: provider education, restructuring of payment incentives at a federal level, or scalable value-based agreements. This will likely require a multi-pronged approach to drive utilization toward cost-saving biosimilar products.

**SPONSORSHIP:** None

## D21 Hereditary Angioedema Real-World Prophylactic and On-Demand Treatment Cost in a 15 Million Commercially Insured Population: Comparison of C-1 Inhibitor (Haegarda)- Versus Lanadelumab (Takhzyro)-Treated Members

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**BACKGROUND:** Three products have FDA approval for prophylaxis against hereditary angioedema (HAE) attacks: intravenous (IV) C-1 inhibitor (C1-INH IV, Cinryze), 10/10/2008; subcutaneous (SC) C1-INH (Haegarda), 6/22/2017; and SC lanadelumab (Takhzyro), 8/23/2018. Four different products are approved for on-demand treatment of acute attacks. Little is known about the real-world total HAE treatment cost associated with the newest prophylactic therapies.

**OBJECTIVE:** Among members newly starting prophylactic therapy with Haegarda (Haeg) or Takhzyro (Tak) in a commercially insured population, to compare: 1) HAE prophylactic drug cost, 2) percentage using any on-demand agents, and 3) cost of HAE on-demand agents.

**METHODS:** From 15 million commercially insured members with integrated medical and pharmacy claims, we identified members with a first claim for Haeg or Tak prior to 2/1/2019 and continuous eligibility for 180 days preceding and following their first Haeg or Tak claim. The comparison sample was further limited to those who used only one prophylactic agent during follow-up and continued therapy for at least 150 days. On-demand agents were defined as CI-INHs Berinert or Ruconest, ecallantide (Kalbitor), or icatibant (Firazyr), covered by the pharmacy or medical benefit. Cost was defined as the plan plus member cost after network discounts. Cost comparisons were made using Student's T-test.

**RESULTS:** There were 85 Haeg and 50 Tak members with first claim before 2/1/2019, 29 of each who met the additional analytic criteria. 23 of 29 (79.3%) Haeg and 21 of 29 (72.4%) Tak were female. Mean age (years) was 40.1 Haeg and 43.5 Tak. Cost of prophylactic therapy for 180 days was: mean $226,989 Haeg vs $278,267 Tak, $P=0.013$. 18 of 29 (62.1%) Haeg vs 19 of 29 (65.5%) Tak had a claim for an on-demand agent. Cost of on-demand therapy for 180 days was: mean $108,025 Haeg vs $82,591 Tak, $P=0.508$.

**CONCLUSIONS:** In this small sample of members newly starting prophylactic therapy for HAE with either SC C1-INH (Haegarda) or lanadelumab (Takhzyro), mean prophylactic treatment cost for 180 days was over $50,000 higher for lanadelumab. There was no difference in the percentage of members with any use of on-demand HAE agents and no significant difference in the mean cost of on-demand therapy. Although the small sample size may impact these findings, these real-world data suggest SC C1-INH may be lower cost than lanadelumab during the first 180 days of HAE prophylaxis treatment.

**SPONSORSHIP:** Prime Therapeutics

## D22 Not a Hard Pill to Swallow: U.S. HAE Patients' Receptivity to Oral Prophylaxis

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**BACKGROUND:** Hereditary Angioedema (HAE) is an ultra-orphan disease. This debilitating disorder is characterized by potentially life-threatening, recurrent episodes of swelling, resulting in significant physical, emotional, and economic burden. Several FDA approved acute and prophylactic treatments are available, administered subcutaneously or intravenously.

**OBJECTIVE:** With oral treatments on the horizon, it is important to understand patients' preferences. At the 2017 FDA Voice of the Patent Summit, HAE patients cited route of administration as the most important factor in their treatment preference. Oral treatment options have successfully helped address unmet needs among patients with several conditions including psoriatic arthritis, metastatic colon cancer, and Gaucher disease.

**METHODS:** Two cross-sectional studies were conducted among U.S. adult patients diagnosed with Type I or II HAE. Respondents were recruited separately for each study from online panels and databases, social media, and the US Hereditary Angioedema Association.

**RESULTS:** Online surveys were completed by 75 patients in the fall of 2018 and by 100 patients in the summer of 2019 with 2 patients responding to both surveys; patients were diagnosed with HAE by a healthcare provider, a mean of 16.7 and 19.4 years ago, respectively. Most patients with HAE surveyed report taking at least one medication for prophylaxis of HAE attacks (64% in 2018 and 85% in 2019). Respondents are generally satisfied with their HAE prophylactic medication, with an average of 65% indicating they are "extremely satisfied". Although all patients HAE taking prophylaxis treatment (100%) agree it is important to take preventative treatment as prescribed, more than half (52%) agree that preventative treatment for HAE is burdensome and only 35% feel in control of their HAE attacks. There is interest in new preventative HAE options, with 98% agreeing they like their current preventative HAE medication, but would prefer an oral treatment if one were available. Convenience is an important factor in HAE prophylaxis among surveyed patients taking HAE prophylaxis. The majority (67%) agree that convenience is the primary reason they would try an oral preventative HAE medication, and 96% agree that an oral preventative HAE medication would fit their life better than an injectable HAE medication.

**CONCLUSIONS:** Although HAE patients report satisfaction with current prophylactic treatments, based on real-world evidence, the majority would prefer an oral option, which would decrease treatment burden and in turn, further increase satisfaction.

**SPONSORSHIP:** BioCryst Pharmaceuticals

## D23 Economic Burden of Acute Steroid-Refractory Graft Versus Host Disease in Commercially Insured Pediatric Patients

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**BACKGROUND:** Acute graft-versus host disease (aGVHD), a potential life-threatening complication of hematopoietic stem cell transplantation (HSCT), often occurs within 100 days of HSCT. While steroids are typically used 1st line, there is no consensus for 2nd line steroid-refractory (SR) treatment. SR aGVHD is associated with significant reductions in pediatric outcomes, but less is known about the economic impact.

**OBJECTIVE:** This study evaluated the economic burden of SR pediatric aGVHD in commercially insured US patient population.

**METHODS:** Retrospective analyses were conducted using medical and pharmacy claims data from the HealthCore Integrated Research Database (study period 01/01/2006-05/31/2019). Included patients (pts) had ≥1 claim for allogeneic HSCT (earliest HSCT claim set as index date), no claims for autologous HSCT, and no pre-index GVHD. Pts were <18 years with no minimum pre- or post-index continuous enrollment. The GVHD cohort included pts with ≥1 claim for aGVHD over 100 days from index with ≥1 claim for any steroid and ≥1 claim for second-line therapy, both on or after the date of the first aGVHD claim. Pts post-HSCT with no GVHD claims over follow-up formed the comparison cohort. Healthcare resource utilization and costs over 12 months from the index date were calculated and compared across cohorts using parametric testing.

**RESULTS:** Thirty-eight pts with SR aGVHD and 184 controls were included. Mean age and sex were similar for aGVHD (5.97 years, 50% female) and control (5.57 years, 45% female). During 12-month post-index follow-up, SR aGVHD pts had higher rates of complications vs controls (* for $P<0.05$): anemia (79% vs 68%), drug-induced anemia* (53% vs 34%), neutropenia (63% vs 53%), thrombocytopenia (58% vs 42%), gastrointestinal complications* (95% vs 65%), and infections* (95% vs 79%). Mean length of stay including ICU was longer by 21.7 days (13.7 ICU days) with the total average of 106 inpatient days for those with SR aGVHD versus 84 days for the controls. More SR aGVHD pts required total parenteral nutrition (71% vs 58%), readmission within 12 months of discharge from index hospitalization* (89% vs 60%), ER visits (34% vs 24%), and outpatient visits* (100% vs 86%). Total 12-month mean medical costs were higher in aGVHD pts: $1,212,945 vs $673,491 ($P<0.01$), mostly due to complication-related costs: $868,965 vs $396,757 ($P<0.01$).

**CONCLUSIONS:** SR aGVHD in pediatric patients following HSCT is associated with incremental 12-month medical costs of >$500,000, driven largely by complications.

**SPONSORSHIP:** Mesoblast

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

## E2 Evaluation of A1c Outcomes for New Members with Type 2 Diabetes Following Pharmacist Consult

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**BACKGROUND:** The number of people with diabetes continues to grow as well as the cost of management. In 2015, 30.3 million Americans or 9.4% of the population had diabetes. In Georgia, 1 in 10 adults were living with diabetes in 2013 and its prevalence has increased from 6.8% in 2000 to 10.7% in 2015. The total cost of diagnosed diabetes was $327 billion in 2017. Formulary management is critical to providing sustainable, high quality healthcare at an affordable price. The 2017 Healthcare Effectiveness Data and Information Set (HEDIS) ranked Kaiser Permanente Georgia (KPGA) highest in hemoglobin A1c<8% control rate in the state. The KPGA New Member Pharmacy program provides pharmacist consultations to adult patients taking chronic medications before their first primary care provider visit. During the consult, pharmacists recommend conversion from non-preferred medications to preferred cost effective alternatives. Further research assessing pharmacist-led formulary conversion recommendations on A1C outcomes is warranted.

**OBJECTIVE:** To evaluate change in baseline A1c at 6 weeks to 9 months following diabetes medication change.

**METHODS:** New members with Type 2 Diabetes continuously enrolled in our health plan between January 1 through October 31, 2018 were included in data analysis. For members who underwent medication change while transitioning to our health plan, A1c was evaluated at baseline and at 6 to 9 months following medication change.

**RESULTS:** 621 patients received a pharmacy new member consult that included a medication change recommendation. After accounting for inclusion/exclusion criteria, a total of 344 were included in the data analysis. The average age was 56 years old and 51% were male. Average baseline A1c 8.49% and was <8% in 44% of patients. 164 patients experienced an increase in A1c during this time period. 180 patients experienced an A1c decrease or no change in A1c control. There were 103 patients started on sulfonylurea and 61% had a follow-up A1c<8%. 138 patients had at least one nurse or pharmacist diabetes care manager follow-up. Patients with at least 1 diabetes care manager touch had approximately 1% A1c improvement. The overall average follow-up A1c was 8.26% and 55% of patients had an A1c of <8%.

**CONCLUSIONS:** There are limitations to the study that may affect the generalization of these results to other settings. Despite the limitations, the New Member Pharmacy program had a positive impact. A pharmacist consult approach to transition patients to a new healthcare setting is a safe and effective method of switching to cost effective diabetes medications while maintaining or improving A1c control.

**SPONSORSHIP:** Kaiser Permanente Georgia

## E3 Improving Five-Star Pharmacy Measures: The Impact of Machine Learning AI Analytics and Personalized Coaching

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**BACKGROUND:** Poor medication adherence negatively impacts healthcare outcomes and costs the industry billions every year. CMS has taken notice, placing significant emphasis on pharmacy measures when evaluating health plans for its Five-Star Quality Ratings System. To increase the percentage of diabetes patients on statins, and to improve overall adherence to statin, RASA, and diabetes medications, health plans may implement a variety of outreach programs focused on improving these metrics.

**OBJECTIVE:** The objective of this study was to evaluate the impact of a high-touch, highly-personalized patient coaching program that used Machine Learning AI analytics to prioritize and inform outreach efforts. The program was designed to improve adherence to statin, RASA, and diabetes medications and to increase statin use across diabetes patients. One-on-one telephonic coaching identified barriers to adherence and established a personalized care plan to support intrinsic motivation and help patients overcome these barriers.

**METHODS:** Machine learning AI analytics were used to stratify a Medicare PDP population of over 360,000 patients and to prioritize them for medication adherence and statin use outreach. The analytics identified patients not likely to be adherent and those most likely to engage with the program. High-touch, personalized coaching addressed each patient's barriers to adherence and helped close knowledge gaps associated with each medication. Targeted provider outreach was also used to augment patient outreach. Adherence and statin use results were evaluated by comparing outcomes for those in the population who were coached and those who were not. Propensity score matching was applied to adjust for innate differences between groups.

**RESULTS:** Results from the analysis showed that the coached group had a higher rate of patients achieving 80% days covered across all three medication classes when compared to the non-coached group. The coached group also demonstrated an increase in diabetes patients taking a statin. Time management, knowledge gaps, and limited motivation were identified as top barriers to adherence. The analysis also identified other factors, such as demographics and social determinants of health, impacting a patient's likelihood to not be adherent in the future.

**CONCLUSIONS:** The analysis demonstrated that the use of machine learning AI analytics and high-touch personalized coaching can improve medication adherence rates and increase the percentage of diabetes patients on a statin.

**SPONSORSHIP:** Health Dialog and Rite Aid

## E4 Healthcare Resource Utilization and Cost of Severe Hypoglycemia Treatment in Patients with Diabetes Treated with Insulin

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**BACKGROUND:** Severe hypoglycemia (SH) is a life-threatening complication of insulin treatment. Healthcare resource utilization (HCRU), i.e., emergency medical services (EMS), emergency department (ED) visits and/or hospitalization, may be required to resolve some SH events. Costs associated with HCRU can vary depending on type of diabetes, type of insulins used, and insurer type.

**OBJECTIVE:** This study aims to characterize HCRU and associated cost related to SH treatment.

**METHODS:** Administrative claims data from the IBM MarketScan Research Database were used. Patients with diabetes (PWD) who received at least one prescription for insulin between June 2016 and November 2017 and who experienced a SH event that was treated with EMS, ED, or hospitalization between December 2016 and November 2017 were included in the analysis. For each PWD, the first SH event that occurred during the study period and involved HCRU was summarized according to the use of EMS, ED, or hospitalization and the associated median cost per event (25th percentile-75th percentile).

**RESULTS:** A total of 9,563 insulin-treated PWD experienced SH during the study period. EMS was called during approximately half of the SH events (50.7%), while during 48.5% of events, the PWD was taken directly to the ED without EMS. During the SH events that involved EMS, most PWD were transported to the ED (84.7%). Of all PWD that visited the ED, 32.7% were hospitalized. Specifically, nearly 18% of these PWD went directly to ED and 15% of these PWD were transported by EMS before hospitalization. The median cost associated with EMS treatment alone was $140 ($49.5-$410.4) per event, while the median cost of ED care in combination with EMS was $1,281.6 ($697.6 $2,481.3). This is almost twice the cost of ED care after the PWD is driven there directly [$678.1 ($96.4-$1,561.2)]. The median cost of hospitalization after treatment in the ED alone was $9,670 ($4,111.1-$19,244.1) and $11,037.5 ($6219.8-$21,252.6) after treatment from EMS and ED. When analyzed by payer type, managed Medicaid is associated with the lowest HCRU costs, followed by Medicare Advantage and commercial payers.

**CONCLUSIONS:** As EMS is the first treatment for about half of PWD experiencing SH events, optimizing EMS care to reduce the proportion of PWD requiring transport to ED could be a substantial cost-saving option for treatment of SH events. This real-world study adds to the limited number of descriptive studies of the costs associated with SH treatment.

**SPONSORSHIP:** Eli Lilly

## E5 Cost-Effectiveness of Oral Semaglutide in Type 2 Diabetes: A US Managed Care Perspective

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**BACKGROUND:** Type 2 diabetes (T2D) represents substantial disease related economic burden in the United States (US). Oral semaglutide

(Rybelsus) is the first tablet formulation glucagon-like peptide-1 receptor agonist (GLP-1RA) for the treatment of adult patients with T2D and has been shown to significantly lower HbA1c and body weight with no increased risk of cardiovascular events.

**OBJECTIVE:** To estimate the incremental cost utility ratio (ICUR) of oral semaglutide (14 mg once daily) vs subcutaneous (SC) GLP-1 RAs (dulaglutide, liraglutide, semaglutide), among adult patients with T2D that are inadequately controlled on one to two oral anti-diabetic drugs (OADs) over a lifetime horizon from a US managed health care perspective.

**METHODS:** A state-transition model utilizing a competing-risk approach was constructed to estimate the lifetime costs and outcomes. Competing risks included non-fatal events (macrovascular and microvascular) and fatal-events (T2D-related or all-cause) and were constructed based on the United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model 1. Baseline cohort characteristics were derived from the 52-week PIONEER 4 trial. Treatment efficacy estimates were obtained from a network meta-analysis, indirectly comparing oral semaglutide to the GLP-1 RAs. Event and disease management costs (including adverse event costs) to a health care payer and utilities were obtained from the published literature. Costs (2019 USD) and outcomes were discounted at 3% annually.

**RESULTS:** In the base-case, oral semaglutide dominated dulaglutide and liraglutide as it was less costly (-$1,656 and -$5,363), with similar but higher life years (0.008 and 0.013 increase) and quality adjusted life years (0.004 and 0.007 increase). Results were robust under tests of uncertainty and remained unchanged across the sensitivity scenarios tested. The predicted total lifetime QALYs for oral semaglutide were comparable to its subcutaneous formulation (12.975 vs 12.986) with a net savings of $1,769 per patient (reverse ICUR of $163,737/QALY gained).

**CONCLUSIONS:** In the base-case, oral semaglutide dominated dulaglutide and liraglutide as it was less costly (-$1,656 and -$5,363), with similar but higher life years (0.008 and 0.013 increase) and quality adjusted life years (0.004 and 0.007 increase). Results were robust under tests of uncertainty and remained unchanged across the sensitivity scenarios tested. The predicted total lifetime QALYs for oral semaglutide were comparable to its subcutaneous formulation (12.975 vs 12.986) with a net savings of $1,769 per patient (reverse ICUR of $163,737/QALY gained).

**SPONSORSHIP:** Novo Nordisk

## E6 Persistence of Semaglutide OW Versus Other Long-Acting GLP-1RAs in a Real-World Setting

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**BACKGROUND:** Once-weekly (OW) subcutaneous semaglutide is the most recent injectable glucagon-like peptide 1 receptor agonist (GLP-1RA) agent approved in the U.S. for adults with type 2 diabetes (T2D), and as such, real-world evidence of its use is lacking. Real-world treatment persistence of semaglutide OW has not yet been assessed, either alone or in comparison to other GLP-1RA agents.

**OBJECTIVE:** This study aimed to evaluate treatment persistence among patients with T2D initiating semaglutide OW compared to other long-acting injectable GLP-1RA agents in a U.S. real-world setting.

**METHODS:** Optum Clinformatics U.S. claims data was used to retrospectively compare treatment persistence among adults (≥18 years) with T2D newly initiating GLP-1RA (semaglutide OW, dulaglutide, exenatide OW, and liraglutide) between 01/01/2018 and 04/30/2019. Patients were followed from GLP-1RA initiation to discontinuation (defined as >60 days gap in supply), end of enrollment or end of available data (06/30/2019). Patients that did not discontinue were considered persistent. Persistence was assessed using a variable follow-up by Kaplan-Meier survival estimates (KMSE) and Cox proportional hazard models.

**RESULTS:** In total, 56,715 patients meeting inclusion criteria initiated semaglutide OW (5.8%), dulaglutide (49.2%), exenatide OW (14.7%), or liraglutide (30.3%). Patients initiating semaglutide OW were younger and fewer had Medicare coverage (mean age ± SD: 55.8 years ± 11.14, Medicare: 17.7%) compared to dulaglutide (62.2 years ± 12.15, 56.2%), exenatide OW (60.6 years ± 11.93, 51.0%), and liraglutide (61.1 years ± 12.11, 56.3%) ($P<0.001$ for all). Semaglutide OW had the highest persistence for all comparisons ($P<0.001$). The KMSE of persistence at 6 months was 74.0% for semaglutide OW, compared to 66.4% dulaglutide, 48.6% exenatide OW and 54.1% liraglutide. Similarly, at 12 months, 67.0% of patients were estimated to be persistent on semaglutide OW, compared to 56.0% dulaglutide, 35.5% exenatide OW and 40.4% liraglutide. Compared to semaglutide OW, the treatment discontinuation risk was higher for dulaglutide (HR = 1.22 [95% CI 1.13,1.32] $P<0.001$), exenatide OW (HR = 2.12 [1.96,2.30] $P<0.001$), and liraglutide (HR = 1.80 [1.66,1.95] $P<0.001$). After adjusting for baseline factors, the risk of treatment discontinuation remained significantly lower for semaglutide OW ($P<0.01$).

**CONCLUSIONS:** In a real-world setting, T2D patients on semaglutide OW had higher persistence than patients on the 3 other long-acting injectable GLP-1RAs included in this study, even after adjusting for baseline characteristics.

**SPONSORSHIP:** Novo Nordisk

## E7 Impact of a Prescriber Call Program in Promoting the Prescribing of the Cardio-Protective Medication Bundle

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**BACKGROUND:** The California (CA) Department of Public Health estimates about 72,000 deaths from cardiovascular disease (CVD) and 8,000 deaths from diabetes occur annually in CA. Per the American Heart Association and American Diabetes Association evidence-based guidelines, statins and angiotensin-converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARB) are recommended to help improve clinical outcomes and reduce mortality rates for patients with CVD and diabetes. Although this cardio-protective medication bundle could substantially prevent CVD events, many patients are not taking them.

**OBJECTIVE:** The goal of this program was to determine the impact of a prescriber call program in increasing the prescribing of a statin, ACEi or ARB in patients with diabetes and/or CVD.

**METHODS:** The program enrolled 8,739 Medicare (MAPD/MMP) and Commercial patients in CA with diabetes and/or CVD with no previous statin fill. Of these identified patients, 3,756 also had no fills of an ACEi or ARB. All physicians received a letter (via fax or mail) encouraging the prescribing of the cardio-protective medication bundle. Physicians of MAPD patients (n = 4,795) received phone calls (call group), while physicians of commercial and MMP patients (n = 3,944) did not (letter only group). A team of pharmacists and technicians called physician offices to illicit a response. Technicians ensured provider offices received the letters while pharmacists engaged in a clinical conversation with providers or their staff. To determine the success of the program, pharmacy claims data were analyzed post-intervention and the differences between the two groups were evaluated. A chi-square analysis was conducted to determine statistical significance.

**RESULTS:** About 10 months after completion of phone calls, 33% (n = 1,600) of patients in the call group were started on a statin compared to 21% (n = 845) of patients in the letter only group ($P<0.00001$).

Also, 15% (n = 282) of patients in the call group were started on an ACEi or ARB compared to 11% (n = 196) of patients in the letter only group ($P = 0.00609$). We observed a 60% decrease in per member per month cost from reduced utilization related to CVD events.

**CONCLUSIONS:** To help improve CVD outcomes and lower mortality rates in patients with diabetes, it is important to increase the prescribing of the cardio-protective medication bundle. MCOs should employ prescriber outreach call programs to achieve higher rates of prescribing. There is a statistically significant difference between a call program and a letter program in accomplishing this goal.

**SPONSORSHIP:** Envolve Pharmacy Solutions

## E8 Efficacy and Pharmacy Budget Impact Comparison Between U-100 Regular Human Insulin and Rapid-Acting Insulin When Delivered by V-Go Wearable Insulin Delivery Device in Type 2 Diabetes

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**BACKGROUND:** Increasing insulin prices have led to a renewed debate to determine if Rapid Acting Insulin (RAI) analogs offer an advantage over less expensive Regular Human Insulins (RHI). The steep increase in the cost of RAI has led to rationing of insulin or the total discontinuance of therapy by many patients due to cost. For many, RHI provides a more affordable option for insulin therapy when compared to RAI, especially if the limitations of the insulin profile can be overcome by delivering RHI through continuous subcutaneous insulin infusion (CSII) using a wearable insulin delivery device. To our knowledge, no data exists in a type 2 diabetes (T2D) population comparing RAI to RHI when delivered via CSII.

**OBJECTIVE:** This analysis compared the efficacy and pharmacy budget impact of RAI versus RHI when delivered by V-Go, a 24-hr wearable patch-like insulin delivery device which provides a preset continuous basal rate of insulin and on-demand bolus dosing.

**METHODS:** This 14-week multi-center prospective, randomized parallel, non-inferiority study was conducted in a real-world practice setting under usual standard of care. Patients administering RAI with V-Go were randomized 1:1 to continue RAI or to switch to RHI. The primary endpoint assessed non-inferiority for the between group net difference in HbA1c derived from a mixed model analysis. Pharmacy budget impact for the cost of insulin was assessed as a secondary endpoint by comparing the insulin cost difference from baseline to study end between groups. Cost comparisons were based on multiplying the total insulin units prescribed at baseline and study end by the average wholesale acquisition cost per branded RAI unit and RHI unit, respectively and normalized to 30 days.

**RESULTS:** One hundred thirteen patients (59 RHI and 54 RAI) were evaluated. Baseline characteristics were similar between cohorts. The mean change in HbA1c with RHI was -0.60% from a baseline of 8.41% vs -0.38% from a baseline of 8.33% with RAI (estimated treatment difference [ETD]: -0.22%; 95% confidence interval [CI]: -0.67% to 0.22%; non-inferiority margin < 0.4% and $P = 0.007$). From a baseline 30-day insulin cost of $515.68 for RHI and $518.31 for RAI, the 30-day cost change at the end of the study was -$250.50 for RHI and +$15.35 for RAI (ETD: -$265.85; 95% CI: -$288.60 to -$243.11; $P < 0.0001$). No significant between group differences for insulin dose or hypoglycemia were observed by study end.

**CONCLUSIONS:** Delivery of RHI with V-Go was proven to be non-inferior to RAI and resulted in statistically significant insulin costs savings in a T2D population.

**SPONSORSHIP:** Valeritas

## E9 Economic Impact of Nasal Glucagon for the Treatment of Severe Hypoglycemia in Patients with Diabetes Treated with Insulin in the US

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**BACKGROUND:** Patients with diabetes on insulin are at risk for severe hypoglycemic events (SHEs). Nasal Glucagon (NG) can be administered to patients experiencing SHEs and may lead to more treat-and-release by Emergency Medical Services (EMS) and possible decreases in Emergency Department (ED) visits based on its improved usability relative to injectable glucagon (IG).

**OBJECTIVE:** A cost-offset model was developed to examine the economic implications associated with the use of NG on a per event basis compared with IG and no glucagon.

**METHODS:** A cost-offset model was developed to mimic the pathways of rescue treatment for patients experiencing SHEs, capturing probabilities, resource utilization and cost data from published sources and IBM MarketScan Research Databases on treatment decisions following SHEs, rates of successful administration for different treatment modalities, EMS and ED treatment. The model was used to evaluate the mean cost per SHE treated with either NG, IG or no glucagon in patients with diabetes treated with insulin. Analyses were performed separately from three different payer perspectives (commercial payer, Medicare Advantage and Managed Medicaid).

**RESULTS:** From the commercial payer perspective, the mean cost per SHE was $1,432 with NG versus $2,239 with no glucagon, resulting in total savings of $807 per SHE, primarily driven by lower rates of ED visits and EMS resource utilization with NG ($583 for NG versus $1,408 for no glucagon). Total savings from Medicare Advantage and Managed Medicaid perspectives were projected to be $316 and $125 per SHE, respectively. Costs per SHE were also lower from all perspectives for NG compared with IG (savings ranged from $929 [commercial], to $502 [Medicare Advantage] and $336 [Managed Medicaid]). At a national level (from all three payer perspectives combined), annual costs of emergency care associated with SHEs for all patients with diabetes using insulin were estimated at $198 million if NG were used versus $294 million without glucagon treatment, resulting in annual savings of $96 million.

**CONCLUSIONS:** Based on the present modeling analysis, the use of NG to treat SHEs may be associated with savings compared with IG or not using glucagon in patients with diabetes treated with insulin in the United States.

**SPONSORSHIP:** Eli Lilly

## E10 Pharmacist-Led PBM-Administered Diabetes Clinical Program Results in Lower Costs and Improved Clinical Outcomes

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**BACKGROUND:** About 30.3 million people had diabetes in 2017, including 7.2 million undiagnosed adults. Total diabetes drug spend trend has been reported to be 7% or more per year and expected to continue to increase. The pharmacist-led PBM administered diabetes clinical program incorporates early alert monitoring for newly

diagnosed people with diabetes, therapy change review by a clinical diabetes specialist pharmacist for all dose escalations and additions to therapy, medication adherence program that engages both members and providers, gaps-in-care identification and resolution, high risk member personal counseling and remote glucose monitoring.

**OBJECTIVE:** To demonstrate the impact of a pharmacist-led PBM diabetes clinical program on financial and clinical outcomes.

**METHODS:** A retrospective analysis using pharmacy paid claims data from January 1, 2018 to October 31, 2019 using Generic Product Identifiers (GPIs) wildcard 27* (Antidiabetics) to identify diabetic medications was performed. Members continuously enrolled in a prescription plan administered by the pharmacy benefit manager (PBM) during the study period, at least 18 years of age at the start of the study period, who had paid pharmacy claims for FDA-approved diabetes medications were included in the analysis. Proportion of patients in 2018 and 2019 who were missing a statin or who were missing metformin was analyzed using chi-square analysis. Change in mean average risk score using risk stratification tool was compared using t-test. Available A1c values for members was analyzed using t-test: Paired Two Sample for Means. Total diabetes drug spend trend net of rebates using per member per month (PMPM) in 2018 and 2019 was evaluated.

**RESULTS:** A total of 884 and 989 unique diabetic patients were identified in 2018 and 2019, respectively. The total diabetes drug spend trend was 0.2% from 2018 to 2019. The proportion of patients with a gap in statin therapy was reduced by 20% ($P<0.05$) and those not receiving metformin was reduced by 41% ($P<0.05$) in 2019 from 2018. Uncontrolled diabetic patients at baseline experienced average 0.8% hemoglobin A1c reduction ($P<0.05$).

**CONCLUSIONS:** A pharmacist-led PBM-administered diabetes program improves both clinical and financial outcomes. With ongoing clinical care coordination and helping ensure patients and providers are following evidence-based national treatment guidelines results in improved clinical outcomes and lower costs. A multifaceted approach, with the variety of patient touchpoints and methods throughout their diabetes journey, enhances clinical care and improves long-term health and financial outcomes.

**SPONSORSHIP:** None

## E11 Trend Analysis of a Diabetes Self-Management Education and Support Service on Clinical Outcomes in a Medicare Advantage Prescription Drug Coverage Type II Diabetes Population

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**BACKGROUND:** Diabetes Self-Management Education and Support (DSMES) services aim to "assist a person in implementing and sustaining behaviors needed to manage their condition on an ongoing basis." Despite its proven benefits, less than 5% of Medicare beneficiaries in the U.S. with diabetes have used DSMES services. Previous studies have evaluated clinical outcomes of DSMES on Texas Medicare Advantage Prescription Drug Coverage (MAPD) patients. However, a study using multiple time points pre- and post-intervention has yet to be explored.

**OBJECTIVE:** To assess the sustained impact of DSMES on glycemic control using multiple time points at 3-month intervals pre- and post-intervention.

**METHODS:** This analysis was conducted on Texas MAPD beneficiaries from various geographic regions of South, South East, West and East Texas, enrolled in a DSMES service from January 2016-November 2018. The intervention was defined as participation in the DSMES curriculum which consisted of 6 weekly classes each covering 2 hours of local diabetes education. Facilitators of the service included health plan employees, nurses and registered dietitians. Service referrals were made via physicians, internal health plan staff, and a reporting tool. Beneficiaries were enrolled if they met the DSMES inclusion criteria: diagnosis of diabetes, HbA1c > 8.5%, new onset or prior history of poor control, or on > 3 oral medications or > 2 oral medications plus incretin mimetics or on insulin therapy. The index date was defined as the last date of the intervention. Four intervals of three months each were created pre- and post-intervention. HbA1c values greater than 16.4% were excluded from analysis. Repeated mixed modeling was conducted to assess differences in pre- and post-intervention HbA1c controlling for various demographic characteristics.

**RESULTS:** 497 beneficiaries were included in the analysis. Average HbA1c pre- and post- DSMES participation was 9.13% and 8.36%, respectively. According to the mixed model, the post-DSMES group, relative to the pre-DSMES group, saw a significant decrease in HbA1c by 0.61% ($P<0.0001$). The East and South East regions, relative to the South region, saw the greatest reductions in HbA1c by 0.88% ($P=0.006$) and 0.42% ($P=0.002$) respectively. Reporting tool referral, relative to PCP referral, showed a decrease in HbA1c of 0.3% ($P=0.03$). Lastly, as age increased the HbA1c decreased by 0.02% ($P=0.009$) for each year.

**CONCLUSIONS:** A statistically significant reduction in HbA1c post-DSMES participation was observed. Further research is needed to evaluate the specific geographic and demographic influences of DSMES participation on clinical outcomes.

**SPONSORSHIP:** None

## E12 NYU Emergency Department Visit Classification Algorithm for Type 2 Diabetes Patients Before and After Diagnosis

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**BACKGROUND:** The New York University Emergency Department Algorithm (EDA) is a tool that can be used to classify emergency department (ED) visits. Adults over 45 years with diabetes account for an estimated 12 million ED visits per year. The EDA can help evaluate the potential need for more effective management of ED use in this patient population.

**OBJECTIVE:** This study sought to assess the association of emergent classification of an ED visit based on the modified EDA with hospital admissions in patients with type 2 diabetes.

**METHODS:** This was a retrospective analysis of adult patients enrolled in commercial health plans diagnosed with type 2 diabetes (index) on at least two separate claims between January 1, 2017 and June 30, 2019. The modified EDA categorized ED visits into three levels: emergent, intermediate, and nonemergent. Study assessments included healthcare resource utilization; proportion of patients with ED visits and hospitalizations 24 months pre- and post-index. Logistic regression analyses, adjusting for patient demographics and comorbidities, estimated the association of emergent ED visits with the probability of hospital admissions.

**RESULTS:** A total of 6,428 patients met the inclusion criteria (45% female) with a mean age of 53 years. In the pre-index period, 3.4%, 0.5% and 7.6% of the patients had emergent, intermediate, and nonemergent ED visits, respectively, compared to 5.8%, 0.82% and 11%, respectively, in the post-index period. In the pre-index period, 682 (11%) patients had at least one hospital admission and 1,438 (23%) in the post-index period. The EDA measure of emergent ED visits was significantly associated with hospitalizations in the pre-index period (odds ratio [OR]: 1.82, 95% confidence interval [CI], 1.28-2.58) and post-index period (OR: 1.48, 95% CI, 1.13-1.94) compared to those with nonemergent visits. In both periods, intermediate ED visits were not significantly associated with hospitalizations compared to those with nonemergent visits.

**CONCLUSIONS:** Emergent ED visits based on the algorithm are positively associated with hospitalizations. As a tool, the EDA can be used to assess trends in ED utilization and applied by health plans toward intervention assessment.

**SPONSORSHIP:** None

## E13 Empagliflozin and the Risk of Heart Failure Hospitalization and Hospital Readmission in Type 2 Diabetes Patients: An Interim Analysis from the EMPagliflozin compaRative effectIveness and SafEty (EMPRISE) Study

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**BACKGROUND:** Heart failure related hospitalizations are associated with a considerable healthcare burden, including frequent early readmissions and post-discharge mortality. In the EMPA-REG OUTCOME trial, empagliflozin (EMPA) reduced the risk of hospitalization of heart failure (HHF) by 35% (HR 0.65; 95% CI 0.50-0.85) among adults with type 2 diabetes (T2D) and established cardiovascular disease. Using 2 US commercial (Optum and MarketScan) and Medicare claims datasets, we evaluated the impact of EMPA on 30 days readmissions and mortality as established healthcare quality measures in the US.

**OBJECTIVE:** To compare rates of HHF and 30-day readmission after a heart failure related hospitalization among initiators of EMPA versus dipeptidyl peptidase-4 inhibitor (DPP4i) during the first three years of EMPRISE US (08/2014-09/2017); a five year study program on the comparative effectiveness, safety and health care resource utilization (HCRU) of EMPA for T2D patients in routine care (2014-2019).

**METHODS:** We identified a 1:1 propensity-score-matched (PSM) cohort of T2D patients ≥18 years initiating either EMPA or a DPP4i, and assessed balance on ≥140 covariates including clinical and HCRU related covariates at baseline using standardized differences (SD). We compared the risk of HHF (i.e., a HF discharge diagnosis in the primary (HHF-Specific) or in any position (HHF-Broad) and the risk of HHF with a hospital readmission for any cause within 30 days from discharge. Secondary outcomes included composites of HHF with a readmission or death within 30 days from discharge, among Medicare patients with complete mortality information. In each cohort, we estimated pooled HR and 95% CI.

**RESULTS:** We identified 39,169 PSM patient pairs with mean follow-up of 5.8 months. All baseline characteristics were well balanced (with SD<0.1). Compared to DPP4i, EMPA was associated with large reductions in the risk of HHF-Primary [HR (95% CI)=0.42 (0.31-0.58)] or HHF-Broad [HR=0.59 (0.51-0.69)]. EMPA initiators had a 52% decrease in the risk of HHF with a hospital readmission for any cause within 30 days from discharge [HR=0.48 (0.32-0.72)]. Results were consistent for the composite outcome of HHF with a hospital readmission or mortality in Medicare [HR=0.40 (0.25-0.63) within 30 days after discharge].

**CONCLUSIONS:** Interim results from the first three years of EMPRISE US suggest a significant reduction in the rates of HHF and readmission after a heart failure related hospitalization associated with the initiation of EMPA versus DDP4i.

**SPONSORSHIP:** Boehringer-Ingelheim

## E28 Mortality Associated with Long-Chain Fatty Acid Oxidation Disorders: Observations from an Expanded Access Program for Triheptanoin

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**BACKGROUND:** Long-chain fatty acid oxidation disorders (LC-FAOD) are rare, genetic disorders characterized by impaired fatty acid metabolism. Patients with LC-FAOD experience frequent hospitalizations and high mortality due to serious manifestations that mainly affect the heart (cardiomyopathy), skeletal muscle (rhabdomyolysis), and liver (hypoglycemia). Information on mortality of LC-FAOD in current literature is limited, as is the case for many rare diseases, and suggests mortality rates of 60-90% in patients diagnosed symptomatically. Although newborn screening has improved mortality rates, the number of hospitalizations and deaths remains high.

**OBJECTIVE:** The objective of this abstract is to report disease-associated mortality observed in the triheptanoin Early Access Program (EAP).

**METHODS:** Access to investigational triheptanoin has been provided since February 2013 through a global EAP. Patients with LC-FAOD were eligible for the EAP if they have a serious or life-threatening disease, were failing current management, or were unable to participate in an ongoing clinical trial. Demographics, disease history and clinical outcome were requested from treating physicians via questionnaire and narratives. Mortality data are based on these completed responses and reported serious adverse events.

**RESULTS:** As of September 1, 2018, 91 critically ill patients with LC-FAOD were authorized for treatment under the EAP, and 67 patients started triheptanoin. The most common major clinical events that led to the request were rhabdomyolysis (34/67; 51%), cardiomyopathy (25/67; 37%) and/or hypoglycemia (10/67; 15%). Most patients had multiple events and recurrent metabolic crises despite current management. As of February 28, 2019, 16/67 (24%) treated through the EAP had died. Among these patients were 9 (56%) infants, 6 (37%) children and 1 (6%) adult. None of the deaths were attributed to triheptanoin. Most had life threatening crises at the time of request, and treatment initiation may have been too late to confer benefit. Overall, the majority (45/67, 67%) of patients in the EAP were continuing triheptanoin. The median duration of treatment across all patients was 22.6 months.

**CONCLUSIONS:** The observed mortality rate in critically ill patients with LC-FAOD treated through the EAP further highlights the need for access to early intervention. Additional research is needed to better understand the mortality of this disease.

**SPONSORSHIP:** Ultragenyx

## E30 Impact of Motivational Interviewing Intervention in Texas Medicare Advantage Patients with Diabetes Mellitus

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**BACKGROUND:** Medication adherence in patients with chronic illnesses remains a significant problem and can lead to increased health expenditures and suboptimal health outcomes. The prescribing of maintenance therapies in persons with diabetes, specifically, is driven by evidence-based guidelines, yet adherence remains a challenge. A telephonic motivational interviewing (MI) intervention among Medicare Advantage (MA) beneficiaries who were previously non-adherent to statins has shown improved adherence in these therapies during the 6 months following the intervention. The intervention was tailored by past patient statin adherence patterns identified through trajectory modeling. However, trajectories focusing on adherence to oral antidiabetic medications (OADMs) has yet to be explored.

**OBJECTIVE:** The primary objective of this study was to evaluate if the MI intervention that was developed to enhance statin adherence also impacted adherence to OADMs among persons with diabetes using both statins and OADMs.

**METHODS:** The MI intervention was conducted between January 2017-June 2017 among non-adherent statin users. Four-hundred fifty-six patients (152 interventions and 304 controls) were included in the analysis. Patients with concurrent OADM in both the intervention and control groups were identified using Rx claims data, and adherence rates to OADMs during the 6 months before and after the intervention were determined. The primary outcome was defined as adherent vs. not proportion of days covered (PDC ≥ 0.80 versus < 0.80) for 6 months post MI implementation. Group differences in post intervention adherence were evaluated using chi-square tests and t-tests. Multivariable logistic regression was performed to evaluate the intervention effect on adherence to OADMs, controlling for the baseline characteristics including mean previous PDC (Pre-PDC), gender, language, physician specialty, age subsidy, congestive heart failure, Charlson Comorbidity Index score and risk score.

**RESULTS:** From the intervention group, 53 (34.86%) were identified as an ODAM user, compared to 102 (33.55%) of the control group. There was no significant difference in adherence to OADMs among patients in both the intervention and control groups. Significant predictors of adherence included Pre-PDC≥0.80 (adjusted odds ratio [OR]: 6.57, 95% CI: 2.55-16.94) and prescriber specialty ([OR]: 3.9, 95% CI: 1.37-11.05)

**CONCLUSIONS:** Findings indicate that tailored MI interventions targeting specific medications are needed to enhance adherence among patients with chronic illnesses.

**SPONSORSHIP:** None

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

### F1 Risks and Medical Costs of Concomitant Use of Opioids and Central Nervous System Depressants in the Medicare Population

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**BACKGROUND:** Central Nervous System (CNS) depressants which include benzodiazepines and non-benzodiazepine sedative-hypnotics are commonly used for the treatment of insomnia and anxiety. Among users of opioids, concomitant use of CNSDs might increase the risk of opioid-related overdoses and increase health care utilization. However, little is known about the risk of non-benzodiazepine sedative-hypnotics and medical costs of CNS depressants when used concomitantly with opioids.

**OBJECTIVE:** To 1) estimate the prevalence, 2) examine the risk, and 3) examine the medical costs of concomitant use of opioids and benzodiazepines (COB) and non-benzodiazepine sedative-hypnotics (CONB).

**METHODS:** This retrospective study used Medicare administrative, claims and survey linked dataset on patients prescribed with opioids in 2016. This study included Medicare beneficiaries who were 65 years and older, had at least two opioid prescriptions for at least 15 days of supply. Those enrolled in health maintenance organizations, had cancer diagnoses, or had hospice care were excluded. Concomitant uses were defined as concurrently used opioids and benzodiazepines/non-benzodiazepine sedative-hypnotics for at least 30 cumulative days based on relevant national drug codes. Opioid-related overdose was measured based on relevant ICD-10 codes. Monthly medical costs were measured based on claims and survey data. Survey sampling weights were used to generate national estimates. Logistic regression models were used to examine the risk of COB and CONB. Generalized linear models, with a log link and Gamma distribution, were used to examine medical costs of COB and CONB.

**RESULTS:** Among users of opioid (weighted N = 2,510,744), 21.04% (weighted N = 528,252) were COB and 3.88% (weighted N = 97,409) were CONB. Compared to those used opioids only, COB (OR: 4.70; 95% CI: 1.07, 20.58) and CONB (OR: 4.85; 95% CI: 1.23, 19.11) were more likely to have opioid-related overdoses. For medical costs, COB had 26% higher medical expenditures (estimate: 0.26; 95% CI: 0.02, 0.59), but CONB was not associated with medical expenditures (estimate: 0.20; 95% CI: -0.11, 0.43).

**CONCLUSIONS:** In the Medicare population, one-fifth and 4% of opioid users were COB and CONB. Both COB and CONB were associated with increased risks of opioid-related overdose. However, only COB was associated with increased medical costs.

**SPONSORSHIP:** None

### F2 Budget Impact Analysis of reSET-O, an FDA-Cleared Prescription Digital Therapeutic for Patients with Opioid Use Disorder

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**BACKGROUND:** In 2018, an estimated 10.3 million individuals in the US misused opioids and 2.0 million had an opioid use disorder (OUD). The lack of adequate treatment for many OUD patients has led to high medical costs associated with OUD ($28.9B in 2013). Higher-intensity treatment has been linked to lower annual medical costs (little or no treatment: $31,035; counseling only: $17,017; buprenorphine plus counseling: $13,578) due to downstream effects. Greater adherence decreases costs further. Healthcare strategies to improve treatment and adherence to treatment may provide opportunities for reducing healthcare expenditures. reSET-O is the first FDA-cleared prescription digital therapeutic (PDT) for the treatment of patients with OUD in conjunction with treatment as usual (TAU), and showed increased retention in treatment vs. TAU alone over 12 weeks (80.4% vs 64.1%, respectively).

**OBJECTIVE:** To estimate the 12-week budget impact of a PDT in conjunction with treatment as usual (PDT + TAU) relative to TAU (i.e., buprenorphine treatment), from a third-party payer perspective.

**METHODS:** A hypothetical healthcare plan with 1,000,000 lives was assumed for calculating the per member per month (PMPM) budget impact of the PDT. The difference in costs between a "current market" where PDT + TAU is not available, and a "new market" in which PDT + TAU is available at market uptakes between 10% and 50%. TAU rates and real-world health care costs for TAU-adherent ($3,887) vs. TAU-non-adherent ($11,291) patients were estimated from Truven MarketScan Commercial and Medicare Supplementary Database.

Twelve-week OUD treatment costs were calculated from individual component costs (reSET-O: 1 × $1,500; office visits 6 × $33; urinalyses: 36 × $70; buprenorphine: 3 × $123).

**RESULTS:** Among beneficiaries > 18 years of age, 0.01% were identified as treated with TAU (109 members per million). Budget impact analysis showed that downstream reductions in medical costs ($1,195 per PDT-treated patient) offset the majority of the PDT cost. Incremental per-patient costs for the new market (with reSET-O available) ranged from $3,323 (10% market share) to $16,616 (50% market share), representing a budget impact between $0.001-$0.006 PMPM, respectively.

**CONCLUSIONS:** reSET-O may result in a minimal budget impact due to offsets in medical costs.

**SPONSORSHIP:** Pear Therapeutics and Sandoz

## F3 Prevalence and Burden of Untreated and Under-Treated Opioid Use Disorder: Retrospective Database Analysis

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**BACKGROUND:** Limited evidence exists regarding Opioid Use Disorder (OUD) prevalence, and impact of treatment nonadherence and suboptimal retention on health care resource use (HCRU).

**OBJECTIVE:** A retrospective database analysis was conducted to determine OUD prevalence, assess HCRU and OUD treatment adherence in treated/untreated members.

**METHODS:** IBM MarketScan Commercial Database data was utilized (01/01/14-12/31/16) and included members ≥ 18 years and ≥ 1 diagnosis of OUD or claim for OUD-related treatment. Index date was the first occurring OUD diagnosis claim or pharmacy/medical claim for OUD treatment. Cohort design (treated, untreated, adherent, nonadherent) was employed to assess HCRU among OUD members. Medication possession ratio (MPR) and length of therapy (LOT) were calculated with a composite adherence measure using LOT ≥ 90 and MPR ≥ 80. Descriptive statistics were used for baseline characteristics and costs. Statistical significance of unadjusted differences in baseline characteristics and outcomes between groups were evaluated using chi-square tests (categorical) and t-tests (continuous).

**RESULTS:** Inclusion criteria was met by 15,225 (43.0%) treated and 20,216 (57.0%) untreated members. OUD prevalence increased from 2014(0.54%) to 2016(0.71%). In 2014, 16.5% of members had ≥ 1 opioid claim, 19.23% in 2015, and 18.2% in 2016. For those with ≥ 1 opioid claim, OUD prevalence increased from 1.5% (2014) to 2.0% (2016). Long-term high dose (LTHD) opioid use (≥ 90 days at > 50 morphine milligram equivalents/day in 365 days) increased from 0.5% (2014) to 0.71% (2016). Among LTHD, OUD rate increased from ~12% (2014) to 19% (2016). Proportion of members with ≥ 1 medical/pharmacy OUD treatment-related claim among those with ≥ 1 OUD diagnosis claim, was 33.8% (2014), 37.2% (2015) and 35.1% (2016). The average annual total all-cause costs of untreated OUD members is $31,349. Composite adherence was assessed for 13,816 members and consisted of 6,518 on oral (PO) buprenorphine (BPN; 48.1%), 5,232 PO naltrexone (17.5%), 492 IM naltrexone (26.2%) and 1,574 methadone (37.2%). The average annual all-cause medical costs for members with BPN MPR ≥ 80 ranged from $11,548 for members with LOT ≥ 90 to $9,351 for LOT ≥ 270. The average annual all-cause costs among BPN nonadherent members ranged from $25,779 to $27,327.

**CONCLUSIONS:** Adherence rates to OUD medications are low, and economic consequences of nonadherence and suboptimal treatment retention are significant. Large proportion of members with OUD are untreated and not receiving continuous care. The economic impact of OUD is significant and reinforces the need for interventions to improve treatment adherence and retention.

**SPONSORSHIP:** Braeburn

## F4 Cost-Effectiveness of Office-Based Medications for Opioid Use Disorder in the U.S. from the Health Care Sector Perspective

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**BACKGROUND:** Studies show that office-based medications for opioid use disorder (MOUD) reduces illicit opioid use, opioid related overdose and death, emergency healthcare services, and improves treatment retention. While many patients with OUD are commonly treated with office-based MOUD along with counseling, few studies have investigated the cost-effectiveness of these therapies.

**OBJECTIVE:** To estimate the cost, utility, quality-adjusted life years gained (QALY), and incremental cost-effectiveness ratios (ICER) of five office-based MOUD compared to counseling in the U.S. from a health care sector perspective.

**METHODS:** A Markov model was developed to conduct cost-effectiveness analysis of five MOUD compared to counseling: oral buprenorphine/naloxone (Suboxone), buprenorphine implant (Probupine) for one year followed by buprenorphine/naloxone, buprenorphine extended-release (XR) injection (Sublocade), naltrexone XR injection (Vivitrol), and oral methadone. The Markov model included five health states representing combinations of on or off treatment while either using or not using opioids, and death. Costs and utilities of Markov states and emergency department and hospital visits were included. Cycle length was one month; time horizon was 10 years. Model inputs were obtained from systematic reviews of published literature and public data. The primary outcomes included total costs, QALYs, life-years (LYs), and cost/QALY. One-way and probabilistic sensitivity analyses were conducted.

**RESULTS:** In the base-case, the total costs, QALYs, and LYs, respectively, were counseling: $6,753, 6.24, 8.29; buprenorphine/naloxone: $15,444, 6.27, and 8.30; buprenorphine implant: $19,307, 6.27, 8.31; buprenorphine XR: $38,929, 6.26, 8.30; naltrexone XR: $36,577, 6.30, 8.32; and methadone: $13,492, 6.27, 8.31. ICERs ranged from approximately $191,000 (methadone) to $1,485,000 (buprenorphine XR). To be considered cost-effective at $150,000 per QALY gained, buprenorphine/naloxone's price had to be discounted 61% instead of the 28% assumed in the base-case, buprenorphine implant 74%, buprenorphine XR 91%, naltrexone XR 78%, and methadone 42%.

**CONCLUSIONS:** MOUD results in important gains in quality of life and life expectancy. However, the price of MOUD should be discounted significantly to make treatments more affordable to patients and insurers to encourage broader use. The lack of availability of important parameter estimates were the most important limitations to this analysis.

**SPONSORSHIP:** None

## F5 Community-Delivered Intervention to Improve Community Pharmacist Knowledge of Prescription Drug Misuse Prevention: A Pilot of Texas SPF-Rx

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**BACKGROUND:** Community pharmacists are in a position to act as advocates and liaisons for patients within the healthcare system.

Targeted efforts are needed to equip community pharmacists with tools to provide prescription drug misuse prevention counseling including referral to treatment when substance use disorder is suspected.

**OBJECTIVE:** To pilot an intervention to sequentially train federally-funded Substance Abuse Prevention and Treatment Block Grant (SABG) recipients to perform on-site, academic detailing in independent community pharmacies (ICPs) throughout Texas. The broad goal of the intervention is to raise awareness on the risks of overprescribing to young adults, safe storage and disposal of drugs, and utilization of the Prescription Monitoring Program (PMP) among pharmacists.

**METHODS:** SABGs were trained and provided an encounter guide to collect data on 19 items (both closed- and open-ended) related to pharmacist counseling on controlled substance risks, safe storage, safe disposal, and use of the PMP. SABG members completed an online form and provided additional comments to record their interaction with community pharmacists. Pilot site visits were completed from 6/2019-9/2019.

**RESULTS:** Of the 64 ICPs visited, 44 resulted in a successful discussion with the pharmacist. Pharmacists reported counseling patients on controlled substance misuse (95.6%), discussing safe storage (93.2%) and disposal (95.5%) of controlled substances. However, only 68.9% reported using the PMP all of the time. At the end of the visit, Pharmacist Education Pocket Cards were distributed to all 44 (100%) pharmacists, and PMP Best Practice Guidelines were distributed to 37 (84.1%) pharmacists. Qualitative analysis of comments showed that pharmacists were receptive to the intervention and had questions specifically about best practices for PMP use and drug disposal options.

**CONCLUSIONS:** The quality of care in community pharmacies may be improved by educational outreach in the form of academic detailing. Based on this pilot, the intervention will be modified to include recent legislative changes in Texas that have mandated pharmacists check the PMP and provide information to patients about disposal options.

**SPONSORSHIP:** Substance Abuse and Mental Health Services Administration (SAMHSA) State Opioid Response grant (TI081729-01) via the Texas Health and Human Services Commission (THHSC).

## F6 Short-Term Real-World Study of the Impact of Adherence to Opioid Use Disorder Treatment on Direct Costs

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**BACKGROUND:** An estimated 2 million people in the US have an opioid use disorder (OUD). Compared to minimal or no treatment, exposure to OUD treatment reduces cost. While greater treatment adherence to buprenorphine treatment is related to lower long-term healthcare costs, little is known about the short-term economic impact of OUD treatment adherence. An analysis of the short-term economic impact of OUD treatment is needed to inform value assessments and health economic modeling.

**OBJECTIVE:** To estimate 12-week cost differences between buprenorphine-adherent and non-adherent patients.

**METHODS:** A retrospective study using administrative claims data from 01/15/15 to 03/30/18 in Truven MarketScan claims. Adult patients with ≥1 OUD diagnosis (diagnosis codes 304.X [ICD-9] and F11.X [ICD-10]) treated with buprenorphine were identified. First OUD diagnosis was defined as the index date, and 12-weeks continuous enrolment were required post-index. Adherence to treatment was defined as proportion of days covered (PDC) by buprenorphine across the 12 weeks (adherent: PDC≥0.8; nonadherent: PDC<0.8). All-cause medical (e.g., inpatient, outpatient) and pharmacy (e.g., prescription) costs were assessed and adjusted to 2019 U.S. dollars.

**RESULTS:** Of 81,539 adult patients identified with an OUD diagnosis, 9,850 (12.1%) met inclusion criteria of 12 weeks of continuous enrollment. Overall, 65.31% of included patients treated with buprenorphine were adherent and 34.69% were non-adherent. Compared to adherent patients, non-adherent patients had significantly higher average 12-week outpatient costs ($7,386 vs. $2,305; $P<0.001$). Inpatient costs for non-adherent patients ($3,471) were also higher than those adherent to treatment ($622; $P<0.001$). Pharmacy costs were higher among adherent vs. non-adherent patients ($960 vs $362; $P<0.001$). On average, costs were $7,332 more for non-adherent patients than adherent patients ($P<0.001$).

**CONCLUSIONS:** Adherence to treatment is associated with significant and substantial short-term, per-patient reductions in outpatient and inpatient costs. These findings complement long-term assessments of the economic value of OUD treatment adherence as a major determinant of patient and economic outcomes.

**SPONSORSHIP:** Pear Therapeutics and Sandoz

## F13 Medicaid Spending Associated with Relapse Episodes in Beneficiaries with Schizophrenia

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**BACKGROUND:** Schizophrenia affects between 0.25% and 0.64% of adults in the United States. Although pharmacological and psychosocial therapies are available to treat schizophrenia, a majority of patients will experience multiple episodes of relapse, which are associated with significant healthcare costs. Recent guidelines have recommended the initiation of specific treatments (e.g., long-acting injectables) after two treatment failures with oral antipsychotics.

**OBJECTIVE:** This study aims to describe the occurrence of relapse episodes among patients with schizophrenia as well as the cumulative healthcare costs associated with relapse episodes.

**METHODS:** Medicaid data (2010-2018) from Iowa, Kansas, Mississippi, Missouri, New Jersey, and Wisconsin was used to identify adults with schizophrenia receiving antipsychotics (APs). The first schizophrenia diagnosis following AP initiation defined the index. Relapse episodes were identified based on a cost algorithm in which episodes were identified as the consecutive weeks with highest cost increases compared to the 12-month pre-index period or with highest absolute costs. Relapse episodes and their associated healthcare costs ($2,018 USD) were described in the post-index period.

**RESULTS:** Overall, 3,625 patients were identified as relapsers. On average, they had 5.8 relapse episodes over an observation period of 4 years. The mean duration of relapse episodes was 29.1 weeks and their associated healthcare cost was $28,258, on average. Of all relapsers, 20.8% experienced a single relapse episode and 16.0%, 13.1%, 8.7%, 7.3%, and 34.1% experienced 2, 3, 4, 5, or ≥6 episodes, respectively. The mean duration of episodes was 77.2 weeks among patients who experienced a single relapse and the mean cumulative duration of episodes increased from 64.3 to 74.3 weeks for patients with 2 to ≥6 episodes. While the average healthcare cost per week of relapse episode was similar across episodes, the average relapse cost was $62,447 among patients with a single relapse and the average cumulative relapse costs further increased from $71,750 to $88,121 for patients with 2 to ≥6 episodes.

**CONCLUSIONS:** In this study of Medicaid beneficiaries with schizophrenia relapses, most patients experienced multiple relapse episodes and their cumulative healthcare costs generally increased with the number of episodes experienced. While specific treatment guidelines for patients with schizophrenia are being developed, the results of this study highlight the importance of considering costs associated with potential relapses when selecting pharmacologic treatments.

**SPONSORSHIP:** Janssen Scientific Affairs

## F14 Real-World Treatment Patterns with Second-Generation Oral Antipsychotics Among People with Schizophrenia Insured by Medicaid

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**BACKGROUND:** Schizophrenia (SZ) is a severe, chronic mental health disorder. SZ treatment guidelines recommend continuous use of antipsychotics (APs). However, AP treatment changes are common among people with SZ, including discontinuation and switching. Treatment changes are associated with increased health care resource use (HCRU) and medical costs.

**OBJECTIVE:** This study investigated treatment changes and HCRU among people with SZ who initiated second-generation oral antipsychotics (SGAs) using recent data from a 6-state Medicaid database (2009-2018).

**METHODS:** Adults diagnosed with SZ who initiated commonly-prescribed SGAs and were continuously enrolled in their health plan for ≥12 months before and after the initial SGA prescription (index date) were identified. Five treatment pattern groups were defined: 1) continuous and unchanged treatment (≥12 months treatment on index SGA), 2) discontinuation (no new AP for >30 days after end of index SGA), 3) switching (new AP prescribed ≤30 days after end of index SGA), 4) substantial dose adjustment (≥50% increase or ≥30% decrease in dose of index SGA), and 5) augmentation (new SGA prescription before last day of supply of previous SGA). Use of inpatient services during the 12 months post-index date was examined descriptively by treatment pattern group.

**RESULTS:** Of 10,444 eligible patients, the mean age was 44.5 years and 52.8% of patients were male. Index SGAs included: risperidone (28.3%), quetiapine (24.2%), olanzapine (17.8%), aripiprazole (15.5%), ziprasidone (8.4%), and lurasidone (5.8%). Regarding patterns of SGA use, only 4.6% had continuous and unchanged treatment with index SGA over 12 months. Most patients (58.4%) met criteria for discontinuation, 3.2% switched to a different AP, and the remainder had a substantial dose adjustment (19.7%) or augmentation with another SGA (14.0%). Among patients who had a discontinuation or medication switch, median times to treatment change were approximately 1 month and 1.2 months, respectively. Of those who switched to a different AP, most switched to a different oral SGA (60.8%). Patients who had continuous and unchanged treatment with their index SGA had the lowest average number of annual all-cause inpatient admissions per patient (0.4) compared to patients who discontinued (1.0 per patient) or switched (1.9 per patient).

**CONCLUSIONS:** Discontinuation from AP treatment is common among people with SZ and occurs quickly after SGA initiation. There is a need for better treatment options that are less likely to result in medication changes.

**SPONSORSHIP:** Alkermes

## F15 Readmissions and Healthcare-Related Costs Among Medicaid Beneficiaries with a Diagnosis of Bipolar Disorder, Schizophrenia, or Both

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**BACKGROUND:** Bipolar disorder (BPD) and schizophrenia (SCZ) are associated with use of high-cost healthcare resources. Long-acting injectable second-generation antipsychotics have been reported to reduce hospitalization in SCZ and BP but previous real-world studies assessing outcomes among antipsychotic formulations have conflicting results. This study assesses evidence from a state Medicaid population.

**OBJECTIVE:** To assess readmissions and total direct medical costs among Medicaid beneficiaries with either BPD, SCZ, or both utilizing oral (PO) or long-acting injectable (LAI) second-generation antipsychotics (2GAP) after controlling for demographic and clinical covariates.

**METHODS:** This cross-sectional analysis reviewed paid prescription and medical claims of adult Oklahoma Medicaid beneficiaries (≥18 years) with diagnosed and treated BPD and/or SCZ between 01/01/2013-12/31/2017. The index date was defined as initial PO or LAI 2GAP between 01/01/2014-12/31/2016. One-year, post-index readmissions and total direct medical costs were analyzed via robust generalized linear models, controlling for pre-index costs, demographics (age, sex, race, residence), comorbidities (Deyo-Charlson, obesity), year, BPD or SCZ diagnoses, and PO or LAI 2GAP use.

**RESULTS:** Overall, 2,523 members met full inclusion criteria, averaging 39.1±11.8 years and 74.0% female, with 68.3% diagnosed with BPD, 14.3% SCZ, and 17.4% with both. LAI use was low (7.1% overall; 24.7% BPD; 29.2% SCZ; 46.1% both). Results from the multivariable analyses indicated that individuals with both BPD and SCZ had higher odds of any readmission (OR=2.4, 95% CI: 1.8-3.3; $P<0.001$) and a higher number of readmissions (IR=2.3, 95% CI: 1.8-2.8; $P<0.001$) vs. BPD alone. Individuals with both BPD and SCZ were associated with 24.5% higher adjusted costs ($P<0.001$) than BPD alone. The Deyo-Charlson Comorbidity Index was also predictive of a higher odds of any readmission (1.3x; $P<0.001$), increased number of readmissions (1.4x; $P<0.001$), and 8% higher costs. LAI utilization was associated with higher odds of any readmission (OR=1.7 95% CI: 1.1-2.7; $P=0.013$) compared with PO but was not associated with a higher number of readmissions or increased costs when compared with PO.

**CONCLUSIONS:** This investigation of Medicaid beneficiaries indicated that individuals with both BPD and SCZ were associated with higher odds and number of readmissions and increased cost. Use of LAI 2GAPs was associated with an increased adjusted odds of any readmission, but number of readmissions and total medical costs did not differ from POs.

**SPONSORSHIP:** Otsuka Pharmaceutical Development & Commercialization

## F16 Challenges and Best Practices for U.S. Population Health Decision Makers in Schizophrenia Management: A Targeted Literature Review

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**BACKGROUND:** Schizophrenia is a severe mental illness that imposes a substantial burden on the U.S. healthcare system. Population health

decision makers (PHDMs) representing public and private payers have a unique opportunity to affect change in schizophrenia management through resource allocation decisions, disease management initiatives, formulary coverage and other policies that enhance patient access and improve outcomes in these vulnerable patients. A thorough understanding of both challenges faced and strategies implemented by PHDMs may inform optimal schizophrenia population management.

**OBJECTIVE:** To understand recent challenges in managing U.S. patients with schizophrenia, and PHDMs' decision-making processes for addressing unmet needs in this population.

**METHODS:** A targeted literature review was conducted using PubMed, Google Scholar and Ovid to identify relevant publications from 2010-2019 describing challenges and how PHDMs make decisions related to schizophrenia management. Eligible literature included peer-reviewed research studies and grey literature.

**RESULTS:** We retrieved 89 unique publications, 51 of which we included in this review. Key challenges documented in the literature include medication nonadherence, higher acquisition costs for long-acting injectables (LAIs), confusion around how manufacturers may communicate with PHDMs, and political pressures. Of note, medication nonadherence further complicates schizophrenia management as it increases risk of relapse, readmission, and associated healthcare costs. In an effort to contain expenditures, PHDMs have adopted formulary restrictions. However, recent literature suggests that savings attributable to lower drug costs may be negated by higher non-drug healthcare utilization and costs, and strict formularies may interfere with patient adherence and persistence to treatments. Broadly, the literature has documented numerous challenges faced by PHDMs, including the process of obtaining and using clinical trial data, utilization of guidelines and value frameworks, and accountability to quality and cost containment measures. Conversely, limited information exists in the public domain regarding how PHDMs make decisions and what best practices have been implemented within the context of schizophrenia management.

**CONCLUSIONS:** While existing research highlights several challenges leading to current suboptimal management of patients with schizophrenia, specific strategies to improve patient outcomes while managing costs are limited. Future research is needed to understand how PHDMs make decisions and to identify best practices for schizophrenia management.

**SPONSORSHIP:** Janssen Scientific Affairs

## F17 Healthcare Resource Use and Costs Among Medicaid Beneficiaries with Prior Schizophrenia Relapse Before and After Initiation of Once-Monthly Paliperidone Palmitate

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**BACKGROUND:** Schizophrenia is a disabling mental disorder, with the majority of patients struggling with medication adherence and repeated relapses, which lead to substantial economic burden.

**OBJECTIVE:** The objective of this study was to compare healthcare resource use (HRU) and costs after versus before the initiation of once-monthly paliperidone palmitate (PP1M), a long-acting injectable shown to improve adherence and relapse rates, in Medicaid beneficiaries with prior schizophrenia relapses.

**METHODS:** Medicaid data (Q1/2009-Q1/2018) from six states were used to select adults with ≥2 schizophrenia diagnoses initiated on PP1M on or after 01/01/2010. The index date was the first PP1M claim. Patients had ≥12 months of continuous Medicaid enrollment pre- and post-index and ≥1 oral antipsychotic claim in the 12 months pre-index. Analyses were stratified by the number of relapses, defined as a schizophrenia-related inpatient (IP) admission or emergency room (ER) visit during the 12 months pre-index. Generalized estimating equations were used to compare all-cause HRU and costs ($2,018 USD) in the 12 months post versus pre-index; p-values were estimated using non-parametric bootstrap procedures.

**RESULTS:** 1,725 patients with ≥1 relapse were identified (mean age 39.5 years; 43% female). Among them, 961 (56%) had ≥2 relapses, 586 (34%) had ≥3 relapses, and 392 (23%) had ≥4 relapses. Post- versus pre-index, odds of IP admissions and ER visits decreased by 89% and 49% in patients with ≥1 relapse, by 94% and 61% in patients with ≥2 relapses, by 96% and 68% in patients with ≥3 relapses, and by 98% and 68% in patients with ≥4 relapses (all $P<0.01$). Depending on the number of relapses, the number of IP days decreased by 30%-36% and the number of ER visits by 16%-30% (all $P<0.01$). Meanwhile, odds of long-term care (LTC) admissions increased by 43%-76%, and the number of LTC days by 77%-117% (all $P<0.01$). Post-versus pre-index, depending on the number of relapses, pharmacy costs increased by $396-$514 per-patient-per-month (PPPM; $P<0.01$), and medical costs, driven by IP costs, decreased by $391-$1,081 PPPM ($P<0.01$). Total healthcare costs were significantly lower post- versus pre-index among patients with ≥2 (-$209; $P=0.04$), ≥3 (-$467; $P<0.01$), and ≥4 (-$685; $P<0.01$) relapses.

**CONCLUSIONS:** Transition to PP1M in Medicaid beneficiaries with schizophrenia and prior relapses was associated with clinical benefits, including reduced use of all-cause IP and ER services. Significant cost savings were observed in patients with repeated relapses subsequently initiated on PP1M.

**SPONSORSHIP:** Janssen Scientific Affairs

## F20 The Association of Employee Wages with Antidepressant Medication Use in Patients with Mental Health Disorders and Depression in the United States

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**BACKGROUND:** Employee wages have been shown to impact healthcare utilization and costs. For patients with mental health (MH) disorders, the impact on associated medication use is unknown.

**OBJECTIVE:** To assess the association of employee wages with adherence and persistence to antidepressants among employees with any MH disorders and the subset of those with depression enrolled in employer-sponsored health benefit plans.

**METHODS:** The study population comprised 2,388,844 full-time employees with continuous health plan enrollment for whom wage data were available from the IBM Watson MarketScan database in 2017. Individuals with medical claims for any MH disorders were included, as well as a subset of those with depression. Employees were divided into quartiles by annual wage group, with the lowest quartile split into 2 (≤$34,000; $34,001-$45,000; $45,001-$69,000; $69,001-$103,000; and ≥$103,001). MH medication use, antidepressant adherence (using the proportion of days covered [PDC]), and discontinuation were evaluated for each wage group. Linear regression was used to assess differences in outcomes by wage band, while adjusting for patient characteristics and disease severity (using a disease stage scale from 1 to 4).

**RESULTS:** Of the 254,851 employees with an MH diagnosis and 125,851 with depression, prevalence was lowest (4.2%) in the lowest wage group, despite being associated with the highest illness severity

(1.65 vs. 1.45 in the highest wage group; $P<0.0001$). Proportion of enrollees with PDC ≥ 80% was highest in the high-wage group (77% and 79%, respectively, for MH and depression), falling to 73% and 75%, respectively, in the lowest wage group ($P<0.0001$ for both categories). In these 2 diagnosis groups, rates of discontinuation for >90 days were highest in the lowest-wage earners and lowest in the high-wage earners (31% vs. 25% [$P<0.0001$] and 30% vs. 24% [$P<0.0001$] for MH and depression, respectively).

**CONCLUSIONS:** Antidepressant medication adherence and persistence rates were worse in patients with lower income than in those with higher income, despite greater disease severity. These findings provide support for the need to identify and address barriers to diagnosis and proper medication management in lower-income individuals to ensure more effective treatment of MH and depression.

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

## F21 Healthcare Resource Utilization and Costs Associated with Non-Adherence and Non-Persistence to Antidepressants for Major Depressive Disorder

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**BACKGROUND:** Contemporary real-world evidence on the economic impact of antidepressant (AD) non-adherence and non-persistence for Major Depressive Disorder (MDD) is limited.

**OBJECTIVE:** To assess the impact of non-adherence and non-persistence to ADs on healthcare resource use (HCRU) and costs in commercially-insured MDD patients.

**METHODS:** This was a retrospective cohort study using administrative claims data from the IBM MarketScan Commercial database from January 2010-December 2018. We identified newly diagnosed adult MDD patients who initiated AD therapy between January 1, 2011-December 31, 2017. 12-month all-cause HCRU and costs (2019 $US) were assessed for patients who were adherent/non-adherent and persistent/non-persistent to ADs at 6 months. Adherence and persistence were defined as proportion of days covered ≥ 80% and length of therapy without a ≥ 30-day gap, respectively. Multivariable negative binomial regression and two-part models (logistic regression followed by generalized linear models with log-link and gamma distribution) were used to estimate adjusted HCRU and incremental costs of non-adherence and non-persistence, respectively.

**RESULTS:** 209,418 patients met all inclusion criteria. Mean age was 40 years and most patients were female (61%). Almost half were non-adherent (48%) or non-persistent (49%) to ADs at 6 months. Non-adherent patients had higher mean hospitalizations (0.11 vs. 0.08) and ER visits (0.42 vs. 0.29) compared to adherent patients (all $P<0.001$). Similar results were observed in non-persistent patients. Non-adherent and non-persistent patients had higher mean medical ($8,777 vs. $7,978; $8,707 vs. $8,025), inpatient ($2,418 vs. $1,756; $2,354 vs. $1,800), and ER costs ($442 vs. $309; $441 vs. $307) and lower pharmacy costs ($1,691 vs. $2,263; $1,689 vs. $2,280) compared to adherent and persistent patients, respectively (all $P<0.001$). After adjusting for baseline characteristics, non-adherent and non-persistent patients independently had hospitalizations and ER visits 1.3 and 1.4 times more often and had pharmacy fills 0.7 times less often compared to adherent and persistent patients (all $P<0.001$). Adjusted incremental medical, inpatient, ER, and pharmacy costs associated with non-adherence/non-persistence were $531/$462, $581/$497, $121/$121, and -$513/-$525.

**CONCLUSIONS:** Non-adherence and non-persistence with MDD treatments are associated with higher HCRU and medical costs. New therapies that improve adherence and persistence may lower HCRU and medical costs in MDD patients.

**SPONSORSHIP:** Allergan

## F22 Clinical Events Associated with Increased Healthcare Resource Utilization and Costs Among Patients with Major Depressive Disorder

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**BACKGROUND:** The economic burden of major depressive disorder (MDD) is substantial; however, the impact of key clinical events (e.g., hospitalization, suicide attempt/ideation, & treatment failure) on healthcare resource use (HRU) and costs are less established.

**OBJECTIVE:** To estimate the effect of key clinical events on all-cause HRU and costs among patients with MDD in a large health plan.

**METHODS:** Adults aged 18-64 newly diagnosed with MDD and an antidepressant prescription between January 1, 2012 and August 31, 2018 were identified using administrative healthcare claims from a large insurer. Patients with at least 12 months of continuous healthcare coverage before and after initial MDD diagnosis (index date) were included. The independent effect of key clinical events (post-index date) including MDD-related emergency room (ER) visit, MDD-related hospitalization, suicide attempt/ideation, severe mental health disorder, and treatment failure on all-cause total HRU and total costs was assessed using negative binomial and generalized linear models, respectively. Total HRU was reported as a mean composite of inpatient, outpatient, and ER visits; total costs as a mean sum of inpatient, outpatient, ER, and pharmacy costs.

**RESULTS:** A total of 29,335 patients meeting criteria were identified; average age was 39 years and 60% of patients were female. In the adjusted models, the following key clinical events were associated with increased all-cause total HRU compared with not having the event: MDD-related ER visit (9.37 vs 7.76 visits), MDD-related hospitalization (9.39 vs 7.76 visits), suicide ideation/attempt (9.27 vs 7.75 visits), severe mental health disorder (10.25 vs 7.75 visits) (all $P<0.0001$), and failing ≥ 2 treatments (8.28 vs 7.43 visits; $P<0.0001$). Similarly, these events were also associated with higher all-cause total costs when compared to not having the event: MDD-related ER visit ($8,980 vs $7,547; $P=0.0001$), MDD-related hospitalization ($12,156 vs $7,499; $P<0.0001$), suicide ideation/attempt ($10,496 vs $7,499; $P<0.0001$), severe mental health disorder ($12,337 vs $7,513; $P<0.0001$), and failing ≥ 2 treatments ($7,905 vs $7,322; $P=0.008$).

**CONCLUSIONS:** MDD HRU and costs are exacerbated by key clinical events. New MDD therapies that treat patients in the ER or the hospital or prevent suicide attempt/ideation, severe mental health disorder, and treatment failure have the greatest potential to reduce overall MDD costs.

**SPONSORSHIP:** Allergan

## F23 Opioid Use Among Postpartum Depression Patients Enrolled in 50 State and District Medicaid Programs

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**BACKGROUND:** Postpartum depression (PPD) is one of the most common medical complications during and after pregnancy. Symptoms include depressed mood, diminished ability to concentrate and perform usual tasks, and decreased maternal-infant interaction.

**OBJECTIVE:** This study assesses opioid use before and after giving birth among PPD mothers covered by 49 U.S. state and District of Columbia Medicaid programs.

**METHODS:** Patient-level information on demographics, eligibility, medical claims, and pharmacy fills was extracted from the 2010-2012 from the Center for Medicare and Medicaid Services' (CMS) Medicaid Analytic eXtract (MAX). A claims-based algorithm was developed to identify all female Medicaid enrollees between 15 and 50 years of age with evidence of PPD following a live delivery between July 1, 2010 and June 30, 2011. Women were classified as having PPD using a claims-based algorithm drawing on the presence of claims with specific diagnoses (i.e., depression, mood or adjustment disorder) and/or treatments (i.e., psychotherapy, SSRI/SNRI prescription fill, or brain stimulation therapy) depending on the place of service (i.e., inpatient, ER, outpatient, pharmacy). Demographic and clinical characteristics of mothers with PPD, as well as their opioid use six months prior and three to 52 weeks post-delivery, were measured overall and stratified by fee-for-service (FFS) and managed care enrollees.

**RESULTS:** A total of 51,641 mothers were identified as having PPD during the year following live birth. PPD mothers were predominantly white (62.6%), followed by black (17.5%) and Hispanic (11.4%). Nearly 50% of the PPD mothers were between 18 and 24 years of age, with nearly one quarter (24.9%) aged 20 or younger. Nearly half (44.9%) had at least one comorbidity, measured using the Elixhauser comorbidity index. About 35% of mothers had evidence of depression and/or its treatment prior to delivery. Majority (59.2%) of PPD mothers used opioid during three to 52 weeks post-delivery. Among PPD mothers without a history of opioid use during six months prior to delivery, 51.3% used opioid after delivery. Almost 80% of PPD mothers with a history of opioid use continued to use after delivery. Findings were similar between the FFS and managed care cohorts.

**CONCLUSIONS:** Across 49 states and District of Columbia, PPD affects Medicaid patients with varying demographic and clinical characteristics. Opioid use was high among PPD mothers compared with published literature on Medicaid female population and warrants further attention.

**SPONSORSHIP:** Sage Therapeutics

## F24 Rates of Falls and Motor Vehicle Accidents Among Elderly Medicare Patients Treated for Insomnia in the United States

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**BACKGROUND:** 10-15% of US adults suffer from insomnia disorder, characterized by difficulty falling or staying asleep, and/or early morning awakening with a daytime complaint, with higher prevalence among the elderly (aged ≥65 years) than younger adults. Insomnia is known to increase risk of falls and motor vehicle accidents (MVAs) among older adults. Some common insomnia medications may further increase the risk of these potentially costly events.

**OBJECTIVE:** The study compared rates of falls and MVAs between a cohort of elderly Medicare beneficiaries treated with common insomnia medications ("treated") relative to a comparable population with no sleep-related disorders ("controls").

**METHODS:** Medicare health insurance claims data (01 Jan 2011 to 31 Dec 2017) were used to identify beneficiaries aged ≥65 years. Beneficiaries were included in the treated cohort if they: 1) received either ≥1 prescription for a medication with an FDA-approved indication for insomnia OR ≥1 prescription for an off-label insomnia medication and ≥1 insomnia diagnosis in the 12 months prior to treatment initiation; 2) had ≥12 months continuous enrollment pre- and ≥12 months post-treatment initiation; and 3) demonstrated no evidence of insomnia treatment in the 12 month baseline period. A matched control cohort of beneficiaries aged ≥65 years with no evidence of sleep-related disorders was also identified and matched to "treated" patients one-to-one based on age and sex.

**RESULTS:** The study included 1,699,913 patients treated with common insomnia medications. Of treated individuals, 36.2% (615,945) initiated on zolpidem IR, 34.2% on trazodone (581,117), 29.1% (494,665) on benzodiazepines and 0.5% (8,196) on zolpidem ER. Mean age (SD) at treatment initiation was 75.4 years (6.8) and 59.8% were female. Relative to controls, more treated patients experienced a fall (defined as a fall, fracture or traumatic brain injury) or MVA within 12 months following treatment initiation (7.3% vs. 1.5%, respectively). These percentages break down into falls only (7.1% vs. 1.5%), MVAs only (0.2% vs 0.1%) and both falls and MVAs (0.1% vs 0.0). Each insomnia medication was associated with higher risk of falls and MVAs than controls, with benzodiazepine patients having the greatest risk (10.5% vs. 1.6%).

**CONCLUSIONS:** Older adults treated for insomnia demonstrated higher rates of falls and MVAs. While the interaction between insomnia and existing treatments could have driven some of these results, they nonetheless suggest an unmet need for safer therapies among older adults.

**SPONSORSHIP:** Eisai

## F25 Trends in Use of Stimulant Medications in Adults in a Medicaid Program

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**BACKGROUND:** There is limited data on the effectiveness of stimulants for the treatment of attention deficit hyperactive disorder (ADHD) in adults and data suggesting an increase in utilization. There is also a concern of misuse and abuse of stimulant medications in adults.

**OBJECTIVE:** The primary objective of this retrospective, descriptive study is to evaluate the current prescribing patterns and utilization of ADHD medications in adults in the Oregon Medicaid fee-for-service (FFS) population. Additionally, we will describe trends in stimulant and non-stimulant ADHD medication use in patients with existing substance use disorder, the prevalence of concurrent opioid use, and incidence of hospitalizations due to overdose.

**METHODS:** Utilization of ADHD medications over time was described by identifying Medicaid FFS pharmacy claims for adults 18 years and older from 2014 to 2018. A cohort of new start patients were selected and described in more detail. Baseline characteristics, associated diagnoses and the prevalence of concurrent opioid use were collected. Hospitalizations and emergency room visits within 90 days after the first drug claim were evaluated. Lastly, the average daily dose was compared at baseline and at 6 months to assess dose titration over time.

**RESULTS:** Utilization of ADHD medications has increased from a median number of 11 utilizing adults per member per month (PMPM) × 1000 in 2014-2015 to a median of 13 utilizing adults PMPM × 1000 in 2017-2018. A significant portion of patients (n = 1,159; 36%) did not have an ADHD diagnosis in the year prior to the first drug claim. Additionally, 35.6% (n = 1,138) of those prescribed ADHD medications had a concurrent substance or alcohol abuse/dependence diagnosis. Hospitalizations due to drug or alcohol overdose was lose (< 1%) the less than 1% of patients were on concurrent chronic opioids.

**CONCLUSIONS:** Utilization of ADHD medications in adults is marginally increasing over time in Oregon Medicaid and a substantial proportion of patients do not have an appropriate ADHD diagnosis.

**SPONSORSHIP:** None

## G00-G99 Diseases of the Nervous System

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

### G1 Retrospective Commercial Claims Analysis of the Cost of Illness in Patients with Neuromyelitis Optica Spectrum Disease in the United States

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**BACKGROUND:** Neuromyelitis optica spectrum disorder (NMOSD) is a rare autoimmune disease of the central nervous system characterized by inflammatory lesions that mainly affect the optic nerves and spinal cord. Patients with NMOSD frequently experience a relapsing disease course, with repeated attacks leading to accumulating neurological disability. Limited data have been published on real-world healthcare utilization and cost of illness with NMOSD.

**OBJECTIVE:** To evaluate the cost of illness of patients with NMOSD during the postindex follow-up period compared with controls without NMOSD (non-NMOSD) in a U.S. commercial claims database.

**METHODS:** This study used claims from the Truven Health MarketScan Commercial and Medicare Supplemental Databases between 2014 and 2018. Patients were identified as having NMOSD if they had ≥1 inpatient or ≥2 outpatient claims for NMOSD diagnosis ≥60 days apart or ≥2 claims for transverse myelitis (TM) diagnosis in combination with ≥1 claim for optic neuritis (ON) ≥6 months apart. The first claim was the index date, and continuous enrollment ≥6 months before and ≥1 year after the index date was required. Non-NMOSD controls, identified as patients with no medical encounter suggesting NMOSD, TM or ON, were matched 5:1 to patients in the NMOSD group based on similar age, sex, insurance, geographic location and continuous enrollment period. Total cost of healthcare services in Consumer Price Index (CPI)–adjusted 2019 U.S. dollars during the post-index follow-up period was calculated for each patient.

**RESULTS:** A total of 162 patients with NMOSD (mean [SD] age, 43.3 [18] years; 26.5% male, 73.5% female) and 810 non-NMOSD controls (mean [SD] age, 43.3 [18] years; 26.5% male, 73.5% female) were evaluated in the study. The mean [SD] healthcare resource utilization costs per patient during the post-index follow-up period were significantly higher for the NMOSD group vs non-NMOSD controls across all categories, including inpatient ($29,054 [$144,872] vs $1,521 [$10,759]), outpatient ($24,881 [$35,463] vs $4,761 [$26,447]), outpatient emergency room ($2,400 [$7,771] vs $408 [$2,579]) and pharmacy ($6,349 [$20,652] vs $1,580 [$6,607]; $P<0.0001$ for all).

**CONCLUSIONS:** Compared with non-NMOSD matched controls, patients with NMOSD incurred significantly higher costs associated with healthcare resource utilization. These results highlight the cost burden associated with the medical management of patients with NMOSD and the need for more efficacious and regulatory-approved treatments that reduce cost burden to patients.

**SPONSORSHIP:** Genentech

### G2 Temporal Trends in the Diagnosis of Neuromyelitis Optica Spectrum Disorder in US Insurance Claims Databases from 2001 to 2017

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**BACKGROUND:** Neuromyelitis optica spectrum disorder (NMOSD) is a rare autoimmune disease of the central nervous system with core symptoms including transverse myelitis (TM), optic neuritis (ON) and area postrema syndrome (APS). NMOSD is often misdiagnosed as multiple sclerosis (MS), which may lead to MS disease-modifying therapy (DMT) use that could aggravate NMOSD (i.e. β interferons [IFN β], natalizumab [NZ], fingolimod [FG] and alemtuzumab [AL]). NMOSD diagnostic guidelines were revised in 2015 to capture aquaporin-4 immunoglobulin G (AQP4-IgG) testing and a broader spectrum of symptoms. However, data describing subsequent diagnostic pathway trends are limited.

**OBJECTIVE:** Characterize temporal trends in the NMOSD diagnostic pathway in US insurance claims databases from 2001 to 2017.

**METHODS:** This study used claims from the Truven Health MarketScan US Commercial Claims Database between 2000 and 2017. Patients were identified as having NMOSD if within 1 year they had 2 NMO claims or 1 NMO claim and 1 NMOSD core symptom claim (TM, ON or APS). The date of the first NMO or symptom claim was the index date; the date of the second claim was the diagnosis (Dx) date. Enrollment of 1 year was required before and after the index date. Resource utilization, including AQP4-IgG tests, MRI and MS Dx or DMT, was assessed in the year before and after the index date. Results were stratified by time period corresponding to changes in diagnostic criteria (2001-05, 2006-15 and 2015-17).

**RESULTS:** Of 915 patients, the mean (SD) age was 43.0 (13.7) years; 6.3% (n=58; 21 male [M], 37 female [F]) were identified in 2001-05, 73.6% (n=673; 159 M, 514 F) in 2006-14 and 20.1% (n=184; 48 M, 136 F) in 2015-17. The proportion of patients with MS Dx claims before the index date increased from 44.8% in 2001-05 to 45.7% in 2015-17, and the proportion with MS Dx claims after NMOSD Dx decreased from 58.6% to 55.4% during the same time period. Use of AQP4-IgG testing rose from 1.7% in 2001-05 to 26.9% in 2006-15 and 40.2% in 2015-17. Use of MS DMT in the year after NMOSD diagnosis slightly decreased from 20.7% in 2001-05 to 18.5% in 2015-17 (IFN β, 3.3%; NZ, 2.7%; FG, 2.2%; AL, 0.5%; other, 9.8%).

**CONCLUSIONS:** Despite changes to the NMOSD diagnostic guidelines, real-world use of AQP4-IgG testing remains modest, and the proportion of patients with NMOSD receiving an MS Dx or DMT has not substantially changed. These results highlight the unmet need for appropriate diagnosis and treatment of NMOSD.

**SPONSORSHIP:** Genentech

### G3 Identifying Patients with Neuromyelitis Optica Spectrum Disorder in US Insurance Claims Databases from 2001 to 2017

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**BACKGROUND:** Neuromyelitis optica spectrum disorder (NMOSD) can have a similar clinical presentation to multiple sclerosis (MS), and clinical diagnosis is challenging. Core NMOSD symptoms include transverse myelitis (TM), optic neuritis (ON) and area postrema syndrome (APS). There is currently no gold standard for identifying patients with NMOSD in insurance claims databases.

**OBJECTIVE:** Describe the diagnostic pathways of 3 cohorts of patients likely to have NMOSD in US insurance claims.

**METHODS:** This study used claims from the Truven Health MarketScan US Commercial Claims Database between 2001 and 2017. Patients likely to have NMOSD were identified if within 1 year they had 2 NMO claims or 2 claims for either TM or ON ≥60 days apart and 1 core symptom (TM, ON or APS) or 1 NMO claim and 1 core symptom ≥60 days apart. The first claim was the index date, and the second claim was the diagnosis (Dx) date. 1 year of enrollment before and after the index date was required. Use of aquaporin-4 immunoglobulin-G (AQP4-IgG) tests and MRI within 30 days prior to and 6 months after the index date, and MS Dx, MS disease-modifying therapy (DMT) and immunosuppressant (IS) therapy in the year prior to the index date and the year following the Dx date were assessed.

**RESULTS:** Of 1,901 patients, 34.6% had MS claims before the index date, and 48.2% had MS claims after Dx. Of 1,428 patients with claims for AQP4-IgG tests (23.0%) or MRI (71.9%), 57.6% had an MS Dx, 22.1% had MS DMT and 22.2% had IS claims within 1 year after the test. The proportions of patients likely to have NMOSD identified by 2 NMO claims, ON+1 symptom (ON+1), TM+1 symptom (TM+1) and NMO+1 symptom (NMO+1) were 34.2%, 10.3%, 43.0% and 12.6%, respectively. Patients with 2 NMO claims had the highest use of the AQP4-IgG test (28.9%), followed by patients with NMO+1 (24.3%), TM+1 (23.6%) and ON+1 (17.9%). Among patients with 2 NMO claims, ON+1, TM+1 and NMO+1, respectively, 49.1%, 21.4%, 29.2% and 44.4% had MS Dx claims in the year prior to the index date; within 1 year after Dx, 60.6%, 37.3%, 46.2% and 53.1% had MS Dx claims, 14.9%, 20.2%, 19.0% and 31.0% had MS DMT claims and 44.8%, 8.2%, 14.4% and 6.3% had IS claims.

**CONCLUSIONS:** Including patients with NMOSD core symptoms identifies a large proportion of patients who do not appear to have MS but have low use of AQP4-IgG testing and IS therapy. These results highlight the need for a validated algorithm to identify patients with NMOSD in US claims databases.

**SPONSORSHIP:** Genentech

## G6 Healthcare Utilization and Costs in Beneficiaries with Huntington's Disease in the US Medicare Population

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**BACKGROUND:** Huntington's disease (HD) is a genetic, neurodegenerative disease that typically manifests at 30-50 years of age; however, later onset can occur among older individuals. In the US, Medicare provides coverage to individuals with HD who are ≥65 years old, or <65 years with disability for 24 months. Little is known about healthcare utilization (HCU) and cost burden among Medicare beneficiaries with HD.

**OBJECTIVE:** To examine HCU and costs among US Medicare beneficiaries with HD.

**METHODS:** This retrospective study was conducted using 2013-2017 Medicare Research Identifiable Files (100%). Beneficiary patients diagnosed with HD were identified based on having ≥1 medical claim with a diagnosis code for HD (ICD-9-CM: 333.4; ICD-10-CM: G10) during the identification period (2014–2016); date of HD claim was defined as the index date (for multiple HD claims, one randomly chosen as index to capture all disease stages). Patients with HD had continuous enrollment in fee-for-service Medicare 1 year prior to (baseline) and 1 year after (follow-up) index. Patients without HD (controls) were identified using 5% sample and matched 1:1 to patients with HD based on calendar year, age, sex and US geographic region; same index and enrollment requirement as match. Comorbidities were measured during baseline; HCU, costs, and disease stage (early, middle, late) during follow-up.

**RESULTS:** We identified 3,688 patients with HD and 3,688 matched controls. Mean (SD) age was 67.8 (12.4) years, 53.6% female, and 90.6% white with all regions represented (33.2% Midwest, 23.1% Northeast, 30.4% South, 13.3% West). Patients with HD vs controls had similar mean Charlson comorbidity index (2.0 [2.5] vs 2.0 [2.4], $P=0.366$) yet slightly more chronic conditions (5.4 [2.6] vs 5.0 [2.5], $P<0.001$) at baseline. Most patients with HD had late-stage disease (23.0% early, 24.8% middle, 52.1% late) and, compared to controls, had a higher proportion of hospitalizations (26.8% vs 16.8%) and emergency department visits (36.1% vs 26.2%); fewer mean office visits (10.9 [13.6] vs 12.8 [13.0]); and higher use of antidepressants (60.0% vs 32.8%), anxiolytics (28.1% vs 18.6%) and antiepileptics (40.0% vs 23.0%); all $P<0.001$. Mean annual total costs were higher for patients with HD than controls ($41,631 [57,392.5] vs $17,222 [31,217.8], $P<0.001$), primarily driven by outpatient pharmacy costs ($19,182 vs $4,318).

**CONCLUSIONS:** Medicare beneficiaries with HD have significantly higher acute HCU and cost burden compared to beneficiaries without HD.

**SPONSORSHIP:** Genentech

## G7 Nusinersen Adherence Among Patients with Spinal Muscular Atrophy in the Real World

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**BACKGROUND:** Nusinersen (SPINRAZA is the first disease-modifying treatment for spinal muscular atrophy (SMA). Despite clinical advances, repeated intrathecal administration, limited provider capacity and payer coverage restrictions may affect initiation and long-term adherence to the treatment.

**OBJECTIVE:** To characterize 1-year nusinersen adherence among patients with SMA treated in the US.

**METHODS:** This retrospective observational study utilized a large US commercial claims database from January 2017 to December 2018. Patients with SMA who initiated nusinersen after July 1, 2017 were identified based on a combination of diagnostic, procedural, biologic drug codes and payment amount. These patients were followed from the first nusinersen dose to the end of plan enrollment or December 2018. Adherence was determined only in patients with sufficient follow-up (e.g. adherence to the fifth dose was assessed among patients with ≥24 weeks of follow-up) and was defined as the percentage of patients receiving the expected number of doses per product label. Sensitivity analyses allowing 2 weeks' buffer at each scheduled dose were conducted. An additional definition for adherence (e.g. mean number of doses received versus expected) was also explored.

**RESULTS:** 138 patients treated with nusinersen were included (mean age 18 years, standard deviation 15; 54% female). 70 patients (51%) had a scoliosis diagnosis during the study period. Ninety one percent (n=126) had at least 8 weeks' follow-up and 34% (n=47) had 56 weeks' follow-up. Treatment adherence was 21% (n=27/126) at 8 weeks and 13% (n=6/47) at 56 weeks. The mean number of doses was 2.6 (versus 4 expected doses) at 8 weeks and 5.2 (versus 7) at 56 weeks. In sensitivity analyses, adherence increased to 50% and 30% at 8 weeks and 56 weeks, respectively. Among patients with at least 1 year of follow-up, 52% of patients had 5 or 6 doses, 35% had ≤4 doses, and 13% had ≥7 doses in the first year of treatment. Adherence was

higher among patients ≤ 18 years and similar between those with and without scoliosis.

**CONCLUSIONS:** Real-world adherence appears to be low in the first year. Deviation from the recommended dosing schedule may reduce clinical effectiveness of the therapy. Due to the limitations of the database, the extent to which the observed lack of treatment adherence was driven by clinical, logistical or payer restrictions could not be determined. Efforts to increase provider capacity, alleviate payer reauthorization burden and expand treatment options for patients with SMA are needed.

**SPONSORSHIP:** F. Hoffmann-La Roche

## G9 A Budgetary Impact Analysis of BoNT-A Management in the United States Based on a Real-World Longitudinal Study of Adult Upper Limb Spasticity

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**BACKGROUND:** Type A botulinum toxins (BoNT-A) are indicated for treatment of adult upper limb spasticity (AULS), but costs of different interventions in the US vary.

**OBJECTIVE:** To evaluate the budget impact to payers of abobotulinumtoxinA (ABO) utilization compared to onabotulinumtoxinA (ONA) and incobotulinumtoxinA (INCO) using real world evidence for adults with upper limb spasticity.

**METHODS:** A budget impact model developed from the US payer perspective with a 3-year time horizon evaluated the effects of changing market shares of ABO, ONA, and INCO. Interim data from ULIS-III, a 2-year longitudinal, prospective, observational, multinational, cohort study of 1,004 AULS patients receiving BoNT-A injections was used. Intervals between injections and average doses were estimated from the first treatment cycle of 640 patients who had ≥2 injections. The mean intervals between injections were 26.5 weeks (ABO), 21.1 (ONA) and 21.2 (INCO) [Turner-Stokes 2019]. An alternative scenario analysis was based on total approved doses per label (1,000 U for ABO; 400U for ONA and INCO) administered every 12 weeks. BoNT-A unit costs were based on wholesale acquisition costs reported in the Red Book (2019). Other costs included administration costs, derived from the Physician Fee Schedule Search (2016). Patient cost share was excluded as these BoNT-As are typically on the same formulary tier. At baseline, the model assumed the following market shares: 5% (ABO), 90% (ONA) and 5% (INCO). In the model, ABO market shares increased 10% each year as an uptake from ONA with no change in INCO. Deterministic sensitivity analyses assessed the impact of the key parameters on the budgetary findings.

**RESULTS:** In the real-world data scenario, for a health plan of 5,000,000, an increased uptake of ABO from 5% at baseline to 35% at year 3 calculated an accumulated savings of $568,211. Treatment per patient per year with ONA ($5,000) and INCO ($4,101) cost more when compared to treatment with ABO ($3,478). In the analyses based on total approved doses, the annual per patient costs were $11,396 and $9,333, respectively, vs '$8,423. This resulted in a cumulative savings of $1,109,671. One-way sensitivity analyses of the real-world scenario calculated that increasing the uptake of ABO from 5% at baseline to 50% would result in savings of $867,760.

**CONCLUSIONS:** There is potential for cost savings associated with increasing ABO use in both real-world and total approved dose per label scenarios.

**SPONSORSHIP:** Ipsen Biopharmaceuticals

## G10 Patient Experiences and Preferences for Specific On-Demand Treatments for Parkinson's Disease-Related "OFF" Episodes

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**BACKGROUND:** Patients with Parkinson's disease (PD) develop potentially disabling "OFF" episodes—periods when symptoms worsen or reemerge—that may be treated with on-demand therapies.

**OBJECTIVE:** We evaluated patient treatment experiences with PD "OFF" episodes and preferences for on-demand treatment approaches.

**METHODS:** US adults (18-75 years [y]) with a self-reported physician diagnosis of PD for ≥5 y or <5 y with "OFF" episodes on levodopa were recruited via online panels, physician referrals, online support groups, and targeted advertising to participate in an online survey. The survey gave instructions for use of hypothetical on-demand "OFF" episode treatments administered via injection, inhalation, and dissolvable sublingual film and asked participants about treatment preferences. It also asked about their experience with currently available on-demand treatments (apomorphine hydrochloride injection [Apokyn] and inhaled levodopa powder [Inbrija]).

**RESULTS:** Among the 300 participants, 60% were male with a mean age of 59 y. Most participants (98%) experienced "OFF" episodes, with 50% having ≥1 episode/day and 90% having ≥1 episode/week. Among participants who had ever taken apomorphine hydrochloride injection (n=54) or inhaled levodopa powder (n=54), 57% and 59%, respectively, were currently taking those medications. When "OFF" episodes occur, participants most commonly reported waiting until symptoms dissipate or until their next dose of maintenance medication (53%). They also reported taking their next, partial, or extra dose of maintenance medication, calling their doctor, or taking an "OFF" episode medication. When presented with hypothetical on-demand "OFF" episode treatments, 76% of participants rated a dissolvable sublingual film as "easy" or "very easy" to potentially administer without assistance, compared with administration by injection (28%) or inhalation (59%). Of 298 participants with at least some interest in on-demand "OFF" episode treatment, preference ranking for medication administration was dissolvable sublingual film with potential mouth/lip sores (47%), inhaled medicine with potential cough or mild respiratory infection (31%), and injection with potential site reactions (18%).

**CONCLUSIONS:** More than half of participants with on-demand treatment experience for PD-related "OFF" episodes were currently using those treatments. For hypothetical on-demand treatment, a dissolvable sublingual film was rated as the easiest potential route of administration without assistance and, despite potential side effects, was preferred over injection or inhalation.

**SPONSORSHIP:** Sunovion Pharmaceuticals

## G11 Pharmacokinetics of Inhaled Levodopa Co-Administered with Oral Carbidopa in Subjects with Parkinson's Disease Under Fed Conditions

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**BACKGROUND:** CVT-301 is an levodopa (LD) inhalation powder for OFF period symptom treatment in subjects with Parkinson's disease (PD) on an oral dopa-decarboxylase inhibitor/LD regimen.

**OBJECTIVE:** To evaluate pharmacokinetic (PK) profiles and safety of single doses of CVT-301 84 mg, administered with oral carbidopa (CD), and single oral doses of CD/LD, under fed conditions, in subjects with PD.

**METHODS:** In an open-label crossover study, subjects received a single inhaled dose of CVT-301 84 mg administered with CD 25mg followed by oral CD/LD (25/100 mg) or vice versa in a randomized sequence in 2 dosing periods. 4-5 hours after their typical morning oral CD/LD dose, subjects ate a standardized high-fat, high-protein meal. A predose PK blood sample was obtained after the meal, followed by CVT-301 treatment administered with oral CD 25mg, or oral CD/LD 25 mg/100 mg. Blood was sampled at 5, 10, 15, 30, and 45 minutes, and 1, 1.5, 2, 3, and 4 hours postdose to determine plasma LD concentrations. PK parameters were evaluated using a non-compartmental method. Standard safety assessments included treatment-emergent adverse events (TEAEs).

**RESULTS:** 23 subjects (mean age 69.3 years, BMI 26.9, PD duration 8.2 years, baseline LD dose 461 mg/day) were enrolled: 17% at Hoehn and Yahr stages 1-1.5; 57%, stage 2; 26%, stages 2.5-3. One subject discontinued due to TEAE of cough. Primary pharmacokinetic analyses were based on LD concentrations without baseline LD adjustment. Median $T_{max}$ for CVT-301 was 15 min vs 120 min for oral CD/LD ($P<0.001$). $C_{max}$ was lower for CVT-301 (590.3 ng/mL) than oral CD/LD (844.3 ng/mL). C10min, C15min, and C30min values for CVT-301 were approximately twice those for oral CD/LD (523-552 vs 247-301 ng/mL). Coefficient of variation% for CVT-301 was smaller than oral CD/LD. Nine (39.1%) and 2 (9.1%) subjects reported TEAEs following CVT-301 and oral CD/LD administration, respectively. Most common TEAE was cough: 7 (30.4%) in the CVT-301 group vs 1 (4.5%) subject administered oral CD/LD.

**CONCLUSIONS:** In this study pharmacokinetic parameters showed that CVT-301 was more rapidly absorbed and demonstrated lower inter-subject variability than oral CD/LD in the fed condition.

**SPONSORSHIP:** Acorda Therapeutics

## G12 Improvement in Unified Parkinson Disease Rating Scale Motor Scores After CVT-301 Treatment Is Associated with Improved Scores in the Parkinson's Disease Questionnaire Activities of Daily Living

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**BACKGROUND:** In the SPAN-PD study, CVT-301 84 mg significantly improved motor function in patients with Parkinson's disease (PD) experiencing OFF periods at week 12, as measured by lower Unified Parkinson's Disease Rating Scale Part III (UPDRS-III) scores, 30 minutes postdose ($P=0.009$), and 58% of patients achieved and maintained an ON state <60 minutes postdose vs 36% on placebo ($P=0.003$). 71.4% of patients on CVT-301 84 mg reported improvement in Patient Global Impression of Change (PGIC) vs 46.4% on placebo (nominal $P<0.001$). A post hoc analysis showed Parkinson's Disease Questionnaire (PDQ-39) activities of daily living (ADL) subdomain scores correlated with PGIC scores: as PDQ-39 ADL scores decreased (improved), PGIC was more positive. A PDQ-39 ADL mean change of –1.98 units was associated with PGIC outcomes of "a little improvement." Also, the lower the PDQ-39 ADL score, the more positive the perception of improvement. Although not statistically significant, the PDQ-39 ADL treatment difference (84 mg vs placebo) of –2.08 surpassed the desired threshold of –1.98 units.

**OBJECTIVE:** Post hoc analysis to evaluate activities of daily living changes as assessed by PDQ-39 ADL subdomain scores and correlations with changes in the UPDRS-III over the 12-week period of the phase 3 SPAN-PD study.

**METHODS:** PD patients experiencing OFF periods on an oral carbidopa/levodopa regimen were randomized to placebo or CVT-301 60 mg or 84 mg for the treatment of OFF period symptoms as needed up to 5 times/day. PDQ-39 and UPDRS-III were completed at baseline and 4, 8, and 12 weeks.

**RESULTS:** Week 12 UPDRS-III improvements 30 minutes postdose were associated with a –3.43 point mean improvement in PDQ-39 ADL subdomain score, exceeding the –1.98 threshold. Conversely, worsening (or no change) in UPDRS-III scores at 30 minutes postdose was associated with a +1.33 worsening PDQ-39 ADL scores. A ≥30% UPDRS-III improvement, was associated with a –4.42 point improvement in PDQ-39 ADL scores. Responder ON patients showed greater improvements in PDQ-39 ADL (–4.05) than nonresponders (–0.82).

**CONCLUSIONS:** SPAN-PD demonstrated that UPDRS-III scores improved with use of CVT-301 vs placebo. Post hoc analyses showed that UPDRS-III improvements and responder ON status were associated with improvements in PDQ-39 ADL scores.

**SPONSORSHIP:** Acorda Therapeutics

## G16 Economic Burden and Healthcare Resource Utilization Among Patients with Huntington's Disease and Their Care Partners in the US

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**BACKGROUND:** Huntington's Disease (HD) is a rare genetic and neurodegenerative disease, characterized by a triad of cognitive, behavioral, and motor symptoms that progressively lead to increasing disability, loss of independence, and ultimately death, with a tremendous impact on families across generations.

**OBJECTIVE:** Describe the economic burden of HD on patients and care partners, i.e., work productivity and activity impairment (WPAI) and healthcare resource use (HRU).

**METHODS:** A cross-sectional web-based survey was conducted in the US between June and August 2019. WPAI and HRU for HD patients and care partners were compared to that of the general population (gen pop) and that of Parkinson's Disease (PD) patients and care partners, using data obtained from the 2018 US National Health and Wellness Survey (NHWS). The NHWS is a self-administered, web-based survey of a representative sample of US adults, validated and weighted against reliable sources. Bivariate analyses are reported as t-tests for continuous variables and Chi-square for categorical variables.

**RESULTS:** A total of 41 individuals who self-reported having been diagnosed with HD and 80 care partners were identified. Mean age was 45.6 yrs (68.3% female) and 46.8 yrs (81.3% female), respectively. Currently employed individuals with HD reported high absenteeism (14.1%), presenteeism (46.4%) and an overall work productivity impairment of 50.9%, which was not different from the burden in PD patients (15.0%, 46.6% and 48.6%, respectively), but higher than the gen pop (6.8%, 18.8%, 20.5%). The pattern observed for care partners was similar. Employed HD care partners reported an absenteeism of 5.8% vs. 8.9% for PD and 4.5% for care partners in the gen pop, 21.7% of presenteeism vs. 24.3% (PD) and 22.8% (gen pop); and 24.7% vs. 27.3% and 16.5% of overall work productivity impairment. Preliminary HRU results were also higher for HD, as patients visited the ER 1.09 ± 1.80 times in the past year vs. 0.31 ± 1.06 in the gen pop; HD care partners visited the ER on average 0.96 ± 1.50 times and had 0.56 ± 1.28 hospitalizations, whilst gen pop care partners reported 0.17 ± 0.59 ER visits and were hospitalized 0.07 ± 0.38 times.

**CONCLUSIONS:** Individuals with HD and care partners in the US experience a significant economic burden, with elevated HRU and significant WPAI, which is comparable to the burden for PD (although beginning at an earlier age), and higher than for the gen pop. Overall,

these results highlight the sizeable economic burden of HD, and the need for better healthcare planning.

**SPONSORSHIP:** F. Hoffmann-La Roche

## G20 Treatment Patterns and Relapses Among Treatment-Naive MS Patients

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**BACKGROUND:** Disease-modifying therapies (DMTs) can reduce multiple sclerosis (MS) relapse rates but effectiveness may vary across individual DMTs. It is important to understand treatment patterns and effectiveness in reducing MS relapses using real-world data.

**OBJECTIVE:** Describe treatment patterns and post-DMT relapses among newly treated MS patients in relation to prior DMT relapses.

**METHODS:** IBM MarketScan research databases were used to identify adults with MS newly initiating DMTs (index event) from 1/1/2011-4/1/2016 with 12 months of continuous pre- and post-index medical and pharmacy benefits enrollment. MS was determined by ≥2 non-diagnostic claims with an ICD-9-CM (340) or ICD-10-CM (G35) code. Patients did not have a prescription for a DMT in the 12-month pre-index period. Non-persistence was defined as discontinuing index therapy (>60 days without DMT) or switching DMTs. MS relapses were defined using a validated claims-based algorithm. Logistic regression models were used to determine the association of DMT type (oral, injectable, and infusion) on 12-month persistence and experiencing a post-index relapse adjusting for patient characteristics and number of prior relapses.

**RESULTS:** 9,378 newly treated MS patients met all inclusion criteria. Average age was 46.7 years; 73.3% were female. The majority of patients started with an injectable (65.5%) or oral (26.1%) DMT. A marked reduction in relapses was observed pre- to post-index (32.9% to 24.0%) and was highest among oral users (35.8% to 21.6%). Patients with no pre-index relapse (vs those with ≥3) were more likely to be relapse free post-index (81.6% vs 31.4%). Non-persistence was observed in 39.1% of patients and was lowest among oral users (33.4%). Those on oral agents were more likely to be persistent at 12 months (OR=1.45, $P<0.0001$) and less likely to have a relapse post-DMT initiation (OR=0.75, $P<0.0001$) compared with those on injectable agents. Those with more pre-index DMT relapses were more likely to have a post-DMT relapse (OR=1.73, $P<0.0001$).

**CONCLUSIONS:** Non-persistence rates were high among all MS patients, though those on oral agents were lower. Oral users were also less likely to experience a relapse after initiating treatment. Despite the effectiveness of DMTs in reducing relapses, the low persistence to any treatment highlights an unmet need in the MS treatment landscape.

**SPONSORSHIP:** Celgene, a wholly-owned subsidiary of Bristol-Myers Squibb

## G21 Cost and Utilization Among Patients with Multiple Sclerosis Newly Initiating a Disease-Modifying Therapy

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**BACKGROUND:** Multiple sclerosis (MS) is a chronic dysimmune condition with early onset of disease. MS relapses can be reduced with the use of disease-modifying therapies (DMTs). Information on real-world healthcare costs and utilization associated with DMTs is limited.

**OBJECTIVE:** To describe the healthcare cost and utilization among MS patients newly initiating a DMT.

**METHODS:** Adults (≥18 y) initiating DMTs (index event) from 1/1/2010-9/30/2017 with 12 months of continuous enrollment pre- and post-index were identified from the Optum Clinformatics database. Eligible adults had ≥2 MS claims and no DMTs during the pre-index period. All-cause and MS-related (inpatient claims with MS primary diagnosis, outpatient claims with MS diagnosis in any position and MS treatments), healthcare expenditures and utilization were captured in the 12-month pre-index and 12-month post-index periods.

**RESULTS:** 5,906 MS patients were included in the study (mean age: 46.6 y; female: 74.2%). The majority initiated injectable DMTs (n=3,748; 63.5%), followed by orals (n=1,701; 28.8%) or infusions (n=457; 7.7%). Overall, relapses decreased from pre- to post-index for all routes of administration: oral, 24.3% to 16.1%; injection, 25.0% to 17.1%; infusion, 29.3% to 15.5%. During post-index period, mean [SD] all-cause total costs were lowest for oral initiators ($70,970 [$36,681]) compared with injectable ($82,521 [$58,569]) and infusion ($80,871 [$49,627]) initiators. MS-related total costs for patients post-initiation were lowest for oral initiators ($65,149 [$65,133]) compared with injectable ($76,197 [$60,204]) and infusion ($72,703 [$47,287]). The mean change in MS-related medical costs resulted in the lowest increase post-index for oral initiators (oral: $1,087 [$29,600]; injectable: $1,458 [$20,888]; infusion: $20,076 [$49,785])For all patients, MS-related inpatient admissions decreased from 8.6% pre-index to 3.3% post-index. Post-index, oral initiators had the shortest mean length of stay compared with injectable or infusion (8.02 [9.66] to 10.11 [25.1] and 35.17 [88.66]). Overall, MS-related ER visits slightly increased from pre- to post-index (0.2 [0.77] to 0.3 [0.98]).

**CONCLUSIONS:** Among patients newly initiating DMTs, oral initiators had the lowest all-cause and MS-related total cost of care and the lowest inpatient length of stay, suggesting that access to additional agents may yield healthcare savings.

**SPONSORSHIP:** Celgene, a wholly-owned subsidiary of Bristol-Myers Squibb

## G22 Patient-Reported Outcomes from a Prospective Observational Registry of Repository Corticotropin Injection for the Treatment of Multiple Sclerosis Relapse

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**BACKGROUND:** Effective treatment of relapse is critical for minimizing disability in patients with multiple sclerosis (MS). Repository corticotropin injection (RCI) is approved by the US Food and Drug Administration for treatment of MS exacerbations.

**OBJECTIVE:** This multicenter, prospective, observational registry study aimed to characterize treatment patterns, recovery, and safety outcomes from patients receiving RCI for acute MS relapse.

**METHODS:** Subjects were recruited during routine care after initiation of RCI for an MS exacerbation. Subjects completed the MS Impact Scale (MSIS-29v1), Expanded Disability Status Scale (EDSS), Work Productivity and Activity Impairment Questionnaire: MS (WPAI:MS), and Health Resource Utilization (HRU) questionnaire. Changes from baseline (enrollment) were evaluated at predefined timepoints. Adverse events (AEs) were assessed throughout the study.

**RESULTS:** In all, 125 subjects received at least 1 dose of RCI. Participants were predominantly female (88.0%) and white (84.0%) with a mean age of 47.0 years. Mean MSIS-29v1 physical subscale

scores (primary endpoint) decreased from baseline (55.69) at month 2 (-7.99, $P=0.0002$) and month 6 (-9.64, $P<0.0001$). Mean EDSS scores decreased from baseline (3.92) at month 2 (-0.37, $P<0.0001$) and month 6 (-0.45, $P<0.0001$). MS has appreciable impact on patient functioning and work productivity. Among employed subjects (n = 50), changes from baseline on the absenteeism, presenteeism, and lost work productivity domains (WPAI:MS) were mostly unremarkable. On the activity impairment domain, significant improvements from baseline to months 2 and 6 (all $P\leq0.0011$) were seen for the index exacerbation plus all relapses. The mean number of MS-related outpatient visits (HRU) decreased from baseline at all time points assessed. The mean number of MS-related emergency department (ED) visits also decreased from baseline at most time points. Thirty-five subjects (28.0%) reported 83 AEs, the most common being MS relapse, urinary tract infection (UTI), and nasopharyngitis. Eleven subjects (8.8%) reported 16 serious AEs, the most common being MS relapse, UTI, and asthenia.

**CONCLUSIONS:** Clinically meaningful improvements on the MSIS-29v1 physical subscale and the EDSS along with the low incidence of serious AEs support the efficacy and safety of RCI for MS relapse. Work productivity measures were unremarkable owing to the small number of employed patients. Significant improvements on the activity impairment domain and decreases in outpatient and ER visits were noted with RCI therapy.

**SPONSORSHIP:** Mallinckrodt Pharmaceuticals

## G23 Healthcare Resource Utilization in Patients with Multiple Sclerosis Who Are Adherent Versus Non-Adherent to Disease-Modifying Drugs over 6 Years

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**BACKGROUND:** Multiple sclerosis (MS) is a chronic disease often requiring long-term treatment with disease-modifying drugs (DMDs). Non-adherence to DMD regimens is a risk factor for poor outcomes in patients (pts) with MS; however, the impact of long-term DMD adherence on healthcare resource use (HCRU) has not yet been adequately quantified.

**OBJECTIVE:** To estimate the impact of long-term DMD adherence on HCRU in pts with MS.

**METHODS:** This was a retrospective administrative claims analysis of the 2011-2017 US MarketScan Commercial database records. Pts, age 18-65 years (yr), had ≥3 ICD-9/10 340/G35 diagnosis claims or >1 diagnosis and >1 DMD claim within 1 yr (i.e. index-date was the first MS diagnosis or DMD claim in 2012), and had continuous eligibility 1-yr prior to baseline and ≥3 yrs follow-up. Adherent pts were those with a proportion of days covered (PDC) ≥0.8 and non-adherent pts were those with PDC <0.8. Adherent pts were matched to non-adherent pts using propensity score (PS) matching with baseline variables: age, sex, US region, Charlson Comorbidity Index (CCI), and occurrences of relapse in prior yr. Generalized linear models were used to compare annualized HCRU on inpatient (IP), outpatient (OP), emergency room visits (ER), IP length of stay (LOS), and magnetic resonance imaging (MRI) between the two cohorts.

**RESULTS:** A total of 15,617 pts met eligibility criteria (mean age = 47.3 yrs; female = 77.8%) and 6,121 PS matched pairs were analyzed. After PS matching, both pt cohorts had similar baseline characteristics (age, sex, US region, CCI, occurrence of relapses). Median follow-up duration was 5.6 yrs. Adherent pts had significantly fewer annualized number of IP visits (0.06 vs 0.12 per person-yr; $P<0.0001$), ER visits (0.25 vs 0.39 per person-yr; $P<0.0001$), OP visits (17.06 vs 19.54 per person-yr; $P<0.0001$), and MRIs performed (0.73 vs 0.77 per person-yr; $P=0.0024$) vs non-adherent pts. Average IP LOS was also less for adherent pts vs non-adherent pts (6.6 vs 8.6 days; $P<0.0001$).

**CONCLUSIONS:** This study indicates that out of 15,617 pts with MS, only 42% of pts were adherent over a median of 5.6 yrs. Over this period, 43.3% of pts were non-adherent and had a greater annualized HCRU vs adherent pts. The remaining pts (14.7%) were non-DMD treated. This is the first study to report on the long-term impact (>1-2 yrs) of adherence with a DMD for MS on annualized HCRU. This study suggests if pts with MS are treated with a DMD long term, adherence has an important impact on HCRU.

**SPONSORSHIP:** EMD Serono, a business of Merck KGaA

## G31 Challenges in Chronic Insomnia: A Targeted Review of the Literature

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**BACKGROUND:** While chronic insomnia is a significant public health concern affecting an estimated 10% to 15% of the U.S. adult population, there remains unmet need for proper recognition, diagnosis, and treatment of patients with the condition. A comprehensive understanding of these challenges could inform optimal patient management.

**OBJECTIVE:** To identify, review, and summarize challenges and unmet needs in the management of chronic insomnia through a targeted literature review.

**METHODS:** We performed a literature review using three databases (PubMed, Google Scholar, Cochrane Reviews) to identify publications from 2000-2019 describing challenges, unmet needs, and burden associated with chronic insomnia. Eligible literature included peer-reviewed research studies, commentaries, systematic reviews, and government publications. We also conducted forward and backward reference searching of retrieved publications. Publications were excluded if they were not specific to insomnia, did not assess a U.S. population, or were not relevant to our study objective.

**RESULTS:** 131 unique records were retrieved from the database search. Among these, 104 studies were then selected for full text screenings, and data were extracted from 85 studies based on our inclusion criteria. In classifying the types of challenges documented, several overarching themes emerged: (i) appropriate treatment options are lacking and have known addiction potential and tolerability issues such as discontinuation syndrome (n = 24 studies); (ii) patients with chronic insomnia have an increased risk of medical and psychiatric conditions such as hypertension and depression (n = 21); (iii) chronic insomnia imposes substantial social and economic burden (n = 20); and (iv) the long-term safety and effectiveness of widespread off-label prescribing of antidepressants and other medications for chronic insomnia are unknown (n = 9). The remaining publications focused on the epidemiology and clinician knowledge/attitudes of insomnia (n = 6 and 5, respectively). Each of these challenges contributes to the substantial burden associated with chronic insomnia.

**CONCLUSIONS:** Chronic insomnia affects more than sleep, increasing the risk of other serious medical conditions, exacerbating the negative effects of existing comorbidities, and creating undue burden for payers. The current literature documents the broad impacts of chronic insomnia and its associated unmet needs, including shortcomings of currently available treatments. There exists a clear need to identify best practices for improving quality of care for patients with chronic insomnia while managing costs.

**SPONSORSHIP:** Eisai

## G32 Patterns and Predictors of Opioid Use Among Migraine Patients at Emergency Departments

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**BACKGROUND:** Migraine is a primary headache disorder associated with high health resource utilization (HRU) and poor quality of life. There is limited evidence on opioid use among patients with migraines, specifically at emergency departments (EDs).

**OBJECTIVE:** 1. To describe opioid use among migraine patients at the ED; 2. To identify risk factors of opioid use for migraine patients presenting to the ED, as a function of demographics, clinical characteristics, past opioid use, past preventive medication use, and past HRU.

**METHODS:** This retrospective study used Electronic Medical Record (EMR) data from Baylor Scott & White Health Plan (BSWHP) from December 2013 to April 2017, retrieved through the Research Action for Health Network (ReachNET). The index date was defined as the first migraine-related ED visit after ≥6 months of initial enrollment. Patients aged ≥18 with a diagnosis for migraine who had at least 6 months of continuous enrollment before and after the index date were included in the study. Descriptive statistics and bivariate analyses were used to compare medication use, HRU, demographics, and comorbidities between opioid users and non-opioid users. Multivariate logistic regression with stepwise selection approach was used to identify predictors of opioid use at the index ED visits.

**RESULTS:** A total of 788 patients were included in the study, with an average age of 44.5 (±14.6) years, 85.9% were female, and 76.1% were White. More than one-third (n=283, 35.9%) of the patients were identified as opioid users at the index ED visit. Morphine (n=103, 13.1%) and hydromorphone (n=85, 10.8%) were the two most commonly used opioids at the ED. More than one-seventh (n=118, 15.0%) of the patients had opioid prescriptions written to be filled at a pharmacy after their index ED visit. During the 6-month pre-index period, 39.5% of the patients used at least one preventive medication. Adjusted analyses showed that pre-index migraine-related opioid use (2-4 RXs OR=1.66; 5-9 RXs OR=2.12; ≥10 RXs OR=4.43), pre-index nonmigraine-related opioid use (≥10 RXs OR=1.93), pre-index ED visits (1-3 visits OR=1.84), age (45-64 years OR=1.45), and sleep disorder diagnosis (OR=1.43) were all significant ($P<0.05$) risk factors for index date ED opioid use, after controlling for covariates.

**CONCLUSIONS:** Migraineurs commonly receive opioids at the ED, indicating a gap between real practice and guideline recommendations. Past opioid use, past HRU, age, and certain comorbidities might be used to identify patients with a high risk of opioid use at the ED.

**SPONSORSHIP:** None

## G33 Estimated Impact on Direct Medical Costs Associated with Eptinezumab Treatment for Migraine

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**BACKGROUND:** Eptinezumab is a monoclonal antibody inhibiting the calcitonin gene-related peptide and is under FDA review for the preventive treatment of migraine.

**OBJECTIVE:** To evaluate the impact of eptinezumab on migraine-specific direct medical costs relative to no treatment based on the efficacy observed in eptinezumab clinical trials in episodic migraine (EM; PROMISE-1 [NCT02559895]) and chronic migraine (CM; PROMISE-2 [NCT02974153]).

**METHODS:** Using published epidemiology and treatment utilization data, a population of migraine prevention-eligible patients (diagnosed with EM or CM and with prior exposure to ≥1 preventive treatment) was estimated for a hypothetical, 1 million member commercial health plan. In PROMISE-1 and PROMISE-2, patients were categorized as EM (4-14 headache/≥4 migraine days/month) and CM (≥15 headache/≥8 migraine days/month) based on monthly frequency at baseline through month 6. In this analysis, eptinezumab efficacy was defined as a categorical shift from EM to no migraine (NM; <4 headache days/month and no migraine-specific direct medical cost) and from CM to EM or NM over 6 months. Migraine-specific direct medical nonpharmacy costs associated with CM and EM were derived from published literature. Difference in costs over 6 months before and after treatment with eptinezumab 100 mg was estimated.

**RESULTS:** The estimated number of migraine prevention-eligible patients was 11,734 (CM: 2,612; EM: 9,122). Categorical shift analysis of trial data revealed that ~50% of EM patients shifted to NM, ~30% of CM patients shifted to EM, and ~30% of CM patients shifted to NM at Month 1. At the population level, the observed categorical shift persisted through 6 months; an estimated 770 patients remained at CM, 5,214 shifted to or remained at EM, and 5,749 shifted to NM. In the CM population, migraine-specific direct medical costs were estimated at $6,571,352 before and $1,972,021 after eptinezumab initiation. In the EM population, migraine-specific direct medical costs were estimated at $10,900,180 before and $6,480,789 after eptinezumab initiation. This represented an estimated reduction in cost of $9,018,722 (52%) across the eptinezumab-treated population.

**CONCLUSIONS:** In clinical trials, eptinezumab 100 mg demonstrated a substantial shift from higher to lower levels of migraine. Application of cost estimates to categorical shift data demonstrated a potential reduction in migraine-specific direct medical costs of >50% when comparing 6 months of no treatment to eptinezumab treatment.

**SPONSORSHIP:** H. Lundbeck.

## G34 Need for a Second Dose for the Treatment of Seizure Clusters: Impact on Resource Utilization

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**BACKGROUND:** Refractory epilepsy increases the risk of seizure emergencies and healthcare utilization. Bouts of increased seizure activity, often referred to as seizure clusters or acute repetitive seizures, may occur outside of hospitals and require outpatient treatment options. Benzodiazepines (eg, diazepam, lorazepam, midazolam) are the cornerstone of treatment but have different bioavailability, dosing, and half-life profiles. Economic modeling for treatment of seizure clusters includes direct costs, but seizure control and need for a second dose within 6, 12, or 24 hours may also impact costs. An analysis suggested that rescue with diazepam rectal gel may reduce the need for emergency-room treatment by ≥50% vs placebo.

**OBJECTIVE:** To determine the potential role of failure of the initial dose of rescue medication for seizure clusters and the requirement of a second dose, which may have an important impact on hospitalization and total healthcare utilization.

**METHODS:** A review was performed of available data from long-term open label studies of treatments for seizure clusters. Initial seizure control and the need for a second dose of medication was assessed to gauge whether differences between agents might impact healthcare utilization.

**RESULTS:** Long-term studies of 3 rescue medications were evaluated: diazepam rectal gel (N = 149, weight-based dose), intranasal midazolam (N = 175, 5-mg dose), and intranasal diazepam (ongoing, N = 132, weight-based dose). In the rectal diazepam study, 77% of administrations (1,215/1,578) prevented further seizures in the 12 hours after treatment; second doses were not provided in the protocol. In the intranasal midazolam study, 55% (1108/1998 seizure cluster episodes) of patients had no seizures between 10 minutes and 6 hours after dosing; a second dose was given during 40% of seizure episodes (797/1998). In the intranasal diazepam study, a second dose was permitted 4-12 hours after the initial dose, if needed; as of the February 2019 interim data cut, a second dose was given for 8.5% (191/2274) of seizure episodes.

**CONCLUSIONS:** Although wholesale acquisition cost and number of events are important factors in budget-impact and cost-efficacy models, other factors can affect total cost of treatment. For treatment of seizure clusters, these results suggest that the need for a second dose may vary by agent and route of administration. Treatment failure of the initial dose and its impact on utilization should be factored into economic models of the total costs of rescue therapy. Future analyses should explore the rates of hospitalization with different agents.

**SPONSORSHIP:** Neurelis

## G35 Real-World Impact of Antiepileptic Drug Combinations with Versus Without Perampanel on Healthcare Resource Utilization in Patients with Epilepsy in the United States: A Matched Cohort Analysis

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**BACKGROUND:** The use of antiepileptic drug (AEDs) combinations with different mechanisms of action (MOA) is common to treat patients with refractory epilepsy. Limited real-world evidence is available on the association between healthcare resource utilization (HRU) and the use of different AED combinations.

**OBJECTIVE:** To evaluate and compare the impact of various AED combinations with and without perampanel (PER) on HRU.

**METHODS:** A retrospective matched cohort study was conducted using the Symphony claims database (08/2012-07/2018). Inclusion criteria were: (1) ≥ 12 years of age, (2) treated with AED combinations (identified as an overlap in days of drug supply of ≥ 90 consecutive days for ≥ 2 AEDs), (3) ≥ 12 months of continuous clinical activity before the date of initiation of the second AED in the combination (index date) and ≥ 6 months after the index date, and (4) ≥ 1 diagnosis of epilepsy or non-febrile convulsions during the baseline or post-index periods. AEDs were categorized into the following MOA categories: sodium channel blockers (SC), synaptic vesicle protein 2A binding (SV2), and PER. Patients were classified into three MOA-based cohorts: PER + SC, SC + SC, and SC + SV2. PER + SC users were matched 1:1 with SC + SC and SC + SV2 users, separately, based on propensity score. All-cause and epilepsy-related HRU were evaluated during the post-index period (up to 12 months) and included hospitalizations and outpatient (OP) visits. Event rates were compared between matched-cohorts using rate ratios (RRs) from Poisson regression models.

**RESULTS:** After matching, 1,462 and 1,971 patients were included in the PER + SC vs SC + SC and PER + SC vs SC + SV2 matched-cohorts, respectively. Cohorts were well matched with respect to patients' demographics, clinical characteristics, and baseline AED use in both comparisons. During the post-index period, the rate of all-cause hospitalization was significantly lower for the PER + SC vs the SC + SC cohort (RR [95% CI]: 0.72 [0.60-0.86]) and the SC + SV2 cohort (RR [95 CI]: 0.72 [0.72-0.84]). Similar trends were observed for epilepsy-related hospitalizations. In addition, the rate of all-cause OP visits was also significantly lower in the PER + SC cohort vs the SC + SC cohort (RR [95% CI]: 0.93 [0.90-0.96]) and the SC + SV2 cohort (RR [95% CI]: 0.94 [0.92-0.96]).

**CONCLUSIONS:** PER + SC users had significantly fewer all-cause hospitalizations and OP visits, and fewer epilepsy-related hospitalizations compared to patients treated with SC + SC or SC + SV2.

**SPONSORSHIP:** Eisai

## G36 Budget Impact Analysis of Galcanezumab for the Treatment of Adult Patients with Episodic Cluster Headache in the United States

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**BACKGROUND:** Cluster headache (CH) is a debilitating primary headache disorder characterized by attacks of excruciating unilateral head pain lasting up to 180 minutes. Episodic CH is defined by at least two cluster periods that last from seven days to one year when untreated and are separated by pain-free remission periods of ≥ 3 months. Galcanezumab (Emgality) is a calcitonin gene-related peptide (CGRP) antagonist that is approved for the preventive treatment of migraine. It is the only approved medication for the treatment of episodic CH in adults.

**OBJECTIVE:** This study aimed to estimate the budget impact of adding galcanezumab as a treatment for adult patients with episodic CH from a United States (US) commercial plan perspective.

**METHODS:** A budget impact model with a time horizon of up to five years was developed in accordance with guidelines from the AMCP and ISPOR Good Research Practices. The population was based on a hypothetical scenario of one million commercially insured members. The budget impact was estimated by comparing a "current scenario" of treatment options which are currently used but not approved by the FDA for the treatment of CH—topiramate, valproate, lithium, and verapamil—with a "new scenario" that added galcanezumab as a treatment. Calculations relied on epidemiology, market share and drug, administration, and monitoring costs. Deterministic sensitivity analyses were conducted to identify key drivers and assess uncertainties.

**RESULTS:** Over a three-year, base-case period, the analysis estimated 1,331 adult patients with episodic CH would be eligible for treatment. Based on an estimated galcanezumab market uptake, the projected annual increase in the total budget to the US commercial payer was $110,448, $222,442, and $335,998 in years 1, 2 and 3, respectively. The corresponding incremental per member per month cost was $0.01, $0.02, and $0.03. The budgetary change was attributable to the higher cost of treatment with galcanezumab. Sensitivity analyses suggested that drug costs, uptake of galcanezumab, annual number of prescription refills, and the size of the eligible population were key drivers of the results.

**CONCLUSIONS:** The addition of galcanezumab as a treatment for episodic CH for adults is expected to result in a modest increase in healthcare budget from a US commercial payer's perspective, while providing a novel FDA-approved medication option for patients with episodic CH.

**SPONSORSHIP:** Eli Lilly

## G37 Identifying Outcome Measures for Migraine Value-Based Contracting Using the Delphi Method

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**BACKGROUND:** Value-based contracts (VBCs) linking medication payments to predefined performance metrics aim to promote value through aligned incentives and shared risk between pharmaceutical manufacturers and payers. The availability of a new and expensive class of drugs, calcitonin gene-related peptide inhibitors (CGRPi), presents an opportunity for VBC development in the migraine space. However, uncertainty remains around which indicators are most meaningful to all migraine stakeholders, and how feasible it is to collect those indicators.

**OBJECTIVE:** Identify meaningful migraine indicators among key stakeholders to inform VBCs for CGRPi medications.

**METHODS:** This study utilized a modified Delphi survey to incorporate views from 82 stakeholders, including patients (n = 21), neurologists (n = 9), primary care physicians (n = 14), payers (n = 10), employers (n = 18), and pharmaceutical company representatives (n = 10). A list of 15 migraine-related outcomes was created from a literature review and subject matter expert consultation. Stakeholders reported on the value and meaningfulness of these 15 indicators through a 5-point Likert scale and selection of their top 3 most meaningful indicators. All participants except patients and employers used a 5-point Likert scale to rate the feasibility of collecting each indicator. Consensus was defined as ≥75% agreement on the importance and feasibility of an indicator (Likert scores 4/5 or selection of an indicator as most meaningful). A 2-sample t test was performed to examine differences between stakeholder groups.

**RESULTS:** After 2 rounds, consensus was achieved for 9 indicators for importance on the Likert scale. "Decrease in migraine frequency" reached 100% agreement, followed by "increased ability to resume normal activities" at 96%. When asked to choose the 3 most meaningful indicators, 88% of stakeholders selected "decrease in migraine frequency" followed by 80% selecting "decrease in migraine severity." The 2 measures rated as most feasibly collected were "decrease in ED/urgent care visits" and "decrease in migraine frequency" with 95% and 90% agreement, respectively. There were statistically significant differences between nonpatient and patient stakeholders for "decrease in ED/urgent care visits" (20% vs 0%, $P = 0.03$); and employer and patient stakeholders for "decrease in work days missed" (44% vs 5%, $P = 0.01$) and "decrease in ED/urgent care visits" (22% vs 0%, $P = 0.04$) as most meaningful indicators.

**CONCLUSIONS:** The measures "decrease in migraine frequency," followed by "decrease in migraine severity" were identified as top priority migraine indicators.

**SPONSORSHIP:** Express Scripts

## G38 Migraine Rescue and Preventive Therapy Utilization Before and After Initiation of CGRP-Targeted Therapies

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**BACKGROUND:** The FDA recently approved three calcitonin gene-related peptide-targeted (CGRP-t) therapies for migraine prophylaxis. These agents were long-awaited treatments for individuals with uncontrolled migraine. This study was designed to analyze the effectiveness of these therapies by quantifying preventive and rescue treatments before and after initiation of a CGRP-t therapy.

**OBJECTIVE:** Describe changes in migraine regimens before and after start of a CGRP-t therapy.

**METHODS:** Using a Medicaid claims database, recipients were identified for a case control study who initiated erenumab-aooe, fremanezumab-vrfm, or galcanezumab-gnlm from 05/01/2018 to 04/30/2019. Recipients were continuously eligible for six months prior to initiation of CGRP-t therapy and six months post initiation. Level A and B recommendations per treatment guidelines for migraine preventive therapy (antiepileptics, beta-blockers, antidepressants) and rescue therapy (triptans, botulinum toxin, NSAIDS, ergots, opioids, analgesics) were measured based on utilization and costs from pharmacy claims data 180 days before the index date (baseline) and 180 days following the index date (post).

**RESULTS:** We identified 203 recipients who initiated CGRP-t therapy. Of those 203 recipients, 86.7% were female and the mean age was 42.1 years. At baseline, there were 137 recipients using preventive therapy and 126 using rescue therapy (60 recipients were on both preventive and rescue therapies). Post-index, there were 96 recipients on preventive therapies (excluding CGRPs) and 111 on rescue therapy (4 recipients were on both). Preventive therapies decreased by 16.8% from 38.8 days to 32.3 days per utilizer per month (PUPM) from baseline (some recipients were on more than one). Rescue therapy prescriptions decreased from 0.46 PUPM to 0.35, a reduction of 0.11 prescriptions PUPM (23.04%). Costs (amount paid for pharmacy claims) for preventive therapies decreased 11.8% (from $107 to $94 PUPM), and costs for rescue therapy decreased 33.8% (from $39 to $26 PUPM). Costs for CGRP-t therapy increased pharmacy costs by $346 PUPM. Overall migraine medication costs increased from $146 to $466 PUPM (an increase of $320 PUPM).

**CONCLUSIONS:** Decreases in the use of non-CGRP preventive and rescue therapies was associated with initiation of CGRP-t therapy. While CGRP-t therapy increased total migraine medication costs, the decrease in the number of prescriptions for rescue therapy suggests fewer migraines requiring acute treatment post initiation of therapy.

**SPONSORSHIP:** Conduent

## G39 Risk of Hospitalization and Emergency Department Admission in Patients with Epilepsy Treated with Perampanel in Real-World Settings

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**BACKGROUND:** Epilepsy affects 3.4 million individuals in the US, between 20% and 40% of whom remain refractory to treatment, incurring significantly higher costs ($6,000-$7,000; $P < 0.001$) than in patients with stable disease. Adjunctive antiepileptic drug (AED) therapy is the cornerstone of managing patients with refractory disease, however despite the availability of >30 AEDs, outcomes in refractory patients remain suboptimal. Patients with uncontrolled epilepsy who require an emergency department (ED) visit or hospitalization incur excessive clinical and economic burdens to health care providers and society.

**OBJECTIVE:** To evaluate the risk of hospitalization and ED admission in patients with epilepsy following initiation of perampanel treatment.

**METHODS:** Patients 4 to 11 years of age with a diagnosis of POS or ≥ 12 years of age with POS or PGTC who had ≥ 1 perampanel prescription between 1/1/2014 and 3/31/2018 were identified in this retrospective longitudinal cohort study (Optum Clinformatics Datamart). Patients were required to have 12-months of continuous enrollment before (pre-) and after (post-) the date of the first perampanel prescription (index-date). One-year relative-risks of all-cause and epilepsy-related hospitalization and ED admission were estimated following initiation of perampanel treatment. Outcomes were also evaluated among a

subset of patients who were adherent to perampanel treatment, defined as a Medication Possession Ratio (MPR) ≥ 80%.

**RESULTS:** A total of 320 patients were included in the study; mean age 38.2 ± 19 years; 56.6% female. In the overall population, the relative risk of hospitalization or ED admission post perampanel initiation was not statistically significant. Among the 145 patients who had an MPR ≥ 80%, initiation of perampanel treatment resulted in a significantly lower risk of epilepsy related hospitalization (RR = 0.68 CI [0.47, 0.98]), all-cause ED admission (RR = 0.80 CI [0.66, 0.98]) and epilepsy-related ED admission (RR = 0.74 CI [0.57, 0.95]) in the follow-up period.

**CONCLUSIONS:** Adherence to perampanel treatment was associated with significant reductions in one-year hospitalizations and ED visit risk in real world settings. Results suggest that use of novel adjunctive AEDs might potentially reduce resource utilization and costs of refractory epilepsy in the real world. Findings should be confirmed in larger studies.

**SPONSORSHIP:** Eisai

## G52 Lemborexant for the Treatment of Insomnia: Number Needed to Treat, Number Needed to Harm, and Likelihood to Be Helped or Harmed

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**BACKGROUND:** Lemborexant is an orexin receptor antagonist that has been studied for the treatment of insomnia in the US.

**OBJECTIVE:** The study aim is to review the evidence-base for lemborexant for the treatment of insomnia in adults using the metrics of evidence-based medicine to place this intervention into clearer clinical perspective. These metrics include number needed to treat (NNT), number needed to harm (NNH) and likelihood to be helped or harmed (LHH).

**METHODS:** Data were extracted from the randomized placebo-controlled trials of lemborexant for the treatment of insomnia where results are available—SUNRISE 1 (NCT02783729), a 1-month study in persons with insomnia age ≥ 55 years, and SUNRISE 2 (NCT02952820), a 1-year study in adults with insomnia (data are currently available up to 6 months for this study). Lemborexant 10 mg (LEM10) and 5 mg (LEM5) and zolpidem 6.25 mg (ZOL, SUNRISE 1 only) are contrasted with placebo (PBO) using responder rates (as defined by subjective sleep onset latency, sSOL) as well as discontinuations because of an AE. Sleep onset latency is the time that it takes (in minutes) to accomplish the transition from full wakefulness to sleep, normally to the lightest stage of non-REM (rapid eye movement) sleep. Study data were used to calculate NNT, NNH and LHH (defined as the ratio of NNH to NNT) for lemborexant.

**RESULTS:** In SUNRISE 1, the proportions of sSOL responders on Day 30 were 39/194 (20.1%) for LEM10, 45/211 (21.3%) for LEM5, 23/203 (11.3%) for ZOL, and 15/150 (10.0%) for PBO, resulting in NNT values vs. placebo of 10 for LEM10, 9 for LEM5 and 76 for ZOL. Discontinuations because of an AE were 3/268 (1.1%) for LEM10, 2/266 (0.8%) for LEM5, 7/263 (2.7%) for ZOL, and 2/209 (1.0%) for PBO, resulting in NNH values vs. PBO of 616 for LEM10, -488 for LEM5 and 59 for ZOL. In SUNRISE 2, the proportions of sSOL responders at 6 months were 75/249 (30.1%) for LEM10, 78/250 (31.2%) for LEM5, and 45/254 (17.7%) for PBO, resulting in NNT values vs. PBO of 9 for LEM10 and 8 for LEM5. Discontinuations because of an AE were 26/314 (8.3%) for LEM10, 13/314 (4.1%) for LEM5, and 12/319 (3.8%) for PBO, resulting in NNH values vs. PBO of 23 for LEM10 and 265 for LEM5.

**CONCLUSIONS:** In general, most of the efficacy outcomes yield NNT values for lemborexant vs. placebo < 10 and denote that lemborexant is a potentially efficacious intervention. In all instances, LHH for sSOL response vs. AE-related discontinuation for LEM10 and LEM5 was > 1, denoting a favorable benefit/risk ratio.

**SPONSORSHIP:** Eisai

# H00-H95 Diseases of the Eye and Adnexa
*(e.g., Macular Degeneration)*

## H1 Dry Eye Disease Among Sleep Apnea Patients in the United States Using Continuous Positive Airway Pressure or Other Nasal Mask Therapy Devices: Prevalence Rates and Patient Characteristics

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**BACKGROUND:** Sleep apnea can be effectively treated using continuous positive airway pressure (CPAP) or other nasal mask therapy (NMT) devices. However, air can leak from the vents and sides of these devices and flow past the eyes, leading to increased ocular surface dryness and associated symptoms during the daytime.

**OBJECTIVE:** The objective of this study was to examine the prevalence rate of dry eye disease (DED) as well as demographic and clinical characteristics in patients using CPAP or NMT devices to treat sleep apnea in the United States.

**METHODS:** This was a retrospective, real-world study using the IBM MarketScan claims database. Included patients were aged ≥ 18 years and had ≥ 1 claim for CPAP or other NMT devices after a diagnosis of sleep apnea between 2013 and 2018. The date of the first CPAP/NMT claim was considered the index date. Patients had to have ≥ 12 months of medical and pharmacy benefits in both the pre- and post-index periods. The DED prevalence rate was reported descriptively for the overall sample, as well as by index year, age, gender, and DED-related comorbidities.

**RESULTS:** Overall, 350,420 patients met the eligibility criteria and were included in the study. The mean ± standard deviation age was 53 ± 12 years and 63% of patients were male. 86% and 14% of patients with commercial and Medicare insurance, respectively. The most common comorbid conditions were diabetes (23%), fatigue (21%), and depression (16%). The most prescribed concomitant medications were high blood pressure medications (59%), antidepressants (33%), and anxiety medications (32%). The 1-, 2-, and 3-year prevalence rates of DED were 6.2%, 10.0%, and 13.0%, respectively. In the index years 2014, 2015, 2016 and 2017, the 1-year prevalence rates were 6.5%, 6.3%, 6.1%, and 5.7%, respectively. The prevalence of DED increased with age, with the 1-year rate ranging from 2.2% in the 18-24 years age group to 17.6% in the 75+ years age group. The prevalence of DED was also higher among women than men (1-year: 9.6% vs. 4.2%). In addition, a higher DED prevalence was observed among CPAP/NMT users who had inflammatory or metabolic comorbidities, with 1-year prevalence rates of 17.2%, 8.7%, 8.6%, 8.0%, and 7.8% in patients with psoriasis, irritable bowel syndrome, chronic pulmonary disease, rheumatoid arthritis, and diabetes, respectively.

**CONCLUSIONS:** The prevalence of DED in CPAP/NMT users seems to be slightly higher than in the general population. CPAP/NMT users who are female, older, or have comorbid inflammatory or metabolic conditions may experience higher rates of DED.

**SPONSORSHIP:** Sun Pharmaceutical Industries

## H3 Clinical and Economic Burden of Neovascular Age-Related Macular Degeneration in a Commercially Insured US Patient Population (2015-2018)

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**BACKGROUND:** Research on the clinical and economic burden of neovascular age-related macular degeneration (nAMD) by severity and laterality is limited.

**OBJECTIVE:** To assess the clinical and economic burden of nAMD and its treatment by severity and laterality.

**METHODS:** From IQVIA's claims database, US patients aged ≥ 50 years with commercial insurance and ≥ 1 claim for nAMD from 2016-2017 were identified and followed for 1 year, after stratification by disease status (active choroid neovascularization [CNV], inactive CNV, inactive scar) and laterality (unilateral, bilateral). Annual all-cause healthcare resource utilization and direct medical costs were estimated over the 12-month post-index period. Projection analysis was used to determine the national prevalence of nAMD in the commercially insured US population.

**RESULTS:** In total, 6,076 patients with nAMD were identified (74.7% unilateral; 23.4% bilateral). Disease status included 60.1% of patients with active CNV, 17.2% with inactive CNV and 5.9% with inactive scar at baseline. Overall, 65.8% used anti-vascular endothelial growth factor (anti-VEGF) therapy over the follow-up period and mean (standard deviation [SD]) annual outpatient nAMD visit burden was 6.6 (4.8); patients with active CNV had the highest utilization (7.7 [4.6]). For the subset with anti-VEGF treatment, mean (SD) duration of anti-VEGF therapy was 7.7 (4.5) months over 1 year. Overall, mean (SD) anti-VEGF related outpatient visit burden was 3.9 (4.2), with the highest utilization seen in active CNV patients (5.1 [4.2]). Mean nAMD-related outpatient costs were $6,838 (SD $10,794), driven primarily by anti-VEGF injection-related outpatient costs $5,357 (SD $ 9,380). Mean per patient costs of nAMD-related outpatient visits were ~4 and ~7 times higher, respectively, for the active CNV group ($8,657 [SD $11,570]) compared to the inactive CNV ($2,406 [SD $5,510]) and inactive scar ($1,198 [SD $3,035]) groups. Mean nAMD-related outpatient costs were higher among bilateral patients compared to unilateral patients in all severity groups (data not shown). The projected prevalence of nAMD in the US for 2017 among people aged 50-64 years with commercial insurance (44.6 million) was 0.2% and slightly higher (1.2%) among those ≥ 65 years (50.4 million).

**CONCLUSIONS:** The clinical and economic burden of nAMD treatment is substantial to US commercial insurance plans and the healthcare system, where burden increases among those with active CNV and those with bilateral disease. Appropriate treatment may reduce the proportions of patients with active CNV and preserve visual acuity while lowering costs.

**SPONSORSHIP:** Allergan

## H4 Cost-Effectiveness Analysis of Brolucizumab Versus Aflibercept and Ranibizumab in Neovascular Age-Related Macular Degeneration

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**BACKGROUND:** Neovascular (wet) age-related macular degeneration (AMD) is an advanced form of AMD characterized by choroidal neovascularization and vascular leakage. Patients with wet AMD can have decreased visual acuity and are at increased risk of developing severe visual impairment and blindness.

**OBJECTIVE:** An economic model was developed to estimate the cost-effectiveness of brolucizumab from a US payer perspective over a 5-, 10-, 20-year, and lifetime time horizon.

**METHODS:** A Markov model with annual cycles was utilized with health states for on-treatment, off-treatment, and death. Model substates for vision impairment level were based on best-corrected visual acuity (BCVA) measured using Early Treatment Diabetic Retinopathy Study (ETDRS) letter scores. The baseline efficacy at Year 1 for brolucizumab was based on pooled data from the HAWK and HARRIER clinical trials. The efficacy inputs for ranibizumab and aflibercept were based on the results of a systematic literature review and network meta-analysis of clinical trials assessing wet AMD treatments. Only the most effective fixed-dosing regimens were included in the model (i.e. every 8 weeks (q8w)/q12w for brolucizumab, q8w for aflibercept, q4w for ranibizumab), and drug costs were based on WAC (per injection: $1,850 for brolucizumab and aflibercept, $1,950 for ranibizumab). Administration and monitoring costs were also included in the model. As patients moved between health states and BCVA substates, they accrued health-state and event-specific costs; they also accrued QALYs based on the BCVA status of the treated eye.

**RESULTS:** Brolucizumab was less costly than both aflibercept and ranibizumab over each time horizon. Five-year total costs were $44,680 for brolucizumab, $50,813 for aflibercept, and $89,733 for ranibizumab; total lifetime costs were $63,665 for brolucizumab, $72,247 for aflibercept, and $128,261 for ranibizumab. In addition to being less costly, brolucizumab yielded slightly more QALYs than both aflibercept and ranibizumab. Five-year total QALYs were 2.951 for brolucizumab, 2.946 for aflibercept, and 2.944 for ranibizumab; total lifetime QALYs were 4.577 for brolucizumab, 4.569 for aflibercept, and 4.566 for ranibizumab. As brolucizumab was both less costly and yielded more QALYs than both comparators, brolucizumab was a dominant treatment.

**CONCLUSIONS:** Brolucizumab can be cost-saving and cost-effective compared to aflibercept and ranibizumab due to the potential for lower costs and slightly more QALYs.

**SPONSORSHIP:** Novartis

# I00-I99 Diseases of the Circulatory System
*(e.g., Atrial Fibrillation, ACS, Pulmonary Hypertension)*

## I1 Identifying Adherence Trajectories to Angiotensin-Converting Enzyme Inhibitors/Angiotensin Receptor Blockers Among Patients with Comorbid Diabetes and Hypertension Enrolled in a Medicare Advantage Plan

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**BACKGROUND:** Patients with comorbid diabetes (DM) and hypertension (HTN) are associated with increased costs, resource utilization and a four-fold increased risk of cardiovascular disease. Commonly prescribed medications include Angiotensin Receptor Blockers (ARBs) and Angiotensin-Converting Enzyme Inhibitors (ACEIs). However, these medications are associated with suboptimal adherence leading to inadequately controlled blood pressure. Unlike traditional single estimates of proportion of days covered (PDC), Group-based trajectory modeling (GBTM) is a newer technique that can graphically display the dynamic nature of adherence.

**OBJECTIVE:** To evaluate adherence trajectories using GBTM among patients with comorbid DM and HTN enrolled in a Texas Medicare Advantage Plan (MAP) for future development of a tailored motivational interviewing (MI) intervention to improve patients' adherence to ACEI/ARBs.

**METHODS:** 22,744 patients with a prescription of ACEI/ARBs were identified between July 1, 2017 and December 31, 2017. Patient adherence was measured using PDC during the one-year follow-up period. PDC was calculated separately for each month during the follow-up period and a binary indicator for "full adherence," defined as PDC ≥ 0.8 vs. non-adherence was created for each consecutive month. The 12 binary indicators of full adherence were modeled as a longitudinal response in a logistic group-based trajectory model. The final trajectory model was estimated using 2-5 adherence groups assessing each through comparison of the Bayesian criteria, clinical relevance, and a 5% minimum membership requirement.

**RESULTS:** The 4-group trajectory model was selected based on the above criteria. Four distinct adherence trajectories were identified in the selected model which included: (1) patients with rapid decline (RD) adherence (12.6%); (2) patients who were consistently adherent (58.5%); (3) patients with gaps in adherence (GA, 12.2%), and (4) patients with gradual decline (GD) adherence (16.6%). While the overall PDCs of the adherent group and the RD group were 0.94 and 0.23 respectively, there was a statistically significant difference among the mean PDC's within all 4 groups ($P < 0.0001$).

**CONCLUSIONS:** Just over half of the patients were consistently adherent, indicating a need for adherence counseling in the non-adherent groups. The adherence trajectories will be helpful in developing an MI intervention customized to potential barriers unique to each trajectory.

**SPONSORSHIP:** National Heart, Lung, and Blood Institute

## 12 Evaluation of Practice in Acute Coronary Syndrome Management: A Conceptual Framework

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**BACKGROUND:** Based on the AHA report in 2018 on heart diseases, acute coronary syndrome (ACS) is found to be the main factor for developing heart failure, myocardial infarction and sudden death. Multiple studies have analyzed the pattern of practice in ACS management in different countries to compare between the guideline and experience-based management to rationalize current implemented practice. Even though the treatment guidelines are generally followed, certain patient care parameters such as risk stratification, assessment of patient compliance are neglected that could potentially impact overall therapeutic outcomes.

**OBJECTIVE:** To develop a conceptual framework to assess the contemporary treatment practice in ACS patients

**METHODS:** In this observational study, an assessment tool was developed particularly to achieve its objectives. This tool is made to assess the current practice in management of ACS in the ICU and later to be compared with the recent management guidelines. We used the Australian Clinical Guidelines for the Management of ACS 2016 to build up this tool as it has detailed protocol. The duration of this study was five weeks, from May 18 to June 22, 2017. ACS patients were admitted to the ICU at a Tertiary Hospital, Ajman, UAE.

**RESULTS:** A comparison was done between experience driven practice and evidence-based practice in ACS patients in the ICU. Lack of documenting risk stratification in the patient file which allows better treatment selection and more individualized goals of therapy was the main finding. Only 12.5% had a formal risk assessment documented. Therapeutic management protocols were followed, but individualization lacked in 50% of the cases with similar results seen during discharge. Inappropriate dosage regimens were observed in 25% of the cases. Even though relevant symptoms and cardiac enzymes were resolved in all cases before discharge, there was lack of appropriate ADR/ME detection, assessment and documentation in all cases except 1 where ADR/ME were deemed severe. Furthermore, patient education in terms of compliance to medications was inadequate, patient information leaflets were not provided during discharge especially for patients with polypharmacy.

**CONCLUSIONS:** This framework model highlights possible barriers that could be avoided by following an evidence-based conceptual algorithm. Some of the suggested improvements include adequate documentation of the risk stratification strategies used. Additionally, reasons of inadequate prognosis should be identified prior to changing the therapy plan. Further researches on personalized patient care could help in developing this framework model.

**SPONSORSHIP:** None

## 14 Examining Titration Patterns for Selexipag in Real-World Practice Using U.S. Specialty Pharmacy Data

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**BACKGROUND:** Selexipag is a prostacyclin receptor agonist approved (2015) by the US Food and Drug Administration for pulmonary arterial hypertension (PAH) treatment. As in GRIPHON (pivotal long-term RCT), the package insert describes bid administration with a recommended starting dose of 200 ug with weekly titration to individualized maximum tolerated dose (MTD) up to 1,600 ug BID. Selexipag is known to be efficacious at any individual maintenance dose in mono- or combination therapy. Currently, there is limited data available documenting real-world utilization of selexipag in the treatment of PAH.

**OBJECTIVE:** Examine the real-world titration patterns for selexipag and the effect of prior prostacyclin (PGI2) use on titration patterns and discontinuation.

**METHODS:** This was a retrospective study using de-identified U.S. specialty pharmacy data of adult patients who had ≥ 1 selexipag shipment between 01JAN2016-29MAR2019. Patients were required to: have a 1st shipment (index date) dose of 200μg BID to ensure they were new initiators and attain a maintenance dose during the study period. Maintenance dose was reached when the dose shipped was consistent for a 30-day supply. Patients were stratified based on their 1) titration pattern: patients who titrated > 8 days/200 μg (> weekly) vs ≤ 8 days/200 μg (≤ weekly); and 2) prior PGI2 use (naïve vs prior-use). Cox regression was used to examine time-to-discontinuation during the study period.

**RESULTS:** A total of 3931 of 6709 patients met the selection criteria. Mean age was 58 years, and 73% were female. Mean time to maintenance dose was 14 weeks. Most patients titrated > weekly (3381, 86%) and few (550, 14%) titrated ≤ weekly. The most frequent maintenance dose (39.5%) was 1,600 μg, with most of the ≤ weekly group reaching that dose (92.5%) compared to 28.4% overall in GRIPHON. Titration adjustment before the maintenance dose was observed in 43.6% of patients. Most (3408, 86.7%) patients were PGI2-naïve; their median maintenance dose was lower compared to the prior-use group (1200 vs 1,600 μg, $P < 0.05$). There was a higher risk for discontinuation in the naïve group than in the prior-use group (HR: 1.33; 95% CI: 1.01-1.76).

**CONCLUSIONS:** Mean titration time was longer than the 12 weeks allowed in GRIPHON. Few patients had prior-use of PGI2 though it had a low impact on titration patterns or level of maintenance dose

achieved. Recently, efforts are underway to educate patients and providers about the "dose adjustment" process to help patients reach "personalized dosing". Further research to assess its impact on titration patterns and dose achieved will be needed.

**SPONSORSHIP:** Actelion Pharmaceuticals US

## I5 Direct Healthcare Costs Among Heart Failure Patients with Reduced and Preserved Ejection Fraction in the US

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**BACKGROUND:** Limited evidence exists of the real-world economic burden of patients with heart failure (HF), especially when subclassified into HF with reduced ejection fraction (HFrEF) and HF with preserved EF (HFpEF).

**OBJECTIVE:** To quantify direct healthcare costs to US payers attributed to patients with HF, including HFrEF and HFpEF.

**METHODS:** A retrospective, longitudinal cohort study using linked claims and electronic medical record (EMR) data from IBM. Adult patients were indexed on HF diagnosis (ICD-10-CM: I50.x) from Jul 2012-Jun 2018 with 6-month minimum baseline and varying follow-up (FU). Patients were classified as HFrEF or HFpEF at index according to the last observed EF-specific diagnosis code during FU, including index date (HFrEF: I50.2x, HFpEF: I50.3x). Not all indexed patients could be classified as HFrEF or HFpEF. HF hospitalisations (hHFs) were defined as a hospitalization for HF (primary diagnosis) of ≥1 overnight stay. Urgent HF visits were defined as an emergency room visit for HF (primary diagnosis) which is not an hHF. Costs per-patient per-month incurred during FU are reported, inflated to 2018 USD via the Consumer Price Index for Medical Care.

**RESULTS:** 109,721 patients with HF were identified (median FU: 18 months); 23,956 (22%) were classified as HFrEF (median FU: 21 months) and 33,781 (31%) as HFpEF (median FU: 20 months). Mean age at indexing was 73 years (HFrEF: 73 years, HFpEF: 75 years) and 50% were women (HFrEF: 39%, HFpEF: 58%). Mean total monthly costs (all-cause) for the full sample was $9,290 per-patient (HFrEF: $11,053, HFpEF: $7,482). On average, inpatient costs contributed to 69% ($6,438) of total costs (HFrEF: $8,022 [73%], HFpEF: $4,668 [62%]). Outpatient costs contributed to 26% ($2,395) of total costs (HFrEF: $2,603 [24%], HFpEF: $2,318 [31%]) and medication costs contributed to 5% ($457) of total costs (HFrEF: 4% [$429], HFpEF: 7% [$495]). HF-related medication costs accounted for 15% ($67) of all medication costs (HFrEF: 18% [$77], HFpEF: 15% [$75]). Mean monthly cost of HF-specific events among resource-users was $2,754 for hHFs (HFrEF: $3,372, HFpEF: $1,916) and $122 for urgent HF visits (HFrEF: $88, HFpEF: $108).

**CONCLUSIONS:** In this contemporary, longitudinal, linked claims-EMR US study, the mean total monthly cost per HF patient was ~$9,000 and was numerically higher for HFrEF compared with HFpEF. Inpatient costs accounted for ~60-75% of all costs; this proportion was numerically higher for HFrEF versus HFpEF. Medication costs accounted for a minority of total direct healthcare costs in patients with HF.

**SPONSORSHIP:** AstraZeneca

## I6 Three-Month Hospitalization and Health Care Costs Following Initiation with Sacubitril/Valsartan: A Contemporary Claims-Based Analysis of Commercial and Medicare Advantage Enrollees

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**BACKGROUND:** In a 2017 pre-post analysis of 606 patients, decreased medical costs offset increased pharmacy costs following sacubitril/valsartan (SAC/VAL) initiation between Oct 2015 and Jun 2016. Now that it has been 4+ years since SAV/VAL's launch, contemporary-newer and larger-data are needed to understand whether a medical cost offset persists.

**OBJECTIVE:** To examine real-world hospitalization and health care costs during the 3 months pre- and post-SAC/VAL initiation.

**METHODS:** We used retrospective claims data from the Optum Research Database (US commercial and Medicare Advantage [MA] enrollees) to identify adults initiated on SAC/VAL (≥1 pharmacy claim) between Oct 2016 and May 2018. We compared hospitalizations (HF [diagnosis code in first-listed position] and all-cause) and all-cause health care costs in the 3 months pre- and post-SAC/VAL initiation with McNemar and paired t-tests, respectively. Age, gender, and plan type were described as of initiation date; comorbid conditions were described in the 12 months pre-initiation.

**RESULTS:** We identified 6842 adults initiated on SAC/VAL; mean (SD) age 69 (12) years, 66% male, 82% MA enrollee, 93% hypertension, 78% ischemic heart disease, 53% diabetes, 44% atrial fibrillation, and 25% cerebrovascular disease. The percentage of patients hospitalized was lower in the 3 months post- vs pre-initiation (HF: 6% vs 17%, $P<0.001$; all-cause: 16% vs 32%, $P<0.001$); including among MA enrollees (n=5,579; HF: 6% vs 17%, $P<0.001$; all-cause: 18% vs 32%, $P<0.001$) and commercial enrollees (n=1263; HF: 3% vs 15%, $P<0.001$; all-cause: 9% vs 31%, $P<0.001$). Differences in mean all-cause health care costs were observed between the 3 months post- vs pre-initiation. Hospital costs were lower (overall (i.e., all patients): $4,241 vs $7,574, $P<0.001$; MA: $3,761 vs $6,275, $P<0.001$; commercial: $6,360 vs $13,310, $P<0.001$), while outpatient pharmacy costs were higher (overall: $3,021 vs $1578, $P<0.001$; MA: $3,046 vs $1,620, $P<0.001$; commercial: $2,909 vs $1,391, $P<0.001$). In total, costs were lower (overall: $12,544 vs $14,602, $P<0.001$; MA: $11,238 vs $12,132, $P=0.009$; commercial: $18,312 vs $25,511, $P<0.001$).

**CONCLUSIONS:** In a retrospective claims-based study of 6,842 patients initiated on SAC/VAL, mean total health care costs were $2,058 lower in the 3 months following initiation as compared with the 3 months prior to initiation. Findings from this updated and larger analysis suggest a more substantial medical cost benefit following SAC/VAL initiation, compared with 2017 study findings.

**SPONSORSHIP:** Novartis

## I7 Evaluation of Treatment Patterns for Chronic Heart Failure and Associated Costs of Different Dosing Levels of Sacubitril/Valsartan Among Mississippi Medicaid Beneficiaries

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**BACKGROUND:** Entresto [sacubitril/valsartan (S/V)] was approved in 2015 to reduce the risk of cardiovascular death and hospitalization among chronic heart failure (HF) patients with reduced ejection fraction. S/V is available in three dosing strengths – low (24/26 mg), medium (49/51 mg), and high (97/103 mg). Real-world evidence on

effectiveness and the dose-specific impact on costs of S/V among HF patients is limited.

**OBJECTIVE:** To evaluate changes in costs and adherence associated with different dosing levels for S/V among Medicaid beneficiaries with HF.

**METHODS:** A retrospective observational study was conducted using Mississippi Division of Medicaid claims data from January 1, 2015 to August 31, 2019. Beneficiaries initiating S/V were included in the study cohort if they were continuously enrolled for 3 months before initiating S/V and 3 months after reaching a S/V stable dose. A stable dose of S/V was defined as 3 months of S/V treatment without a dose change. The first day of S/V stable dose initiation was identified as the post-index date. Medical and pharmacy costs were calculated for the 3 months pre-treatment and 3 months stable dose treatment period. Generalized estimating equations with gamma distribution and log link function were used to test difference in costs pre and post treatment with S/V. Adherence was measured using proportion of days covered (PDC). PDC ≥ 80% was considered treatment-adherent. All analyses were adjusted for demographics and adherence.

**RESULTS:** 475 beneficiaries were included in the study cohort with 179 (37.7%) maintained on low S/V dose (LD), 125 (26.3%) on medium S/V dose (MD), and 171 (36.0%) on high S/V dose (HD). Adherence rates varied slightly among groups; 58.5% for HD, 50.4% for MD and 53.7% for LD. All groups had a significant ($P < 0.001$) increase in unadjusted pharmacy costs post treatment; $1,434 for LD, $1,180 for MD, and $1,113 for HD. When adjusting for age, race, sex, and adherence, the LD group showed a post-treatment increase of $3,890 ($P = 0.157$) in total costs, while the MD and HD groups showed reductions in total costs of $9,967 ($P < 0.001$) and $6,053 ($P = 0.061$), respectively compared to LD group.

**CONCLUSIONS:** Cost savings occurred for beneficiaries maintained on a MD or HD of S/V. Although the increase in total cost for the LD group was not significant, additional research may be needed to determine if this dose is cost-effective. Since the number of beneficiaries that remain adherent at MD and HD is suboptimal, future interventions should target treatment adherence to maximize S/V cost benefit.

**SPONSORSHIP:** None

## I10 Stroke Disparities in Patients Receiving Tamoxifen Therapy

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**BACKGROUND:** Disparities in breast cancer is a prevalent issue because groups such as Black Non-Hispanic (BNH) patients generally suffer from significantly worse outcomes. Observing outcomes in hormonal therapy (HT) is important to address these disparities because HT is first line treatment in many types of breast cancer. Tamoxifen is a widely used drug in HT and yet its phase 3 studies were conducted in majority on White Non-Hispanic (WNH) patients, bringing to question its outcomes in other races. It has been established that genetic differences could increase adverse events of tamoxifen such as stroke, but no studies have examined racial/ethnic disparities at the population level in those using this drug. This study observed the link between rate of stroke and race in patients on tamoxifen treatment to determine if further study of disparities with this drug is warranted.

**OBJECTIVE:** Determine if a disparity exists in rates of stroke between BNH and WNH populations that use tamoxifen.

**METHODS:** The National Health and Nutrition Examination Survey (NHANES) Database was sampled for our analysis. NHANES is a nationally representative survey conducted in 2 year cycles. BNH and WNH cohorts receiving tamoxifen were assessed for history of stroke. Odds ratio (OR) for stroke in the BNH group was calculated in reference to non-BNH tamoxifen users. OR was calculated in the WNH group in reference to non-WNH patients, and again in reference to the BNH cohort. OR shall be evaluated using a two-sided Chi-squared test with alpha = 0.05 using SAS software.

**RESULTS:** This study represents 347,948 patients on tamoxifen from 2005-2016 (BNH: 40,964/ WNH: 293,862). Mean age of the sample population is 60 (SD ± 13.3) (BNH: 59 (SD ± 14.1)/WNH: 60 (SD ± 13.9)). Bivariate analysis shows that OR of stroke in the BNH cohort was 375% above non-black tamoxifen users [OR:3.75, 95% CI (3.62-3.89)]. OR in the WNH cohort was 22% less than non-white tamoxifen users [OR:0.78, 95% CI (0.76-0.81)], and 68% less than BNH patients specifically [OR:0.32, 95% CI (0.31,0.33)].

**CONCLUSIONS:** BNH patients receiving tamoxifen had higher rates of stroke, indicating a disparity possibly linked to the drug. However, the lack of detail the stroke events in the referenced database lead to an inconclusive outcome on the role of genetics in this racial disparity. Further study of disparities with tamoxifen usage is needed to re-evaluate guidelines and optimize therapy for BNH patients.

**SPONSORSHIP:** The National Heart, Lung, and Blood Institute

## I13 Translating the Landmark DAPA-HF Trial Findings to a US Payer Setting: Medical Care Cost-Offsets Associated with Dapagliflozin Compared to Standard of Care

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**BACKGROUND:** The landmark Dapagliflozin And Prevention of Adverse-outcomes in Heart Failure (DAPA-HF) trial in chronic HF patients with reduced ejection fraction (HFrEF) demonstrated that treatment with dapagliflozin (DAPA) had a lower rate in the primary composite endpoint of CV death, hospitalization for heart failure (hHF) and urgent heart failure visit (UHFV) compared to placebo (PBO) when used in addition to current standard of care (hazard ratio: 0.74; 95% confidence interval: 0.65 to 0.85).

–**OBJECTIVE:** The objective of this study was to estimate the direct medical care cost-offsets of lower rates of hHF, UHFV and CV death events associated with DAPA from a US payer perspective.

**METHODS:** DAPA-HF event rates were used to predict hHF (including first and recurrent events), UHFV and inpatient CV death incidence in a modelled cohort of 1,000 HFrEF patients over 3 years. Published event costs were applied to predicted incidence of hHF ($12,459), UHFV ($1,641) and inpatient CV death events ($25,210). CV deaths occurring without an associated hospital admission were assumed to incur no additional costs (58% of CV deaths based on post-hoc analysis of DAPA-HF). Long-term management and medication costs were not considered. Subgroup analysis based on event rates from the trial for patients aged < 65 or ≥ 65 years at baseline was also conducted. Costs were inflated to 2018 values with future costs were discounted at 3% per annum.

**RESULTS:** Over 3 years for every 1,000 HFrEF patients, 80 fewer hHF events were estimated with DAPA-treatment compared to PBO treated patients, resulting in a NNT of 13 (DAPA: 255 hHF, PBO: 335 hHF). Similarly, an estimated 12 UHFV events were avoided (DAPA: 9, PBO: 21; NNT: 85) and 34 fewer CV deaths were predicted (DAPA: 177, PBO: 211; NNT: 30) per 1,000 patients treated with DAPA. The estimated medical care cost-offset, for every 1000 patients, associated with DAPA treatment was $1,343,691 over three years, or a 21% reduction in comparison with PBO (DAPA: $4,923,327, PBO: $6,267,018). In subgroup analysis, for every 1,000 patients, cumulative cost-offsets of $1,398,307 and $1,339,073 (23% and 21% reduction in medical care

costs) were estimated in patients aged <65 and ≥65 years at baseline, respectively.

**CONCLUSIONS:** HFrEF imposes a significant burden on both healthcare payers and patients. Based on the landmark DAPA-HF trial, treatment with DAPA may result in substantial medical care cost-offsets for both Commercial and Medicare payers as a result of the reduction in incidence of hHF, UHFV and CV death.

**SPONSORSHIP:** AstraZeneca

## I14 Health Care Resource Use and Costs of Commercially Insured Patients with Heart Failure with Reduced Ejection Fraction Who Develop Worsening Chronic Heart Failure Versus Those Who Remain Stable

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**BACKGROUND:** With evolving standard of care (SOC) for chronic heart failure with reduced ejection fraction (HFrEF), updated estimates of health care resource use (HCRU) and costs are needed to understand the economic and clinical unmet needs in patients who develop worsening chronic HFrEF (WCHF) versus those who remain stable.

**OBJECTIVE:** To compare HCRU and costs of HFrEF patients with WCHF vs stable HFrEF patients using data from a commercial database.

**METHODS:** Using a commercial health insurance perspective, data from patients aged 18 to <65 years with HFrEF (1 inpatient or 2 outpatient claims of systolic HF or 1 outpatient claim of systolic HF plus 1 outpatient claim of any HF using ICD-10 codes) identified from the MarketScan claims database during the year of 2016 were analyzed. This retrospective observational study included patients with a first claim of HFrEF (index date) who had continuous enrollment 12 months pre- and post-index date. Patients were designated as having WCHF (HF hospitalization or outpatient IV diuretic use) or remaining stable during the worsening assessment period (12 months after the index date). HCRU and costs (inpatient, outpatient and emergency department [ED]) were compared between patients with WCHF and stable patients during the worsening assessment period and the follow-up period (12 months post-worsening assessment period or until end of data available) using generalized linear models adjusting for baseline clinical and demographic characteristics.

**RESULTS:** Of 16,646 commercially insured HFrEF patients, 26.8% developed WCHF within 12 months. During the worsening assessment period, WCHF patients had greater HCRU than stable patients, with mean HF-related outpatient visits (8.16 vs 4.33) and ED visits (1.02 vs 0.24; both $P<0.0001$); and all-cause inpatient (1.79 vs 0.51), outpatient (30.02 vs 20.39), and ED visits (2.48 vs 0.98; all $P<0.0001$). Mean HF-related total costs for patients with WCHF vs stable patients were $43,997 vs $4,612; all-cause total costs were $104,438 vs $26,470 (both $P<0.0001$). Mean post worsening follow-up period was 310 and 329 days for WCHF and stable patients, respectively. Similar trends observed in the worsening assessment period for HF-related and all-cause mean HCRU and costs were also observed for WCHF vs stable patients during the follow-up period.

**CONCLUSIONS:** Total and HF related HCRU and costs were significantly greater in WCHF patients compared to stable patients. These data suggest an ongoing unmet need in WCHF to improve clinical and economic outcomes.

**SPONSORSHIP:** Merck & Co.

# J00-J99 Diseases of the Respiratory System
*(e.g., Asthma, COPD, Rhinitis, RSV)*

## J1 Estimating the Economic Impact of the Cell-Based Influenza Vaccine Versus the Standard Egg-Based Quadrivalent Influenza Vaccine in the U.S.: A Comprehensive Real-World Evidence Evaluation of Healthcare Costs for the 2017-18 Influenza Season

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**BACKGROUND:** Seasonal influenza causes significant annual burden to U.S. society. This includes both economic burden as well as burden of disease. The suboptimal effectiveness of seasonal influenza vaccines has been recently explained by the selection of the vaccine strains (especially A/H3N2 viruses) that differ from WHO seed strain during the traditional egg-based vaccine manufacturing process. Cell-based vaccine production potentially avoids such adverse selection in antigenic structures, improving match between WHO seed viruses and final strains selecting for manufacture. The latter could be helpful to reduce the burden of the disease and its economic impact.

**OBJECTIVE:** This research aimed to compare the annualized mean all-cause total healthcare costs between propensity-score matched subjects vaccinated with cell-based quadrivalent influenza vaccine (QIVc) or the standard egg-based quadrivalent influenza vaccine (QIVe) in the U.S. during the 2017-18 flu season.

**METHODS:** A retrospective cohort analysis of subjects 4-64 years old was conducted using administrative claims data in the U.S. Baseline characteristics included age, gender, payer type, region, Charlson Comorbidity Index, comorbidities, indicators of frail health status, and pre-index hospitalization rates. Treatment selection bias was adjusted through 1:1 propensity score matching (PSM). Economic outcomes were compared using paired t-test including annualized mean all-cause costs. Costs were adjusted using generalized estimating equation (GEE) models, with two-part models for hospitalizations and ER visits. With the GEEs, adjustment for outliers (99th percentile) was also performed and predicted healthcare costs were obtained through bootstrapping (500 replications).

**RESULTS:** During the 2017-18 flu season, the PSM sample comprised 555,062 recipients of QIVc and 555,062 of QIVe. In pair-wise comparisons, QIVc was associated with lower mean annualized all-cause costs per patient (US $8,956 vs. US $9,307; $P\leq0.0001$) mainly driven by lower hospitalizations costs (US $1,670 vs. US $1,897; $P\leq0.0001$) and outpatient medical services (US $4,935 vs. US $5,024; $P=0.02$). Following GEE adjustment, QIVc was associated with lower predicted mean annualized all-cause costs compared to QIVe (incremental cost difference of US $470.93 per patient), again driven by lower hospitalizations costs ($219.82) and outpatient medical services ($243.39), all of which were statistically significant.

**CONCLUSIONS:** QIVc was associated with significantly lower all-cause economic costs during the 2017-18 flu season compared to QIVe among the 4-64-year-old population.

**SPONSORSHIP:** Seqirus Vaccines

## J2 Economic Assessment of Adjuvanted Trivalent Influenza Vaccine Compared to Trivalent High-Dose Influenza Vaccine Among the U.S. Elderly: A Comprehensive Real-World Evidence Evaluation of Direct Healthcare Costs for the 2017-2018 Influenza Season

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**BACKGROUND:** Influenza incurs a substantial economic burden (as much as $11.2B in the U.S. annually) due to physician office visits, emergency room visits (ER), and hospitalizations, especially in the older adult population. Within recent published literature, comparisons of adjuvanted trivalent influenza vaccine (aTIV) and trivalent high dose influenza vaccine (TIV-HD) have shown different clinical benefits; however, study populations and statistical methodologies varied.

**OBJECTIVE:** This research aimed to assess the annualized mean all-cause and influenza-related total healthcare costs of aTIV compared to TIV-HD among subjects 65+ years for the 2017-18 flu season.

**METHODS:** A retrospective cohort analysis of older adults was conducted using professional fee, prescription claims and hospital charge master data in the U.S. Baseline characteristics included age, gender, payer type, region, Charlson Comorbidity Index, location of vaccine receipt, comorbidities, indicators of frail health status, and pre-index hospitalization rates. Treatment selection bias was adjusted through 1:1 propensity score matching (PSM). Economic outcomes were compared using paired t-test including annualized mean all-cause costs and influenza-related costs, which included the costs of influenza-related hospitalizations, ER visits and physician office visits (along with associated outpatient pharmacy). Costs were adjusted using generalized estimating equation (GEE) models, with two-part models used for influenza-related costs. With the GEEs, adjustment for outliers (99th percentile) was also performed and predicted healthcare costs were obtained through bootstrapping (500 replications).

**RESULTS:** During the 2017-18 flu season, the PSM sample comprised 234,313 recipients of aTIV and 234,313 recipients of TIV-HD. Following GEE adjustment, predicted mean annualized all-cause and influenza-related costs per patient were statistically similar between aTIV and TIV-HD (US $9,999 vs. US $10,022 and US $28.21 vs. US $31.77, respectively). Both aTIV and TIV-HD were comparable in terms of predicted mean annualized costs for influenza-related hospitalizations (US $27.59 vs. US $26.29) and influenza-related ER visits (US $3.97 vs. US $4.49). However, aTIV was associated with significantly lower mean annualized costs for influenza-related physician office visits (US $1.10 vs. US $1.36).

**CONCLUSIONS:** In adjusted analyses, total all-cause and influenza-related healthcare costs during the 2017-18 flu season were comparable for older adults vaccinated with aTIV or TIV-HD.

**SPONSORSHIP:** Seqirus Vaccines

## J3 Short- and Long-Term Impact of Influenza Infection on Health Resource Utilization and Diabetes Complications of Type 2 Diabetes Patients

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**BACKGROUND:** Influenza can be a severe infection in patients with chronic disease and can lead to complications or exacerbations of the underlying comorbidities. Type 2 diabetes mellitus (T2DM) is a chronic disease that puts patients at high risk for flu-related complications. Influenza infection may lead to long-term worsening of diabetes and associated complications in T2DM patients. However, the long-term impact of influenza on this patient population is not well studied.

**OBJECTIVE:** To evaluate the short- and long-term impact of influenza on T2DM patients' health resource utilization (HRU) and incidence of diabetes complications.

**METHODS:** A retrospective cohort study was conducted using US commercial claims data from the 2016-17 flu season, comparing the HRU and incidence of complications among T2DM patients (flu vs. non-flu). Patients who had flu were matched with non-flu controls (1:5) using propensity score (caliper method). Medical expenses, hospitalizations, change in Diabetes Complications Severity Index (DCSI) score, cardiovascular disease (CVD) complications, and acute complications (hypo- and hyper-glycemic incidents) in the 12 months (Q1-Q4) following influenza infection were analyzed and compared.

**RESULTS:** 7,776 T2DM patients with influenza were identified and matched with controls (n = 38,880). During Q1 (first 91 days) following flu diagnosis, the patients in the flu cohort, compared to controls had 53.16% higher medical expenditure ($3,993 vs. $2,607, $P < 0.001$), 140.91% more hospitalizations (0.053 vs. 0.022, $P < 0.001$), and 42.86% more acute complications (0.032 vs. 0.022, $P < 0.001$). Utilization rates remained higher during Q4 (273-364 days): compared to the controls, the flu cohort had 14.29% higher medical expenditure ($3,311 vs. $2,897, $P = 0.0151$), 16.67% more hospitalizations (0.028 vs. 0.024, $P = 0.063$), and no difference in acute complications. In the year following flu infection, the flu cohort had 12.83% more patients newly diagnosed with a CVD complication ($P = 0.044$) and 18.26% increase in DCSI score ($P < 0.001$), compared to the controls.

**CONCLUSIONS:** T2DM patients who suffered from influenza had significantly higher HRU both in the short-term and up to one year following infection. In addition, the flu cohort had a significant increase in chronic complications related to diabetes over the year following flu infection. The data from this large cohort study may suggests that influenza could have a sustained negative impact on both HRU as well as worsening of diabetes-related chronic complications in the T2DM population.

**SPONSORSHIP:** Genentech

## J4 New Initiators to Asthma Biologics: A Pre/Post Analysis of Total Cost of Care and Asthma-Related Events Among 14 Million Commercially Insured Members

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**BACKGROUND:** Asthma affects approximately 25 million Americans with an estimated societal cost of $56 billion. Guidelines recommend biologics for patients with severe allergic or eosinophilic asthma. Little is known about the real-world utilization patterns of asthma biologics, and their impact on total cost of care.

**OBJECTIVE:** To identify members newly initiating asthma biologic and describe persistence, total cost of care, and asthma event rate before and after initiating biologic.

**METHODS:** Integrated pharmacy and medical claims data among 14 million commercially insured members were queried from Jul 2017 to Dec 2018 to identify members with at least one claim for an asthma biologic: reslizumab, benralizumab, mepolizumab, or omalizumab. Members were continuously enrolled 182 days before (pre-period) and 182 days after (post-period) their index claim. Members were new starts defined as no asthma biologic in the pre-period. Persistence was defined as member having asthma biologic claims indicating dosing according to prescribing information during the post-period. All

medical and pharmacy claims plan plus member paid costs were captured in the pre- and post-period to determine total cost of care (TCC). Post-period TCC was broken into medical and pharmacy cost with and without asthma biologics. Asthma-related events (hospitalizations and/or ER visits) were identified in the pre- and post-period and described at a member level.

**RESULTS:** Between Jul 2017 and Dec 2018, 1,492 commercially insured members newly initiated asthma biologic and met continuous enrollment criteria: 30 reslizumab, 84 benralizumab, 432 mepolizumab, 946 omalizumab. 52% of members persisted on asthma biologic therapy during the post-period. Average per member pre-period TCC was $10,913 (medical $7,221 and pharmacy $3,692) and average post-period TCC was $28,233 (non-asthma biologic medical $7,436, non-asthma biologic pharmacy $4,337, asthma biologic $16,460). Members experiencing 1 or more asthma-related events were 2.5% in the pre-period and 1.3% in the post-period.

**CONCLUSIONS:** Among 1,492 commercially insured members newly starting an asthma biologic, average TCC increased 158% in the 6 months after starting therapy compared to 6 months prior with 95% of the cost increase due to the asthma biologic. The pre- to post-medical cost increased 3%. Although the asthma medical event rate was infrequent prior to asthma biologic, the rate decreased 48% in post-period. With a better understanding of real-world utilization and cost of asthma biologics, health insurers may implement value-based agreements for fair pricing to value.

**SPONSORSHIP:** Prime Therapeutics

## J5 Characteristics of New Users of Fluticasone Furoate/Umeclidinium/Vilanterol or Multiple-Inhaler Triple Therapy in Patients with Chronic Obstructive Pulmonary Disease

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**BACKGROUND:** Current guidelines suggest use of triple therapy for chronic obstructive pulmonary disease (COPD) patients on inhaled maintenance therapy who remain uncontrolled or at risk of future exacerbations. In a previous study, 90.4% of new multiple-inhaler triple therapy (MITT) users had a history of exacerbations or maintenance medication use prior to initiation. Fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) was approved in 2017, and these users have not been assessed.

**OBJECTIVE:** To assess baseline characteristics of new initiators of FF/UMEC/VI or MITT.

**METHODS:** We identified patients from the Optum Clinformatics Data Mart initiating FF/UMEC/VI between 10/01/2017–09/30/2018. In parallel, treatment patterns of new users of MITT consisting of an inhaled corticosteroid (ICS), long-acting muscarinic antagonist (LAMA), and long-acting β-agonist (LABA) were assessed. Index date was defined as earliest fill for FF/UMEC/VI or dispensing date that completed MITT. Eligibility criteria included: age ≥40 years, 12 months' continuous enrollment pre-index, and ≥1 diagnosis of COPD in any position in 12 months pre-index. Patients were excluded for use of their index identified therapy in the 12-month pre-index period. Baseline characteristics of interest were patient sociodemographics and comorbidities, patterns of COPD medication use, and exacerbation history. No statistical analysis was conducted to assess between-group differences.

**RESULTS:** Overall, 3,933 FF/UMEC/VI users and 18,244 MITT users met the study criteria. FF/UMEC/VI and MITT initiators were similar in baseline demographics and comorbidities with 83.2% vs 74.8% >65 years, 96.4% vs 86.3% Medicare enrollees, and 2.8 vs 3.0 mean Quan-Charlson comorbidity score, respectively. The majority of FF/UMEC/VI initiators switched from MITT (38.5%), followed by ICS/LABA (19.0%), LAMA/LABA (9.1%), and LAMA (5.7%). MITT initiators moved from ICS/LABA (36.1%), followed by LAMA (17.4%), and LAMA/LABA (5.5%). For new FF/UMEC/VI and MITT users respectively, 46.7% vs 45.0% had both a baseline exacerbation and controller medication, and 35.0% vs 41.9% had only a controller medication. 89.1% of new FF/UMEC/VI users vs 93.8% of new MITT users had at least one previous exacerbation, maintenance medication use, or both in the 12 months prior to initiation.

**CONCLUSIONS:** In the real world, triple therapy in COPD is frequently utilized after previous maintenance medication use or exacerbation, suggesting that most triple therapy initiators may not have been adequately controlled.

**SPONSORSHIP:** GlaxoSmithKline

## J6 "In the Patient's Own Words": Lateralizing Data Using Artificial Intelligence to Improve Quality of Life in Moderate to Severe Asthma

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**BACKGROUND:** Lack of adherence with prescribed medication increases costs and exacerbates health outcomes including quality of life (QoL). In asthma, patient-specific nuances of care are overlooked with traditional survey evaluation methods. The trUStr chatbot lateralizes SMS and wearables data, asynchronously, using artificial intelligence (AI) and nudge to arrive at a continuously populating window of real world evidence (RWE). The consequent intelligent patient reported outcomes (iPROs) are then transformed from the patient's own words into lateralized inferences concerning quality of life.

**OBJECTIVE:** This study modeled patient-centric structural determinants of adherence rates among moderate-to-severe asthma patients to explore how trUStr may improve adherence as well as collect valuable RWE. The first hypothesis was that age and medical condition should have a significant effect on adherence. The second was that behavioral nudging would not only increase adherence but also the frequency and depth of conversation.

**METHODS:** The population (N = 37,359) comprised US commercially-insured patients identified from administrative claims in the "HealthCore Integrated Research Database" (HIRD) as having >1 medical claim with an ICD-10-CM diagnosis code for moderate or severe persistent asthma (J45.4x or J45.5x) between 04/01/2018 and 03/31/2019. Two Structural Equation Models (SEMs) estimated direct, indirect and total effect sizes of age and medical condition on "Proportion of Days Covered" (PDC) and "Medical Possession Ratio" (MPR), mediated by patient medical and pharmacy visits. 14 additional SEMs were evaluated to lateralize the trUStr findings and conduct sensitivity analysis.

**RESULTS:** HIRD data evaluated through the trUStr lens revealed mean adherence rates of 59% (S.D. 29%) for PDC and 58% for MPR (SD 36%). Each additional year of patient age yielded a positive effect on the adherence rate. Each additional modeled reward and interaction with trUStr revealed a positive effect on increasing the adherence rate as well as depth and frequency of communication.

**CONCLUSIONS:** The trUStr model presents an opportunity to increase adherence by ~40%, reduce the patient response burden, shorten trials, and bring new meaning to text-based data.

**SPONSORSHIP:** Sanofi

## J7 Effect of an Asthma-Related Educational Intervention Targeting Pharmacies in a Managed Care Organization CHIP/Medicaid Network in the Provision of Pharmaceutical Care Incentive Programs for Asthma and Patients' Process and Outcomes Measures

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**BACKGROUND:** Asthma is a chronic inflammatory lung disease that causes a substantial clinical, humanistic, and economic burden on society. Patient education and compliance monitoring are the mainstays of asthma self-management. Pharmaceutical Care Incentive (PCI) programs provide pharmacist reimbursement incentives for providing inhaler training and compliance monitoring. The PCI program aims to improve members' health and minimize their medical costs.

**OBJECTIVE:** To evaluate the impact of an educational intervention targeting pharmacists on utilization, clinical, and economic outcomes in patients with asthma.

**METHODS:** This study follows a pre-post intervention design. In January 2019, community pharmacists and technicians in a Managed Care Organization (MCO) CHIP/Medicaid Network were recruited for an educational intervention on optimizing asthma management and utilizing PCI program codes for reimbursement. The study population included beneficiaries visiting the network pharmacies with at least one asthma-related pharmacy and medical claim. Process, outcomes, and cost variables for the identified cohort were captured from January 1 to June 30 for 2018 and 2019. Variables of interest included: incidence of PCI claims for compliance monitoring and inhaler training, utilization and adherence to asthma pharmacotherapies, the incidence of asthma-related emergency department (ED) visits, length of stay (LOS) for asthma-related hospitalizations, and direct medical costs.

**RESULTS:** Between the months of January 1 and June 30 pre and post-intervention, the incidence density of PCI claims per 100 patient-months for compliance monitoring and inhaler training were significantly increased from 0.76 to 1.65 (n = 2,460, $P < 0.001$) and 0.05 to 0.20 (n = 2,460, $P < 0.001$), respectively. Furthermore, the incidence density of ED visits for asthma exacerbation was reduced from 0.43 to 0.22 per 100 patient-months (n = 2,460, $P = 0.002$), and hospital LOS was significantly reduced from 1.79 days to 1.30 days (n = 2,460, $P = 0.008$). However, direct medical costs were not statistically significant ($1,833.74 in 2018 vs $1,203.51 in 2019, $P = 0.26$). Lastly, among patients who received asthma-related medication counseling, adherence improved from 23 % to 34 % (n = 198, $P < 0.001$).

**CONCLUSIONS:** This intervention was designed to educate the pharmacy personnel of an MCO CHIP/Medicaid Network to optimize asthma-related point-of-sale counseling. Results demonstrate a post-intervention reduction in asthma-related ED visits and hospital LOS, reduction in direct medical costs, and improved medication adherence.

**SPONSORSHIP:** Global Institute for Hispanic Health

## J15 Modeling Survival and Long-Term Health Outcomes of Patients with Cystic Fibrosis Aged ≥6 Years Homozygous for the F508del-CFTR Mutation Treated with Tezacaftor/Ivacaftor

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**BACKGROUND:** Tezacaftor/ivacaftor (TEZ/IVA), a combination cystic fibrosis (CF) transmembrane conductance regulator (CFTR) modulator targeting CFTR protein defects, is approved in the US to treat patients (pts) aged ≥ 6 y with CF homozygous for the *F508del-CFTR* mutation (*F/F*) or with ≥ 1 *CFTR* mutation responsive to TEZ/IVA based on in vitro data and/or clinical evidence.

**OBJECTIVE:** To examine projected survival and long-term health outcomes in *F/F* pts aged ≥ 6 y treated with TEZ/IVA + best supportive care (BSC) vs BSC alone using simulation modeling.

**METHODS:** The model was adapted from a previously published lifetime individual pt simulation model in CF. Base-case analysis was performed using a modeled cohort representative of eligible *F/F* pts in the US with baseline characteristics derived from *F/F* pts aged ≥ 6 y in the US CF Foundation Patient Registry (CFFPR). Clinical efficacy inputs were derived from TEZ/IVA pivotal trials: EVOLVE (≥ 12 y) and EMBRACE (6 to < 12 y). Age-specific annualized lung function decline rates based on analysis of the CFFPR were used to model disease progression over the lifetime with BSC alone. Following initial acute improvement in ppFEV1, TEZ/IVA is assumed to reduce the long-term lung function decline rate by 61.5% vs BSC alone based on long-term clinical study findings in pts ≥ 12 y. Survival, lung transplant, and time spent in ppFEV1 strata were examined. Survival outcomes when TEZ/IVA was initiated at various ages (6, 12, 18, or 25 y) were modeled to examine the potential impact of early treatment initiation.

**RESULTS:** Mean baseline age and ppFEV1 of the modeled cohort were 21 y (SD = 10.5) and 74.4 percentage points (SD = 25.8), respectively. TEZ/IVA was projected to increase median predicted survival by 12.4 y vs BSC alone (51.4 vs 39.0 y). Pts treated with TEZ/IVA were predicted to spend a greater proportion of their lifetime with higher lung function than those treated with BSC alone (ie, on average, 44% of lifetime with ppFEV1 ≥ 70 percentage points with TEZ/IVA vs 29% with BSC alone). Despite longer life expectancy, the predicted proportion of TEZ/IVA-treated pts undergoing lung transplant was approximately half that of patients who received BSC alone (4.6% vs 8.7%). Assuming TEZ/IVA initiation at age 6, 12, 18, or 25 y, the incremental median predicted survival vs BSC alone was 26.5, 19.1, 14.3, and 9.9 y, respectively.

**CONCLUSIONS:** TEZ/IVA is projected to improve survival and long-term health outcomes in *F/F* pts aged ≥ 6 y. Based on this model, earlier treatment with TEZ/IVA is expected to lead to greater projected survival gains.

**SPONSORSHIP:** Vertex Pharmaceuticals

## J16 Modeled Survival Gains and Cost-Effectiveness of Trikafta (Elexacaftor/Tezacaftor/Ivacaftor) in the Treatment of Patients with Cystic Fibrosis in the US

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**BACKGROUND:** Elexacaftor/tezacaftor/ivacaftor (ELX/TEZ/IVA) is a breakthrough therapy recently approved in the US to treat the underlying cause of cystic fibrosis (CF) in patients aged ≥ 12 yrs who have at least one *F508del* mutation in the *CFTR* gene.

**OBJECTIVE:** We estimated survival and cost-effectiveness (CE) of ELX/TEZ/IVA in the largest group of indicated patients who did not previously have a treatment for the underlying disease. Because standard CE methods have limitations when applied to lifelong, life-extending treatments for rare, chronic diseases, we explored the impact of alternative assumptions to address these limitations.

**METHODS:** A validated lifetime patient-level simulation model was used to estimate survival and CE in the US of ELX/TEZ/IVA with best supportive care (BSC) vs BSC alone in a simulated cohort of patients heterozygous for *F508del* and a minimal function mutation (F/MF)

aged ≥12 yrs (mean age: 26.2 yrs); outcomes were also evaluated for a simulated cohort of F/MF patients initiating ELX/TEZ/IVA treatment at age 12. Clinical efficacy inputs were derived from a Phase 3 study in F/MF patients (NCT03525444), in which ELX/TEZ/IVA significantly improved ppFEV1 by 14.3 points vs placebo through 24 weeks and lowered the rate of pulmonary exacerbations treated with IV antibiotics by 78%. Model assumptions were varied to quantify the impact of reasonable alternatives to standard C methods (1) discount rate (base case [BC]: 3.0% costs and health, alternate scenario [AS]: 3.0% costs, 1.5% health); (2) utility values (BC: no treatment-specific utilities, AS: 0.15 ELX/TEZ/IVA-specific utility increment); (3) disease management costs during extended survival (BC: included, AS: excluded); (4) generic pricing (BC: ELX/TEZ/IVA price constant over lifetime horizon, AS: price reduced at patent expiry).

**RESULTS:** ELX/TEZ/IVA was projected to increase median survival of F/MF patients aged ≥12 yrs by 21.8 yrs (61.2 vs 39.4 yrs for BSC alone). The BC incremental CE ratio (ICER) was $549,500. Applying all 4 alternate assumptions doubled the incremental quality-adjusted life-years and reduced the ICER by 75%, to $136,700. In the cohort of patients initiating at age 12, the incremental survival benefit was 37.0 yrs, and the ICER was $88,300 when all 4 alternate assumptions were applied.

**CONCLUSIONS:** ELX/TEZ/IVA is projected to substantially increase survival for CF patients in the US; initiating treatment at the youngest indicated age is expected to provide even greater survival benefit. Estimates of CE of this novel, life-extending therapy are highly sensitive to modeling assumptions.

**SPONSORSHIP:** Vertex Pharmaceuticals

## K00-K93 Diseases of the Digestive System
*(e.g., Crohn's Disease, IBD, IBS)*

### K1 The Economic Burden of Eosinophilic Esophagitis in the USA: A Retrospective, Matched Cohort Study

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**BACKGROUND:** Eosinophilic esophagitis (EoE) is a chronic, immune-mediated disease of the esophagus, characterized by esophageal dysfunction and eosinophil-predominant inflammation. There are currently no FDA-approved therapies for EoE in the USA. The healthcare costs associated with EoE are not well understood; relevant studies are limited and outdated.

**OBJECTIVE:** This retrospective, matched cohort study assessed the economic burden of EoE in the USA.

**METHODS:** The US healthcare claims databases Truven Health MarketScan Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits were used to identify patients diagnosed with EoE from January 2008 to September 2016. All-cause healthcare resource utilization (HCRU) and costs were recorded 12 months before (baseline) and 12 months after (study period) the date of diagnosis (index). A cohort of individuals without EoE was matched 1:1 for age, sex, geographic region, Charlson Comorbidity Index (at baseline) and time from eligibility start date to index date. Generalized linear models were used to compare cohorts. Generalized estimating equations controlled for correlation between pairs.

**RESULTS:** Overall, 16,094 pairs were included in the EoE and matched cohorts. Of patients with EoE, 73.9% underwent a diagnostic endoscopy during the study period vs 1.7% of controls. Inpatient admissions and ER visits occurred more frequently in patients with EoE than in controls (both $P<0.0001$). Patients with EoE were significantly more likely to have an outpatient visit than matched controls were, including visits to a gastroenterologist or a psychologist ($P<0.0001$). During the study period, the mean (SD) annual total healthcare cost in patients with EoE was $12,268 ($26,852) vs $4,325 ($16,011) in the control cohort; the predicted mean cost difference was $5,907 ($P<0.001$). The predicted mean differences were: for inpatient costs, $726 ($P<0.001$); for ER costs, $537 ($P<0.001$); and for outpatient costs, $3,123 ($P<0.001$). Patients with EoE also had higher pharmacy (predicted mean difference $546 [$P<0.001$]) and endoscopy costs (predicted mean difference $3,259 [$P<0.001$]).

**CONCLUSIONS:** This study using US healthcare claims data shows that patients with EoE bear a significant burden of disease and unmet needs remain, leading to higher HCRU and costs than patients without EoE.

**SPONSORSHIP:** Shire Human Genetic Therapies, a Takeda company

### K2 Evaluating the Economic Burden and Hospitalization Among Patients with Inflammatory Bowel Disease in the US Veterans Health Administration Population

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**BACKGROUND:** Inflammatory bowel disease (IBD) is a chronic condition that affects quality of life, work productivity, and health care resource use while imposing a significant burden on patients, providers, and payers. Measuring the current economic burden of IBD provides important information on its impact on society.

**OBJECTIVE:** To assess economic burden and examine significant demographic and clinical predictors for hospitalization for IBD patients in US Veterans Health Administration (VHA) population.

**METHODS:** Adult patients with ≥1 diagnosis for IBD (International Classification of Disease, 9th revision, Clinical Modification code 555, 556; ICD-10-CM: K50, K51) during the identification period (01OCT2014-30SEP2017) were included from the VHA population. The first IBD diagnosis was designated as the index date (case cohort). Patients without IBD diagnosis, but with the same age, sex, race, and index year as an IBD patient, were identified as controls. The index date for controls was randomly selected to minimize bias. Patients were required to have continuous enrollment for 12 months pre and post (follow-up) index date. Health care costs and utilizations during the follow-up period were compared among case and control patients. Among case (IBD) patients, predictors of hospitalization were examined using logistic regression (covariates included age [ref: ≥65 years], race [ref: white], Charlson comorbidity index [CCI]). Odds ratio (OR) and 95% confidence interval (CI) were reported.

**RESULTS:** A total of 55,343 patients were included in each cohort. The mean age was 64 years and 92% were males. IBD patients had higher mean CCI scores (1.24 vs 0.98; $P<0.001$) than control patients. During follow up, the IBD cohort had an almost five times higher proportion of patients with ≥1 hospitalization (11.9% vs 2.8%; $P<0.001$) and incurred significantly higher inpatient ($4,199 vs $966), outpatient ($5,712 vs $2,356), pharmacy ($1,951 vs $528), and total healthcare costs ($11,862 vs $3,850) compared to the control cohort. Among IBD patients only, higher CCI score (OR: 1.33, 95% CI: 1.31-1.35), age ([18-25 years: OR: 2.62, 95% CI: 1.84-3.72]; [26-34 years: OR:1.64; 95% CI: 1.46-1.85]; [35-54 years: OR: 1.34; 95% CI: 1.25-1.45]; [55-64 years: OR: 1.49; 95% CI: 1.39-1.59]), and race (black: OR: 1.16, 95% CI: 1.07-1.25) were significant predictors of a hospitalization.

**CONCLUSIONS:** Patients diagnosed with IBD had significantly higher economic burden and hospitalization than those without IBD. Higher CCI score, age, and black race were significant predictors of hospitalizations.

**SPONSORSHIP:** None

## K6 Pharmacist Consultation in Individuals with Chronic Idiopathic Constipation or Irritable Bowel Syndrome with Constipation: Results from the BURDEN-CIC and BURDEN IBS-C Surveys

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**BACKGROUND:** With the wide availability of over-the-counter drugs to treat symptoms of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C), individuals with CIC and IBS-C are likely to self-treat their constipation and may not present to a healthcare provider (HCP). Pharmacists can play a critical role in engaging with these individuals to address concerns and optimize treatment.

**OBJECTIVE:** The purpose of this analysis is to explore the use of pharmacists as medical consultants to patients with CIC and IBS-C.

**METHODS:** The BURDEN-CIC and BURDEN IBS-C IRB-approved online surveys (conducted between June 29, 2016, and January 30, 2017) were designed to better understand the experiences, attitudes, and unmet needs of patients with CIC or IBS-C. BURDEN-CIC and BURDEN IBS-C used proprietary databases to identify patients with CIC and IBS-C symptomatology, respectively, either by self-reporting a formal diagnosis of CIC or IBS-C or by fulfilling Rome IV criteria in the survey.

**RESULTS:** A total of 1,223 participants with CIC and 1,681 participants with IBS-C completed the survey. Of participants with CIC (n = 188) and IBS-C (n = 431) who were not formally diagnosed, only 1.4% and 2.8%, respectively, had ever discussed their symptoms with a pharmacist. Of participants with CIC (n = 1,035) and IBS-C (n = 1,250) who were formally diagnosed, 28.5% and 24.3%, respectively, discussed their symptoms with a pharmacist. Diagnosed participants with IBS-C were more likely to discuss symptoms with a pharmacist after consulting an HCP (13.9%) compared to before meeting with an HCP (10.4%). Examples of HCPs include a medical doctor, physicians' assistant, nurse, or nurse practitioner. Participants who self-managed their symptoms prior to consulting an HCP (CIC, n = 1,079; IBS-C, n = 1,347) had attempted various methods of treating their symptoms, including nonprescription over-the-counter medications (39.8% and 28.9%, respectively), probiotics or prebiotics (20.1% and 18.2%), fiber (40.5% and 41.3%), and stool softeners (36.8% and 28.5%). On average, these participants had tried 3.4 (CIC) and 3.7 (IBS-C) over-the-counter products prior to speaking with an HCP.

**CONCLUSIONS:** Results from BURDEN-CIC and BURDEN IBS-C reveal that individuals with CIC or IBS-C who were not formally diagnosed were not utilizing pharmacists as a source of information for managing their symptoms, even though nearly half of individuals with CIC or IBS-C are using over-the-counter medications to treat their symptoms before consulting an HCP.

**SPONSORSHIP:** Salix Pharmaceuticals

## K7 Efficacy and Safety of Plecanatide in Patients with Irritable Bowel Syndrome with Constipation: Per Protocol Analysis of 2 Pooled, Randomized Phase 3 Studies

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**BACKGROUND:** Irritable bowel syndrome with constipation (IBS-C) is a chronic condition that impacts quality of life. Plecanatide, a uroguanylin analog, was evaluated in 2 identically designed, 12-week, phase 3 trials of adults with IBS-C.

**OBJECTIVE:** This study aims to pool these results to evaluate efficacy and safety of plecanatide.

**METHODS:** Eligible patients (aged 18-85 yrs) meeting IBS-C Rome III criteria were randomized to once-daily placebo (PB), plecanatide 3 mg, or plecanatide 6 mg. Primary efficacy endpoint in both trials was the percentage of overall responders (OR), defined as patients who were both abdominal pain responders (≥ 30% decrease in worst abdominal pain vs baseline) and stool frequency responders (increase ≥ 1 complete spontaneous bowel movement vs baseline) in the same week for ≥ 6 of 12 treatment weeks. Plecanatide 3 mg and 6 mg were compared to PB. Safety and tolerability were assessed. Efficacy and safety data from both studies were pooled.

**RESULTS:** A total of 1818 patients were included in the combined per protocol population (PB, N = 602; 3 mg, N = 621; 6 mg, N = 595). Per protocol patients completed treatment or discontinued due to an adverse event (AE) or lack of efficacy and were diary/treatment compliant with no major protocol violations. Demographics were similar between treatment groups and across studies. Plecanatide treatment resulted in a significantly greater percentage of OR than PB (PB, 17.6%; 3 mg, 27.5%; 6 mg, 30.4%; $P < 0.001$ for both doses). A significantly greater percentage of plecanatide-treated patients were weekly abdominal pain responders ($P < 0.001$ for both doses) and weekly stool frequency responders (3 mg, $P = 0.001$; 6 mg, $P < 0.001$) for ≥ 6 of 12 weeks. Plecanatide significantly improved patient-reported symptoms (including stool consistency and straining severity) at Week 12 with significant improvements seen by Week 1 ($P < 0.001$ for both doses). Limited differences between 3 mg and 6 mg plecanatide were identified. AEs were similar in all groups; diarrhea was the only AE occurring in ≥ 2% of patients with an incidence greater than PB (PB, 1.0%; 3 mg, 4.3%; 6 mg, 4.0%). Rates of discontinuation due to diarrhea were low (PB, 0%; 3 mg, 1.2%; 6 mg, 1.4%).

**CONCLUSIONS:** The main symptoms of IBS-C (abdominal pain and reduced stool frequency) as well as secondary symptoms were significantly improved with 12 weeks of once-daily plecanatide treatment compared with PB. In plecanatide-treated patients, there were low AE and discontinuation rates, including diarrhea. Plecanatide is a safe and effective treatment option for patients with IBS-C.

**SPONSORSHIP:** Salix Pharmaceuticals

## K8 Incremental Burden of Nonalcoholic Steatohepatitis Among Patients with Type 2 Diabetes Mellitus

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**BACKGROUND:** The prevalence of nonalcoholic steatohepatitis (NASH), an inflammatory liver disease and leading cause of cryptogenic cirrhosis, continues to rise. Insulin resistance is implicated as a key mechanism leading to NASH and Type 2 Diabetes Mellitus (T2DM) is frequently observed in patients with NASH. The burden of NASH, partially in relation to T2DM, has not been well examined, and is important to characterize as new pharmacologic therapies emerge.

**OBJECTIVE:** To compare liver disease progression, healthcare resource utilization (HCRU) and cost between T2DM patients with and without NASH.

**METHODS:** In a national commercial health plan claims database, patients with evidence of T2DM between 10/1/15 and 10/31/17 were identified. Among those with a diagnosis of NASH (T2DM + NASH), the first NASH diagnosis date was defined as index date. For patients without a diagnosis of NASH (T2DM only), index date was defined by adding offsets after the 1st T2DM diagnosis date (median days between 1st T2DM diagnosis and 1st NASH diagnosis in those with NASH). Patients with hepatitis or alcohol abuse in 1 year pre-index

were excluded. The two study groups were 1:1 matched based on propensity scores. Outcome measures, including disease progression (cirrhosis, hepatocellular carcinoma (HCC), or liver transplant), all-cause death, HCRU and cost, were compared between matched groups.

**RESULTS:** A total of 5,582 T2DM patients had NASH and 837,852 had T2DM alone. After matching, both groups had 5,582 patients with balanced pre-index characteristics. During the follow-up period (mean of 18.5 and 20.4 months for T2DM+NASH and T2DM only), T2DM+NASH patients had significantly higher risk to progress to cirrhosis (hazard ratio (HR)=22.5, 95% confidence interval (CI): 26.9-54.9, $P<0.0001$) and HCC (HR=11.6, 95% CI: 4.2-32.4, $P<0.0001$), and had a 43% higher risk of death (HR=1.43, 95% CI: 1.11-1.83, $P=0.005$) compared to those without NASH. T2DM+NASH patients also had more hospitalizations (incidence rate ratio (IRR)=1.65, 95% CI: 1.57-1.73) and emergency room visits (IRR=1.19, 95% CI:1.14-1.25; all $P<0.0001$). The overall incremental cost associated with NASH was $1,812 per patient per month (95% CI: $1,578-$2,060), in which 81% was driven by inpatient care and 55% by disease progression.

**CONCLUSIONS:** NASH significantly increased the risk of cirrhosis, HCC, death, HCRU and cost among this T2DM population. NASH disease progression accounted for approximately half of the overall incremental cost burden. Our results provide real-world insight into the burden of NASH and may assist in value determination for emerging NASH therapies.

**SPONSORSHIP:** Anthem

## K9 Cost-Effectiveness of Avatrombopag for the Treatment of Thrombocytopenia in Patients with Chronic Liver Disease

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**BACKGROUND:** Patients with chronic liver disease (CLD) often have severe thrombocytopenia (platelet counts <50,000/mL) that can complicate the invasive diagnostic and therapeutic procedures these patients require as part of their clinical management, due to the increased bleeding risk. Avatrombopag is a thrombopoietin receptor agonist (TPO-RA) that is approved for the treatment of thrombocytopenia in patients with CLD as an alternative to platelet transfusions for patients undergoing a procedure.

**OBJECTIVE:** The aim of this study was to evaluate the relative cost-effectiveness of avatrombopag compared with platelet transfusion or treatment with lusutrombopag, another TPO-RA also approved for the treatment of thrombocytopenia in adult patients with CLD.

**METHODS:** A decision-tree model was developed from a US payer perspective to capture the clinical events observed in registration trials, and to project potential longer-term complications resulting from a major bleed or thromboembolic event in the scenario analyses. Treatment costs were taken from publicly available data sources; avatrombopag and lusutrombopag estimates were calculated from the US prescribing information and Phase 3 study data. The interventions were evaluated in the overall trial population, patients with platelet counts <50,000/mL, and in subpopulations with higher (>40,000/mL to <50,000/mL) and lower (<40,000/mL) Baseline platelet counts. The primary metric for this economic analysis was the per-person total cost, the cost of prophylactic platelet transfusions required, and the incremental cost per prophylactic platelet transfusion avoided.

**RESULTS:** In the overall population, avatrombopag reduced the need for platelet transfusions and produced cost-savings per person compared to Intended Platelet Transfusion (80% fewer prophylactic platelet transfusions), resulting in a relative cost savings of $4,250. The cost for lusutrombopag (15% more platelet transfusions) relative to avatrombopag was $5,819 higher than the cost of avatrombopag. Similar results were seen in both the higher and lower platelet count subgroups. The one-way and probabilistic sensitivity analyses showed that the use of avatrombopag remained cost-saving over a wide range of changes in input variables, with the incremental cost-effectiveness ratio falling into quadrant IV (decreased costs while prophylactic platelet transfusions were avoided).

**CONCLUSIONS:** From the cost-effectiveness standpoint, the use of avatrombopag is a practical strategy compared with the cost of both platelet transfusion and lusutrombopag, as it saves costs and reduces the need for prophylactic platelet transfusions.

**SPONSORSHIP:** Dova Pharmaceuticals

# L00-L99 Diseases of the Skin and Subcutaneous Tissue *(e.g., Psoriasis, Pressure Ulcers)*

## L3 Costs and Treatment Patterns Among Patients with Atopic Dermatitis Using Advanced Therapies in the United States: Analysis of a Retrospective Claims Database

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**BACKGROUND:** Many patients with atopic dermatitis (AD) are not adequately controlled with topical regimens alone.

**OBJECTIVE:** This analysis examined the management of patients using phototherapy and systemic agents and its associated costs.

**METHODS:** The IQVIA Health Plan Claims dataset from 1/1/2013-7/31/2018 was analyzed. Patients aged ≥12 years with AD (ICD-9/10-CM: 691.8/L20.x) who newly initiated an advanced therapy after the availability of dupilumab (March 28, 2017) and had ≥6 months continuous enrollment immediately before (pre-index) and immediately after (post-index) their first advanced therapy claim (index) were included. Advanced therapies included oral corticosteroids (OCS), systemic immunomodulatory agents (SIA; cyclosporine, methotrexate, azathioprine, mycophenolate), phototherapy (PT), and dupilumab (DUPI). All-cause healthcare resource use and costs were reported descriptively and compared using omnibus one-way analysis of variance (ANOVA) test statistics.

**RESULTS:** 1,980 patients were included (61.1% female; mean age=41.2 years [SD=17.4], with 11.3% <18 years). Pre-index, 65.2% of patients used topical corticosteroids (TCS; 40.7% and 32.1% used medium and high potency, respectively). The most commonly initiated advanced therapy was OCS (N=1,453; 69.2% prednisone), followed by DUPI (N=265), SIA (N=99; 47.5% methotrexate), and PT (N=163). A total of 17.4%, 26.3%, and 14.1% of DUPI, SIA, and PT patients, respectively, were prescribed OCS within 6 months post-index; 62.6%, 49.1%, 64.6%, and 36.2% of OCS, DUPI, SIA, and PT patients were prescribed TCS within 6 months post-index. Also, within the 6-month post-index observation period, a total of 5.5% of patients had an in-patient hospitalization, 35.6% had an emergency room visit, and 99.4% had an outpatient visit. Mean annualized total costs in the post-index period were $20,722 (SD=$47,014), including $11,196 (SD=$41,549) in medical costs ($7,973 [SD=$35,133] in outpatient visit costs) and $9,526 (SD=$21,612) in pharmacy costs. Mean annualized total costs varied significantly by index treatment based on the omnibus ANOVA ($P<0.05$): DUPI=$36,505 (SD=$14,028), OCS=$17,924 (SD=$49,019), SIA=$24,762 (SD=$47,583), and PT=$17,549 (SD=$57,238).

**CONCLUSIONS:** Challenges remain for AD patients who require advanced therapy. Switching to, and combination therapy with OCS and TCS were common within 6 months of initiating an advanced therapy. Patients also incurred significant costs, particularly pharmacy and outpatient costs.

**SPONSORSHIP:** Pfizer

## L4 Retrospective Analysis of Time to Biologic and Associated Healthcare Costs for Plaque Psoriasis Patients Initiated on Topical Therapy in a National Health Plan

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**BACKGROUND:** Adult patients with plaque psoriasis (PsP) are usually started on topical therapy. Time to progression to biologic therapies can impact outcomes and costs for these patients.

**OBJECTIVE:** This study identified PsP patients initiated on topical therapy to determine number of days to switching to systemic or biologic therapy and associated costs.

**METHODS:** Adults over the age of 18 diagnosed with PsP (index date), a prescription for topical therapy between January 1, 2012 and August 31, 2018, with at least 6 months eligibility pre and post diagnosis, were identified using administrative healthcare claims from a large insurer. Patients with psoriatic arthritis, pregnancy or near the end of life were excluded. The identified cohort was analyzed and evaluated for the time to switch from topical therapy to either systemic or biologic therapy, associated healthcare costs and resource utilization. Per patient per month (PPPM) medical costs and pharmacy costs were calculated for the follow up period.

**RESULTS:** A total of 40,396 patients meeting criteria were identified. The majority of patients (51%) were between the ages of 41-64 (median 55), were female (51%), had commercial coverage (73%) and were largely from the east coast (32%). Among patients that switched, the mean time to switch from topical therapy to systemic (n = 357) or biologic (n = 356) therapy was 50 or 55 days, respectively, during the 6-month follow-up period. During the follow-up period, 33% of the study population (14,187) had PsP specific visits to a dermatologist (28%; mean 1.44 visits) or PCP (8%; mean 1.21 visits). Per patient per month (PPPM) medical costs were $85 and PPPM pharmacy costs were $96, of which $67 were due to topical therapy for a total mean cost for PsP patients of $765 during the follow-up period.

**CONCLUSIONS:** PsP patients treated by health care providers are initiated on topical therapy but move to systemic or biologic therapy within 2 months. The time to switch to systemic or biologic therapy can impact the costs of treatment in these patients.

**SPONSORSHIP:** Bausch Health

## L5 Real-World Healthcare Resource Utilization and Costs of Patients with Psoriatic Arthritis Treated with Ixekizumab

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**BACKGROUND:** Ixekizumab, a high affinity IL-17 inhibitor biologic, was approved for treatment of PsA in 2017. Economic outcomes of PsA patients treated with ixekizumab in the Real World are limited.

**OBJECTIVE:** Describe healthcare resource utilization (HCRU) and costs of patients with PsA treated with ixekizumab.

**METHODS:** This retrospective cohort study used IBM MarketScan Commercial and Medicare Supplemental administrative claims databases. Adults (age ≥ 18 years) initiating ixekizumab between 1/1/2016-7/31/2019 were initially identified. The index date was the first outpatient pharmacy prescription for ixekizumab preceded and followed by 12 months of continuous enrollment with medical and pharmacy benefits. Patients were required to have at least one PsA diagnosis (ICD-9 696.0x or ICD-10 L4050-L4059) in the 12 months prior to or on index. All-cause HCRU and costs (adjusted to 2019 dollars) were reported per patient per month (PPPM) during 12 months of follow-up. Healthcare costs were also assessed after adjusting PsA treatment costs for discount rates reported by the Institute for Clinical and Economic Review (ICER).

**RESULTS:** A total of 496 patients met all selection criteria (mean age 51.1 years; 50.4% female). The majority (91.9%) were treated with a different biologic prior to ixekizumab (most common types were secukinumab [34.9%], adalimumab [28.8%] ustekinumab [21.4%]) and 93.4% had comorbid psoriasis. Over 12 months of follow-up, 6.9% and 24.8% of all patients had an inpatient admission or emergency room visit respectively (mean number of admissions 0.12 [SD = 0.06] and ER visits 0.27 [SD = 0.20] PPPM). The mean total all-cause and PsA-related healthcare costs measured PPPM were $7,638 (SD = $5,370) and $6,113 (SD = $2,431), of which pharmacy costs for PsA treatment were the primary driver (97.5% of PsA-related costs). While ixekizumab costs ($5,233 [SD = $2,497]) accounted for 85.6% of PsA-related healthcare costs, only 3.5% were patient out of pocket expenses (96.5% were health plan paid). Adjusting for the ICER discount rate reduced ixekizumab costs by 44.0% and other PsA treatment costs by 27.4% which decreased all-cause and PsA-related costs by $2,509 PPPM.

**CONCLUSIONS:** Among PsA patients treated with ixekizumab, outpatient pharmacy costs for PsA treatment represent the majority of total and PsA-related healthcare costs. While ixekizumab was the primary driver of PsA-related healthcare costs only 3.5% of costs were patient out of pocket expenses.

**SPONSORSHIP:** Eli Lilly

## L6 Guselkumab for Psoriatic Arthritis: Results from Systematic Literature Review and Network Meta-Analysis

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**BACKGROUND:** The efficacy of the interleukin (IL)-23 subunit p19 inhibitor guselkumab (GUS) for psoriatic arthritis (PsA) has recently been demonstrated in two Phase 3 trials (DISCOVER 1 & -2) but has not been evaluated versus existing targeted therapies for PsA.

**OBJECTIVE:** To compare GUS to targeted therapies for PsA through network meta-analysis (NMA).

**METHODS:** A systematic literature review was performed to identify PsA randomized controlled trials (RCTs) from 2000 to 2018. Bayesian NMAs were performed to compare treatments on American College of Rheumatology (ACR) 20/50/70 response, Psoriasis Area Severity Index (PASI) 75/90/100 response, Health Assessment Questionnaire Disability Index (HAQ-DI) score, and modified van der Heijde-Sharp (vdH-S) score. Analyses used random effects models that adjusted for placebo response via meta-regression on baseline risk when feasible. Results are summarized by ranking treatments according to surface

under the cumulative ranking curve (SUCRA) scores, which reflect the proportion of treatments that a given intervention is estimated to be better than.

**RESULTS:** Twenty-six Phase 3 studies were included. Studies were placebo-controlled up to 24 weeks and evaluated 13 targeted therapies for PsA. For ACR 20 response, GUS 100 mg every 4 weeks (Q4W) and every 8 weeks (Q8W) ranked 5th and 8th out of 20 interventions and were comparable to IL-17A inhibitor (IL-17Ai) and most tumor necrosis factor inhibitor (TNFi) agents. Similar findings were reported for ACR 50 and 70 results. For PASI 90 response, GUS Q4W and Q8W ranked 1st and 2nd out of 15 interventions and were highly likely to provide a greater benefit than most other agents. Similar findings were reported for PASI 75 and 100 results. For HAQ DI score, GUS Q4W and Q8W ranked 7th and 13th out of 20 interventions and were comparable to IL 17Ai agents and most TNFi agents. For vdH-S score, GUS Q4W and Q8W ranked 3rd and 10th out of 18 interventions, with Q8W comparable to most IL-17Ai and TNFi agents and Q4W possibly providing a greater benefit than IL-17Ai agents and most TNFi agents. Results were robust to sensitivity analyses that controlled for previous exposure to biologics or assessed outcomes at alternative timepoints.

**CONCLUSIONS:** For arthritis efficacy and physical function outcomes, GUS is comparable to most PsA treatments. For PASI outcomes, GUS is highly likely to provide a greater benefit than most other PsA treatments.

**SPONSORSHIP:** Janssen Pharmaceuticals

## L9 Assessing the Relationship Between Patient-Reported Psoriasis Treatment Satisfaction and Work Productivity

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**BACKGROUND:** The association between patient-reported psoriasis treatment satisfaction and work productivity is unknown.

**OBJECTIVE:** To assess the relationship between patient-reported psoriasis treatment satisfaction and work productivity.

**METHODS:** Data were derived from the Adelphi 2019 Psoriasis Disease Specific Programme. Two groups of patients were identified based on their reporting being satisfied or not satisfied with their current treatment. Outcomes for the WPAI and DLQI work/study domains, which were used to account for productivity loss among patients not working, were compared between groups. A sub-analysis based on disease severity was also conducted.

**RESULTS:** Of the 390 patients included, 81 patients were not satisfied (NSP) and 309 were satisfied (SP) with their current treatment. A greater proportion of NSP were female compared to SP (44 [54.3%] vs. 128 [41.4%], respectively, $P<0.05$). A greater proportion of NSP had a DLQI work/study domain score of 2-3 (13 (19.4%) vs. 5 (1.8%), $P<0.0001$). Compared to SP, a greater proportion of NSP had a greater mean overall WPAI score (28.45% vs. 11.28%, $P<0.0001$). Among patients with moderate disease (3-10% BSA), a greater proportion of NSP had a greater mean overall WPAI score compared to SP (25.53% vs. 14.50%, respectively, $P<0.05$); similarly, among patients with severe disease (>10% BSA), a greater proportion of NSP had a greater mean overall WPAI score compared to SP (43.43% vs. 18.46%, respectively, $P<0.0001$).

**CONCLUSIONS:** NSP reported greater impact of psoriasis on work productivity compared to SP, and more severe disease had greater impact on work productivity. Additional research is needed to understand factors impacting treatment satisfaction and its association with work productivity.

**SPONSORSHIP:** Janssen Scientific Affairs

## L10 Real-World Dermatology Visit in Moderate to Severe Plaque Psoriasis Patients Treated with Biologics or Apremilast

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**BACKGROUND:** Moderate-to-severe plaque psoriasis (PsO) is a chronic immune-mediated disease requiring long term treatment. Timely visits to a dermatologist may impact patients' adherence and satisfaction to treatment. However, clinical practices vary and it is unclear how often these visits happen in a real-world setting.

**OBJECTIVE:** To examine the pattern of dermatology visits among PsO patients newly initiating secukinumab (SEC), adalimumab (ADA), ustekinumab (UST), etanercept (ETA), or apremilast (APR) using a large real-world claims database.

**METHODS:** Adult PsO patients newly initiating APR or a biologic from 01/01/2015 to 08/31/2018 with at least one dermatology visit were included. Index date was at the first claim of the index medication. Eligible patients had no prior use of the index medication over the 12-month pre-index, and had continuous medical and pharmacy benefits over the 12-month pre-index and 24-month post-index periods. The number of dermatology visits and average days between visits were examined over the 24-month post-index period. Pattern of visits for patients who discontinued or switched treatment was also examined.

**RESULTS:** Overall, 5,820 patients were included: SEC, 217; ADA, 1,892; UST, 769; ETA, 690; and APR, 2,252. Over the 24-month follow-up period, the average number of dermatology visits was 6.5 (SEC, 7.5; ADA, 5.4; UST, 7.0; ETA, 5.1; and APR, 7.7); patients had more visits in year 1 (3.6) than year 2 (2.9). Median time between visits was 111.8 days (SEC, 117.4; ADA, 117.9; UST, 89.6; ETA, 116.2; and APR, 115.0). Within the 24-month follow-up period, 18.5% of patients had dermatology visits frequently (<every 2 months), 49.8% had a visit every 2-5 months, while 31.7% did not have a visit for 5 months or longer. More APR patients had dermatology visits frequently (<every 2 months) than the other treatment cohorts, and most UST patients visited every 2-5 months. Patients who discontinued or switched from their index treatment had more dermatology visits than patients who were maintained on the same treatment (6.9 vs. 7.2 vs. 5.9, respectively). The average days between visits were shorter among patients who discontinued or switched treatment than patients who were maintained on the same treatment (120.8 vs. 116.7 vs. 151.0, respectively).

**CONCLUSIONS:** Many of the PsO patients who initiated a biologic or APR visited a dermatologist approximately every 2-5 months. Patients who discontinued or switched treatment visited more often than those stayed on the same treatment.

**SPONSORSHIP:** Sun Pharmaceutical Industries

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

## M2 One-Year Cost of Targeted Immunomodulators Across Rheumatology and Dermatology Indications Among Commercially Insured US Population

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**BACKGROUND:** Targeted immunomodulators (TIMs) are used to treat autoimmune diseases including rheumatoid arthritis (RA), psoriatic arthritis (PsA), psoriasis (PsO), and ankylosing spondylitis (AS). Cost of TIMs is a key consideration for payers and it is important to understand the actual cost per patient. The current analysis reports these costs for commonly prescribed TIMs.

**OBJECTIVE:** To estimate the annual cost of TIMs per treated patient across RA, PsA, PsO and AS in a commercially insured US population.

**METHODS:** The IBM MarketScan Commercial Claims and Encounters Database spanning Jan 2015 to Jun 2018 were used for this study. Adults (18-64 years) with RA, PsA, PsO, or AS who had ≥1 claim for abatacept (ABA), adalimumab (ADA), apremilast (APR), certolizumab, etanercept (ETN), golimumab, infliximab (IFX), ixekizumab, rituximab, secukinumab, tocilizumab, tofacitinib, or ustekinumab (UST) were included. Index date was date of first claim for TIMs. Follow-up period was the one year following index date. Patients were classified as new or continuing depending on presence or absence of claim for index TIM pre-index. Patients with other TIMs related diagnoses or cancer were excluded. Cost per treated patient was the sum of index TIM and other non-index TIMs costs, plus associated administration cost divided by number of treated patients. Data analyses were performed using SQL on Databricks platform. Here we report results for commonly prescribed TIMs (≥5%).

**RESULTS:** 48,281 patients were included in study. Overall, patients indexed on ADA (33.6%), ETN (26.4%), APR (8.9%), UST (6.1%), IFX (5.9%), and ABA (5.0%). One-year cost per treated RA patient were: IFX ($47,719), ABA ($52,848), ETN ($53,336), and ADA ($58,820). One-year cost per treated PsA patient were: APR ($34,902), ETN ($53,412), IFX ($57,530), ADA ($60,615), and UST ($71,678). One-year cost per treated patient with PsO were: APR ($32,044), IFX ($53,845), ADA ($58,646), ETN ($63,701), and UST ($69,032). One-year cost per treated patient with AS were: ETN ($52,278), IFX ($53,131), ADA ($56,642). Similar trends were observed among new and continuing patients in RA and PsA, and among continuing patients in PsO and AS. Among new patients, one-year costs for IFX was higher than ADA, and lower than ETN, in PsO and AS, respectively.

**CONCLUSIONS:** One-year cost per treated patient varied considerably among TIMs and indications. Of the two most commonly prescribed TIMs, ETN has a lower cost per treated patient in RA, PsA, and AS but not in PsO suggesting an opportunity for payers to manage these costs.

**SPONSORSHIP:** Amgen

## M3 Real-World Analysis of Treatment Switching Among Patients Stable on Originator Infliximab (Remicade) Switching to an Infliximab Biosimilar or Remaining on Originator Infliximab

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**BACKGROUND:** In the US, there are limited data characterizing switching patterns among patients stable on originator infliximab (IFX).

**OBJECTIVE:** This study compares switching patterns of patients stable on originator IFX switching to an IFX biosimilar (switchers) versus those remaining on originator IFX (continuers).

**METHODS:** Symphony Health Solutions' Patient Transactional Datasets, which includes comprehensive longitudinal US claims data, was used (10/2012-03/2019) to identify adults with ≥2 claims for either rheumatoid arthritis (RA), psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, Crohn's disease (CD), or ulcerative colitis (UC). The index date (on or after 4/5/2016) was the first IFX biosimilar claim for switchers or a random originator IFX claim for continuers. Pre-index, patients had to be stable on originator IFX (i.e., ≥5 originator IFX claims in the 12 months pre-index) and had to have ≥12 months of observation prior to originator IFX initiation (i.e., originator IFX initiation was on or after 10/2013). Switchers were matched 1:3 to continuers using propensity score matching adjusted for covariates such as age, gender, type of chronic inflammatory disease, and duration of treatment with originator IFX pre-index.

**RESULTS:** Among 571 switchers and 1,713 matched continuers, mean age was 56.5 (standard deviation [SD] = 15.7) and 57.1 (SD = 16.3) years, respectively; 66.5% and 67.8% were female; mean duration of treatment with originator IFX pre-index was 762 (SD = 443) and 746 (SD = 480) days. Over a mean post-index period of 314 (SD = 222) and 309 (SD = 227) days for switchers and continuers, respectively, 118 (20.7%) switchers and 152 (8.9%) continuers subsequently switched to either another originator biologic or returned to originator IFX (HR = 2.55; $P < 0.001$). Of 118 switchers, 76.3% switched back to originator IFX and 23.7% switched to another originator biologic. The mean time to switch to another originator biologic (including originator IFX) was 142 (SD = 120) days for switchers and 182 (SD = 147) days for continuers. Similar results were found among the subgroups of patients with RA (HR = 2.16; $P < 0.001$) and with CD or UC (HR = 3.42; $P < 0.001$).

**CONCLUSIONS:** Patients switching from originator to biosimilar IFX were 2.55 times more likely to subsequently switch to either another originator biologic or return to originator IFX, compared to patients remaining on originator IFX, with >75% returning to originator IFX on average within 5 months. Further research is needed to understand the higher rate of switching among patients switching to an IFX biosimilar and its potential impact on clinical outcomes.

**SPONSORSHIP:** Janssen

## M4 Prevalence, Incidence, and Costs of Malignancy, Venous Thromboembolism, Anemia, and Infections in Rheumatoid Arthritis Patients Who Failed First Biologic Disease-Modifying Antirheumatic Drug

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**BACKGROUND:** The burden of malignancy, venous thromboembolism (VTE), anemia, and infections has been discussed in the context of recent launches of Janus kinase inhibitors (JAKi) for rheumatoid arthritis (RA). Understanding the prevalence, incidence, and economic burden of these conditions can help optimize treatment choices after the first biologic disease-modifying antirheumatic drug (bDMARD).

**OBJECTIVE:** To estimate the real-world prevalence, incidence, and costs of these comorbidities among patients who failed a bDMARD and switched to another bDMARD or JAKi (targeted immunomodulator [TIM]).

**METHODS:** From a large US health claims database, this study selected adults with ≥2 RA claims ≥30 days apart who initiated a first bDMARD and switched (index date [ID]; 1/1/2012-3/31/2017) to another TIM. All patients had continuous enrollment of 1 year pre- and ≥1 year post-ID. We estimated baseline prevalence (%) and on-treatment incidence (per 100 patient-years [P100PY]) of malignancy, VTE, anemia, and infections. We compared adjusted mean all-cause healthcare costs (per-patient-per-year [PPPY]) in patients who did vs did not develop these comorbidities while on index treatment.

**RESULTS:** In 4,656 patients (median age 54 years, 78% female), the baseline prevalence was 2.1% for VTE, 5.2% for malignancy, 16.2% for anemia, and 81.1% for infection (13.7% for serious infection, 6.4% for opportunistic infection, and 1.9% for herpes zoster [HZ]). During index treatment, incidence rates (P100PY) were 0.9 for VTE, 2.0 for malignancy, 6.9 for anemia and 89.3 for any infection (12.1 for serious infection, 5.4 for opportunistic infection, and 2.2 for HZ). Total PPPY adjusted healthcare costs were higher in patients with vs without VTE (deep vein thrombosis $67,624 vs $53,463 [$P=0.003$] or pulmonary embolism $92,635 vs $53,435 [$P<0.0001$]), malignancy ($78,968 vs $52,877; $P<0.0001$), anemia ($64,944 vs $51,920; $P<0.0001$), infections ($53,311 vs $49,795 $P=0.0001$), serious infection ($66,967 vs $51,402; $P<0.0001$), opportunistic infection ($58,926 vs $53,424; $P=0.0004$), and HZ ($56,183 vs $53,737; $P=0.29$).

**CONCLUSIONS:** In the real world, RA patients were affected by VTE, malignancy, anemia and infections prior to switching from the first bDMARD to the next TIM. While on next TIM, patients developed new cases of these comorbidities, which were associated with increased adjusted total healthcare costs. Clinicians and population-health decision makers should account for the burden of these comorbidities in selection treatments for RA patients who failed their first bDMARD.

**SPONSORSHIP:** Gilead Sciences

## M5 Treatment Duration and Healthcare Costs in Rheumatoid Arthritis Patients Initiating a Targeted Immunomodulator After a First Biologic Disease-Modifying Antirheumatic Drug

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**BACKGROUND:** For rheumatoid arthritis (RA) patients failing first biologic disease-modifying antirheumatic drug (bDMARD), guidelines recommend initiating another targeted immunomodulator (TIM). Understanding persistency and cost associated with treatments initiated after first bDMARD can help optimize treatments for these patients.

**OBJECTIVE:** To describe real-world persistency and total healthcare costs among RA patients who failed the first bDMARD.

**METHODS:** This large US health claims database study included adults with ≥2 RA claims ≥30 days apart who started a bDMARD (1/1/2012-3/31/2017) and switched (index date, ID) to another bDMARD or Janus kinase inhibitor (JAKi) as monotherapy or in combination with a conventional synthetic DMARD. All patients had continuous enrollment of 1 year pre- and ≥1 year post-ID. The study compared median duration of initiated treatments and total annualized per-patient-per-year (PPPY) healthcare costs (medical and pharmacy) while on treatment (via analysis of variance) and adjusted (via generalized linear model with gamma distribution and log link function) for pre-index costs, patient characteristics, and type of initiated treatment.

**RESULTS:** Among 4,656 patients (median age 54 years, 78% female), treatments lasted for median 9.5 months (overall): 5.8 months for monotherapy (5.1 tumor necrosis factor-α inhibitors [TNFi], 6.9 non-TNFi bDMARD, 6.7 JAKi) and 13.1 months combination therapy (12.3 TNFi, 15.1 non-TNFi bDMARD, 14.3 JAKi). Unadjusted mean PPPY on-treatment healthcare costs totaled $54,637 (overall): $57,791 (monotherapy) vs $51,934 (combination therapy; $P<0.0001$). JAKi, TNFi, and non-TNFi bDMARD costs totaled: for monotherapy ($51,346, $60,195, $55,762, respectively; $P=0.004$) and combination therapy ($47,579, $51,796, $53,870; $P=0.036$). Increased adjusted healthcare costs correlated with: non-TNFi bDMARD (cost ratio [CR] = 1.08, $P=0.013$) and TNFi (CR = 1.17, $P<0.0001$) vs JAKi, age (45-54 years [CR = 1.05, $P=0.076$] and 55-64 years [CR = 1.08, $P=0.015$] vs 18-34 years), locality (Northeast vs South [CR = 1.05, $P=0.004$] or vs West [CR = 1.08, $P=0.002$]), baseline Charlson Comorbidity Index (CCI = 2 [CR = 1.07 $P<0.001$], CCI ≥ 3 [CR = 1.19, $P<0.001$] vs CCI ≤ 1), increased baseline total healthcare costs ($P<0.001$), and pre-index use of opioids ($P<0.001$).

**CONCLUSIONS:** This real-world analysis demonstrated that treatment duration and total annualized healthcare costs varied by TIM initiated after the first bDMARD.

**SPONSORSHIP:** Gilead Sciences

## M6 Risk Factors for Discontinuation of Targeted Immunomodulators Initiated by Rheumatoid Arthritis Patients Failing Their First Biologic Disease-Modifying Antirheumatic Drugs

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**BACKGROUND:** For rheumatoid arthritis (RA) patients who failed a first biologic disease-modifying antirheumatic drug (bDMARD), the American College of Rheumatology recommends a treat-to-target approach. Real-world evidence on factors associated with treatment discontinuation can help optimize treatment decisions.

**OBJECTIVE:** To investigate the predictors of treatment discontinuation in RA patients switching from a first bDMARD to another treatment.

**METHODS:** From a large US health claims database, this study selected adults with ≥2 RA claims ≥30 days apart, who initiated a first bDMARD and then switched (index date [ID]) to another bDMARD or Janus kinase inhibitor (JAKi) as monotherapy or in combination with a conventional synthetic DMARD (csDMARD). All patients had continuous enrollment 1 year pre- and ≥1 year post-ID. Cox proportional hazards models evaluated factors associated with risk of discontinuation.

**RESULTS:** Among the 4,656 patients (median age 54 years, 78% female), 46% initiated monotherapy and 54% combination therapy. The initiated treatments lasted for mean 10 months (monotherapy) and 16 months (combination therapy; $P<0.0001$). Within monotherapy, the risk factors of treatment discontinuation included: initiated treatment (tumor necrosis factor-α inhibitor [TNFi] vs JAKi hazard ratio [HR] = 1.25; 95% confidence interval [CI], 1.09-1.44; $P=0.002$) and baseline characteristics (female sex [HR = 1.15; 95% CI, 1.02-1.30; $P=0.019$], region [South vs Northeast: HR = 1.16; 95% CI, 1.01-1.33; $P=0.033$], payer type [Medicaid or Medicare vs commercial: HR = 1.36; 95% CI, 1.05-1.75; $P=0.019$], short RA duration [HR = 0.92; 95% CI, 0.88-0.96; $P<0.001$)] and increased total drug count [HR = 1.02; 95% CI, 1.01-1.03; $P<0.001$]). Within combination therapy, the risk factors for treatment discontinuation included: initiated treatment (TNFi + csDMARD vs JAKi + csDMARD: HR = 1.31; 95% CI, 1.08-1.59; $P=.006$) and baseline characteristics (short duration of RA [HR = 0.92; 95% CI, 0.88-0.97; $P<0.001$] and increased total drug count [HR = 1.02; 95% CI, 1.02-1.03; $P<0.001$]).

**CONCLUSIONS:** The US claims-based analysis demonstrated the limited durability of available DMARD treatments for RA patients failing their first bDMARD. Monotherapy showed shorter treatment duration than combination therapy. Treatment discontinuation was affected by treatment regimens used and patient characteristics (sex, disease duration, and polypharmacy). Clinicians and population-health decision makers should account for risk factors affecting treatment discontinuation in selecting treatments after first bDMARD.

**SPONSORSHIP:** Gilead Sciences

## M7 Prevalence of Opioid Use and Associated Costs Among Rheumatoid Arthritis Patients at Different Stages of Disease-Modifying Antirheumatic Drug Management

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**BACKGROUND:** The 2015 American College of Rheumatology guidelines recommend a treat-to-target approach for patients with rheumatoid arthritis (RA). Treatment goals include pain management, which remains especially relevant in light of the ongoing opioid epidemic in the US. There is limited real-world evidence on the burden of opioid use in RA patients in the US.

**OBJECTIVE:** This study examined the real-world prevalence of opioid use and costs in three RA populations: naive to disease-modifying antirheumatic drug (DMARD) and patients switching treatment regimens after the first conventional synthetic DMARD (csDMARD) or biologic DMARD (bDMARD).

**METHODS:** This large US health claims database study selected adults with ≥2 RA claims ≥30 days apart who initiated a first DMARD (1/1/2012-3/31/2017, index date [ID]; DMARD initiators), changed (ID) DMARD treatment regimen after first csDMARD (csDMARD-switchers) or initiated (ID) a targeted immunomodulator after the first bDMARD (bDMARD-switchers). All patients had continuous enrollment 1 year pre- (baseline) and ≥1 year post-ID. The study modeled the effect of baseline opioid use on post-ID on-treatment total healthcare cost per-patient-per-year (PPPY), controlling for patient characteristics, baseline total costs, and types of index treatments (via multivariable regression models).

**RESULTS:** The study included 28,201 DMARD initiators, 7,816 csDMARD-switchers, and 4,656 bDMARD-switchers (median age 54 years for all, female range: 73%-78%). At baseline, the prevalence of opioid use comprised 42% (DMARD initiators), 48% (csDMARD-switchers), and 51% (bDMARD-switchers). Total unadjusted mean post-ID PPPY healthcare cost comprised $18,752 (DMARD initiators), $30,742 (csDMARD-switchers), and $54,637 (bDMARD-switchers). The baseline opioid use (except tramadol alone) was associated with increased total post-ID healthcare cost: cost ratio (CR) = 1.31 (95% confidence interval [CI], 1.27-1.34) among DMARD initiators, CR = 1.12 (95% CI, 1.08-1.17) among csDMARD-switchers, and CR = 1.10 (95%CI, 1.07-1.13) among bDMARD-switchers (all $P < 0.0001$).

**CONCLUSIONS:** The prevalent opioid usage in RA indicates an ongoing and potentially unmet need for pain control among DMARD initiators, csDMARD-switchers, and bDMARD-switchers. The pre-index use of opioids was associated with increased healthcare costs post-index. While selecting treatments for RA patients, clinicians and population-health decision makers should account for secondary outcomes such as opioid use and associated costs.

**SPONSORSHIP:** Gilead Sciences

## M8 Impact of a Two to One Step TNFi Policy Change on Treatment Patterns and Costs in Patients with Rheumatoid Arthritis in a Regional Managed Care Organization

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**BACKGROUND:** Rheumatoid arthritis (RA) is a chronic autoimmune disorder characterized by progressive articular disability and high morbidity. To date, TNF-α inhibitors (TNFi) are the most widely prescribed biologic disease modifying antirheumatic drugs (DMARDs) for RA treatment. However, about 40% of patients on TNFi fail to achieve clinical goals. Thus, drugs with other mechanisms of action (Other MoA) targeting different inflammatory pathways have been introduced. In 2017, SelectHealth, a non-profit regional managed care organization, revised their RA clinical utilization management guideline to require failure of only one, rather than two, TNFi before covering agents with Other MoA.

**OBJECTIVE:** To evaluate the number of therapy switches, medication adherence and costs of biologic DMARDs in RA patients before and after the policy change.

**METHODS:** This retrospective cohort study utilized SelectHealth medical and pharmacy claims, including non-pregnant patients aged ≥18 years with at least two diagnoses of RA (ICD-9: 714.0, 714.1; ICD-10: M05.x) between 07/01/2015 and 06/30/2019. The index date was the date of the policy change (04/01/2017). Patients were categorized based on their first biologic DMARD claim (TNFi or Other MoA) pre- and post-index. "TNFi" included adalimumab, etanercept, certolizumab, golimumab, and infliximab. "Other MoA" included abatacept, tocilizumab, rituximab, tofacitinib, anakinra and sarilumab. Drug-related outcomes (number of switches and proportion of days covered [PDC]) and costs (mean monthly copays and overall costs) were evaluated 6 months before and after the policy change.

**RESULTS:** A total of 1,008 unique patients met inclusion criteria of which 801 were initiated on TNFi and 207 initiated on Other MoA drugs. Baseline characteristics were similar pre- vs post-policy change. Across all patients initiating biologic DMARDs, 51 of 930 (5.5%) switched pre-policy change and 58 of 939 (6.17%) switched post-policy change. Adherence, as measured by PDC, was 86% pre- and 90% post-policy change (NS). Average pre- vs. post-policy monthly copays went from $70 to $63 for TNFi and $43 to $56 for Other MoA. Monthly overall costs were $728 before vs. $757 after policy change.

**CONCLUSIONS:** A change in policy requiring failure of only one TNFi reduced multi-use of TNFi and allowed for increased biologic DMARD switching in the period after implementation. Patient medication adherence improved. Average monthly copays and overall costs remained largely the same after the policy change

**SPONSORSHIP:** Sanofi

## M9 Associations Between Pharmacy Channels, Adherence to Biologic Disease-Modifying Anti-Rheumatic Drugs and Chronic Opioid Use Among Patients with Inflammatory Conditions

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**BACKGROUND:** Inflammatory conditions (IC) are complex chronic diseases often treated with biologic disease-modifying anti-rheumatic drugs (bDMARDs). IC patients may also utilize opioids to manage related long and short-term pain. While effective in controlling pain, opioids are associated with misuse, fraud, and abuse. One strategy for opioid minimization is medication optimization and adherence support. Adherent patients have better disease control, negating need for opioids to manage flares. Research evaluating relationship between pharmacy channel, bDMARDs adherence, and opioid use is lacking.

**OBJECTIVE:** To examine associations between pharmacy channels, bDMARD adherence and chronic opioid use.

**METHODS:** This was a retrospective, matched, case-control analysis using pharmacy and medical claims. Commercially insured patients

continuously eligible for pharmacy benefits from January 1, 2015 to December 31, 2017, aged 18-62, and with an IC diagnosis were included. Patients were grouped by pharmacy channel based on filling ≥75% of their bDMARDs through one specific channel—Accredo specialty pharmacy, other specialty pharmacies or retail. Chronic opioid use was defined as ≥90 days continuous use. A multivariable regression model was used to assess associations between pharmacy channel and chronic opioid use as well as adherence to bDMARDs and chronic opioid use, adjusting for demographic characteristics, prevalent user status, disease burden, prior adherence and opioid use, and adjuvant therapy.

**RESULTS:** Final sample included 1,562 patients. Accredo patients had significantly higher adherence to bDMARDs compared to other specialty and retail pharmacies (71.3% vs. 65.9% vs. 65.0%, $P<0.001$). Additionally, adherent patients had significantly lower chronic opioid use compared to non-adherent patients (13.7% vs. 17.8%, $P=0.001$). Overall opioid use (48.1% vs. 48.8% vs. 49.8%, $P=0.731$) and chronic opioid use (15.9% vs. 16.0% vs. 15.4%, $P=0.931$) did not differ significantly between pharmacy channels. Multivariable analysis showed no difference in odds of chronic opioid use across channels, but a 27% lower odds of chronic opioid use among patients adherent to bDMARDs (OR:0.73, $P<0.001$).

**CONCLUSIONS:** While chronic opioid use did not differ between pharmacy channels, our findings showed lower chronic opioid use among patients adherent to bDMARDs and higher adherence to bDMARDs among Accredo patients compared to other pharmacy channels. Specialty pharmacies can play a role in improving adherence to high cost bDMARDs leading to better disease control, thereby lowering need for concomitant opioid use among IC patients.

**SPONSORSHIP:** Express Scripts

## M10 United States Rheumatology Practice-Based Real-World Evidence of Methotrexate Utilization and Response to Therapy in Rheumatoid Arthritis Patients Treated with Intravenous Golimumab: 52-Weeks from the AWARE Study

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**BACKGROUND:** AWARE (Comparative and Pragmatic Study of Golimumab IV [GLM] Versus Infliximab [IFX] in Rheumatoid Arthritis [RA]) is an ongoing Phase 4, prospective, noninterventional, observational, multicenter, 3-year US comparator study that provides a real-world assessment of RA treatment. The primary endpoint of AWARE is the incidence of infusion reactions (Inf Rxns), but the study also records prior and current RA medications, including concomitant methotrexate (MTX). GLM is indicated for treatment of patients (pts) with moderately to severely active RA in combination with MTX.

**OBJECTIVE:** To report prospectively obtained real-world evidence-based data on GLM use without MTX in community rheumatologist settings from AWARE.

**METHODS:** RA pts were enrolled when initiating treatment with GLM (n=685) or IFX (n=585). Treatment decisions, including MTX utilization, are made by treating rheumatologists. Change from baseline (BL) in Clinical Disease Activity Index (CDAI) is based on imputed and inverse probability of treatment weighted data using LOCF for missing data and/or treatment failure rules. Data shown are mean±standard deviation.

**RESULTS:** Among GLM pts, 420 (61.3%) were MTX users (MTX+), 263 (38.4%) MTX nonusers (MTX–). Mean MTX dose±SD among GLM MTX+pts was 16.3±10.7 mg (bionaïve, 18.1±15.3, non-bionaïve, 15.3±6.3). The 2 groups were generally similar at BL. BL CDAI for MTX±30.8±15.1, MTX–=32.6±15.38. Percent pts with categorical CDAI score of moderate or high was 91.7% and 93.2% in GLM±MTX groups. Disease duration was also similar: 8.68±0.405 and 10.02±10.775 in GLM±MTX groups. Over 52 weeks of treatment, the incidence of Inf Rxns in GLM pts was MTX±2.9%, MTX–=5.7%. In bionaïve pts, mean changes from BL in CDAI at 3, 6 and 12 months were GLM MTX+: -7.42, -11.03 and -11.78, MTX–: -7.93, -10.36 and -9.64. Overall discontinuation from the study was GLM MTX+=62.6%, MTX–=72.1%. 18.5% of GLM MTX– pts reported leflunomide use.

**CONCLUSIONS:** In AWARE, BL characteristics of the GLM pts±MTX were similar. Inf Rxns were numerically lower in GLM MTX+pts (2.9%) vs MTX– pts (5.7%) and discontinuations were lower. In a real-world rheumatology practice setting, use of GLM±concomitant MTX led to similar improvements in CDAI scores in RA pts with predominantly moderate to high categorical CDAI disease status at BL.

**SPONSORSHIP:** Janssen Research & Development

## M13 A Real-World Survey of Patients' Experience and Satisfaction with Intra-Articular Triamcinolone Acetonide Extended-Release for the Management of Osteoarthritis of the Knee

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**BACKGROUND:** Osteoarthritis of the knee (OAK) affects 15 million patients in the United States. Intra-articular corticosteroid injections, a mainstay of symptomatic treatment, provide analgesic benefit for approximately 4-6 weeks. Extended-release triamcinolone acetonide (TA-ER) is approved for management of OAK pain and has been in clinical use for 2 years.

**OBJECTIVE:** To examine the effectiveness of TA-ER in improving pain and symptoms of OAK in a real-world sample of patients.

**METHODS:** Patients receiving TA-ER injection in routine clinical practice were eligible and a convenience sample was recruited from physicians' offices. Participants completed interactive surveys via internet or voice response system at baseline and 4 and 12 weeks after TA-ER injection. Pain, stiffness, functional limitation, mood, and treatment satisfaction were assessed using 0-9 numeric rating scales and were grouped by categories (1-3, 4-6, 7-9).

**RESULTS:** 464 patients enrolled in the program. The response rate was 70% at Week 4 and 57% at Week 12. The mean age of participants was 66 years; 67% were female and 67% reported knee pain of >3 years' duration. In the year prior to receiving TA-ER, symptomatic treatments included over the counter pain medications (63%), topical creams (63%), prescription non opioid medications (35%), and narcotic pain medications (26%). Intra-articular treatments included traditional corticosteroids (72%) and viscosupplements (33%). Prior to TA-ER treatment, 72% characterized OAK pain as severe, and most participants reported that OAK pain markedly limited everyday activities on a daily basis (56%). Knee stiffness upon awakening was reported as severe by 56% of patients. Mood impact from OAK pain was rated as substantial by 40% of participants. Following TA-ER, most patients (87%) reported satisfactory relief from OAK pain, and 68% reported onset of pain relief within 2 days of injection. Four weeks following TA-ER, 68% reported mild OAK pain and 76% mild knee stiffness. 70% were satisfied with TA-ER, and 81% of the cohort would recommend TA-ER to others. At Week 12, 44% reported mild pain, 54% mild stiffness, and 59% were satisfied with TA-ER.

**CONCLUSIONS:** OAK imposes tremendous patient burden due to pain, stiffness, and functional impairments. In a real-world cohort, following treatment with TA-ER, patients reported substantial improvements in pain and stiffness and high treatment satisfaction at 4 weeks from injection, with persistence through 12 weeks.

**SPONSORSHIP:** Flexion Therapeutics

## M14 Cost-Effectiveness Analysis of One Year's Management of Symptomatic Osteoarthritis of the Knee with Extended-Release Triamcinolone Acetonide Versus Hyaluronic Acid

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**BACKGROUND:** Osteoarthritis (OA) is a chronic condition associated with substantial pain and functional limitations. Intra-articular injections (e.g., corticosteroids, hyaluronic acid [HA]) are frequently used during patient management. Extended-release triamcinolone acetonide (TA-ER) is approved for treatment of OA of the knee (OAK) pain and demonstrated substantial treatment response in randomized placebo-controlled trials. Evaluation of patient response with repeat administration of TA-ER has been completed.

**OBJECTIVE:** To evaluate the cost-effectiveness of repeat TA-ER administration regimens in comparison to repeat HA administration for treating OAK pain for one year.

**METHODS:** Clinical outcome data from 179 patients receiving two TA-ER administrations in a Phase 3b, open-label study (NCT03046446) were used. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC-A [pain], -B [stiffness], -C [physical function]) scores were assessed at 4-week intervals through 52 weeks after initial injection. Health Utilities Index Mark 3 (HUI3) scores were calculated from WOMAC values. The cost-effectiveness of one-year's management of OAK with TA-ER using 2-4 treatments versus 2 cycles of HA injection treatment was assessed with incremental cost-effectiveness ratios (ICERs). Treatment costs were based on the December 2019 CMS ASP pricing file; ICER < $50,000 was considered cost-effective.

**RESULTS:** In the clinical study, median time to repeat TA-ER administration based on symptom recurrence was 16.6 weeks; 25%, 34%, 21%, and 20% of patients received their second TA-ER injection at 3, 4, 5, and 6 months, respectively. TA-ER treatment was followed by marked improvements in all WOMAC scores, with peak improvement at 4 weeks after treatment. HUI3 change increased to a maximum of 0.318, 4 weeks after the initial injection. The time averaged quality-adjusted life year gains over baseline for treatment intervals of 3, 4, and 6 months were 0.269, 0.240, and 0.231, respectively, which were higher than the reported value for an average of HA therapies (6-month average, 0.118). For one year of OAK management, TA-ER produced ICERs of $8,596 and $5,088 with 3 and 4 treatments, respectively, and was dominant with 2 treatments versus 2 HA treatment cycles.

**CONCLUSIONS:** Repeat intra-articular administration of TA-ER for OAK provided marked improvements in clinical outcomes and quality-of-life measures. TA-ER was cost-effective for one year of OAK management versus HA therapy regardless of treatment frequency (2-4 times/year).

**SPONSORSHIP:** Flexion Therapeutics

## M17 Frequency of Biologic Switching in Ankylosing Spondylitis Patients in the First Year of Treatment and the Higher Healthcare Resource Utilization Profile of Patients Who Switch

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**BACKGROUND:** Little is known about the healthcare resource utilization (HCRU) profile of patients with ankylosing spondylitis (AS) who switch biologics.

**OBJECTIVE:** To describe the frequency of patients switching biologics in the 1st year of treatment and the differences in HCRU compared with patients who are persistent.

**METHODS:** This retrospective study analyzed US commercial claims data (2012-2017). AS patients were ≥ 18 years old, initiating a biologic (adalimumab, certolizumab pegol, etanercept, infliximab, golimumab, secukinumab; 1st claim [index date]), with no claims for any biologics ≥ 1 year prior to index, and continuous enrollment in the 12-months preceding (baseline [BL]) and following (follow-up [FU]) initiation. Patients were required to have either 1) one inpatient AS claim (ICD 9/10), 2) one AS claim (inpatient or outpatient) from a rheumatologist, or 3) at least two AS claims from another provider type in the baseline period. Patients were considered persistent at 12 months if they had a ≤90-day gap in the index treatment. Those initiating a 2nd biologic within 90 days of stopping the 1st were classified as having switched. Patients who discontinued and did not receive another biologic within 90 days were not included in this analysis. All-cause and AS-related HCRU (emergency room [ER] and outpatient visits) were ascertained during BL and FU.

**RESULTS:** The analysis identified 245 switch and 755 persistent patients. Switch patients were more likely to be female vs persistent patients (56% vs 38%). Mean annual all-cause HCRU rate was higher in switch vs persistent patients during both BL (ER: 0.61 vs 0.39 [$P<0.01$]; outpatient: 24.9 vs 20.4 [$P<0.01$]) and FU (ER: 0.58 vs 0.30 [$P<0.01$]; outpatient: 24.7 vs 17.7 [$P<0.01$]). Mean annual rates for AS-related outpatient visits were similar in switch vs persistent patients (3.0 vs 3.5 [$P=0.13$]) at BL but were higher in switch vs persistent patients during FU (6.9 vs 5.3 [$P<0.01$]).

**CONCLUSIONS:** Compared with persistent users, patients switching biologics in the 1st year of treatment had higher all-cause HCRU rates during BL and FU, and higher AS-related outpatient visit rates during FU. The higher HCRU during BL suggests switch patients may have a more complex overall clinical profile which needs to be considered. Understanding reasons for switching may highlight ways to cost-effectively improve persistence and reduce HCRU.

**SPONSORSHIP:** UCB Pharma

## M19 The Feasibility of Using US Claims Data to Track Performance in Duchenne Muscular Dystrophy

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**BACKGROUND:** Numerous measures exist to assess outcomes in Duchenne muscular dystrophy (DMD). However, real-world datasets including these measures to inform the understanding of DMD progression are few. While administrative claims data are commonly used for outcomes research, their utility for assessing DMD patient functional status over time is unclear.

**OBJECTIVE:** To assess the suitability of US claims datasets for assessing function and disease progression among patients with DMD.

**METHODS:** Potential outcome measures were identified from a systematic review on the natural history of DMD; and included clinical events that can define disease progression, or clinical or functional assessments used to track patient status. MarketScan Commercial claims data (2013-2018) were used to identify males ≤ 30 years old with DMD (ICD: 359.1, G71.0), to review the availability of claims data by which to measure such outcomes. These datasets include individual

linked data on outpatient visits, hospitalizations, and medications from those covered under commercial plans.

**RESULTS:** Fifty-five outcome measures were identified from the review; 49 clinical or functional assessments (e.g. the 6-minute walk test), and 6 describing natural history (e.g. age at loss of ambulation (LOA)). From 1,968 males with DMD (median age at baseline, 15 years), records documenting functional assessments as part of standard clinical work-ups (e.g. spirometry) were identified; however, no scores on those assessments were available. Data were available to use as a proxy for outcomes related to natural history; specifically for LOA (by codes for wheelchair use); need for ventilation (by procedural codes for ventilator use or tracheostomy) or respiratory insufficiency (by diagnostic codes); onset of scoliosis (by procedural or diagnostic codes); or cardiomyopathy (by diagnostic codes or commonly-used medications). Data on mortality were only available on a subset of the cohort, and only for inpatient mortality.

**CONCLUSIONS:** Data to directly track functional outcomes in DMD are unavailable in standard claims datasets. While the occurrence of natural history milestones may be inferred, severity cannot, which may be important when considering gradually progressive complications of DMD. Also, ascertainment may be incomplete for outcomes relying on events that can occur outside of insurance coverage. Given the limited functional data within standard claims datasets, prospective initiatives collecting clinical data using standardized protocols may be useful for more accurately assessing progression among patients with DMD.

**SPONSORSHIP:** Sarepta Therapeutics

## M20 Direct Costs of Care Among Commercially and Medicaid-Insured Patients with Duchenne Muscular Dystrophy in the United States

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**BACKGROUND:** Duchenne muscular dystrophy (DMD) is a severe X-linked progressive neuromuscular disease characterized by loss of ambulation, cardiomyopathy, respiratory insufficiency, and early mortality. Managing patients with DMD is healthcare resource intensive but estimates of the costs of care for DMD patients in the United States (US) are few.

**OBJECTIVE:** To estimate direct medical monthly costs of care among DMD patients with commercial or Medicaid insurance coverage in the US.

**METHODS:** MarketScan Commercial and Multi-State Medicaid claims (2013-2018) were used to identify males ≤30 years old with codes for DMD (ICD: 359.1, G71.0; or a prescription fill for eteplirsen) with a minimum of twelve months of continuous follow-up after index. Median (interquartile range [IQR]) monthly costs were estimated stratified by baseline age, and compared to those from age-, sex-, and index-year matched samples without DMD from the commercial and Medicaid datasets. The percentage of costs attributable to outpatient visits, inpatient visits, and medications was tabulated. All costs were inflated to 2018 USD.

**RESULTS:** The median baseline age was similar between the commercial (15 years; n=1,420) and Medicaid (14 years; n=1,722) DMD cohorts. Median (IQR) monthly costs among commercially-insured DMD patients were $1,883 ($657 to $6,796), versus $73 ($21 to $308) among members of the comparison cohort. Medications accounted for 67.3%, outpatient visits 23.9%, and inpatient visits 8.8% of monthly costs. Median costs ranged from $797 ($370 to $2,230) among boys aged 0-3 years (n=59), to $2,408 ($572 to $8,225) among those ≥18 years (n=540) at baseline. Costs were lower among the Medicaid DMD cohort: median (IQR) monthly costs were $1,735 ($367 to $5,281), versus $27 ($0 to $161) among members of the Medicaid comparison cohort. Medications accounted for 51.5%, outpatient visits 36.2%, and inpatient visits 12.3% of monthly costs. Median (IQR) costs ranged from $229 ($45 to $923) among boys aged 0-3 years (n=91), to $3,003 ($700 to $7,654) among those ≥18 years at baseline (n=602).

**CONCLUSIONS:** This study examines the direct medical costs for DMD which were observed to be higher among commercially- compared to Medicaid-insured patients. While medication costs were higher, estimates of other component costs are consistent with an earlier smaller study of commercially-insured DMD patients. These estimates contribute to informing the economic burden of DMD in the US.

**SPONSORSHIP:** Sarepta Therapeutics

## M21 Healthcare Resources Use in Patients with Fragility Fracture in an Integrated Healthcare Organization

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**BACKGROUND:** A fragility fracture is a sentinel medical event and may lead to increased healthcare resource use associated with the fracture itself or the subsequent worsening of comorbid conditions.

**OBJECTIVE:** To evaluate healthcare resource utilization among older adults in the year following a fragility fracture.

**METHODS:** This retrospective cohort study used electronic medical record (EMR) data from Kaiser Permanente Southern California. Eligible patients (pts) were women and men ≥50 years old with an initial (index) fracture during 1/1/2007-12/31/2016 and ≥2 y of prior health plan membership with pharmacy benefits. Fractures with inpatient stays or ambulatory visits accompanied by a repair procedure code qualified. Pts with Paget's disease or non-melanoma malignancy at baseline were excluded. OP-related hospitalizations in the year post-index were evaluated overall, by gender, age, and fracture site. Osteoporosis (OP)-related hospitalizations were those with a diagnosis of OP (ICD-9 733.0x; ICD-10 M81.0), fracture, or after-care of fracture (ICD-9 V54.xx; ICD-10 Z47.89). Rates of hospitalization and ambulatory care encounters (outpatient, urgent care, emergency department, telephone) were age-adjusted by US 2010 census and reported as events per 100 person-years.

**RESULTS:** A total of 63,755 eligible pts with qualifying index fractures were identified; 66.7% (n=42,535) were aged ≥65 years and 69.1% (n=44,068) were female. OP-related hospitalization rate in the 1-year post-index fracture was higher for pts aged ≥65 vs <65 (31.8; 11.3) and for spine vs hip or non-spine/non-hip fractures (43.5; 39.5; 16.7). Age-adjusted OP-related hospitalization, emergency room, and rehabilitation service use were higher for men vs women (19.4; 17.7), (73.8; 66.3), and (31.7; 27.2) respectively while outpatient services use including telephone encounters (192.9; 181.3) and urgent care use (41.4; 36.6) were higher for women. Of all pts with fracture, 22% (n=13,988) used nursing home, home healthcare, or rehabilitation services. Age-adjusted use for these services was highest for pts who incurred a hip fracture (65.6) vs those with spine (44.6) and non-hip/non-spine fractures (19.1).

**CONCLUSIONS:** Effects of fracture may be greater for men, pts with a hip fracture, and those aged 65+. Early identification and better management of high-risk pts with fragility fracture may lead to fewer post-fracture sequelae and decreased resource utilization.

**SPONSORSHIP:** Radius Health

## N00-N99 Diseases of the Genitourinary System
*(e.g., ESRD)*

### N1 Assessing for Potentially Inappropriately Dosed Medications Among Patients with Chronic Kidney Disease

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**BACKGROUND:** Previous research found medication reviews among older adults with chronic kidney disease (CKD) resulted in dose modifications for renally cleared medications. It is unknown if the automated monitoring of prescription claims among patients with CKD is necessary.

**OBJECTIVE:** To determine the prevalence of potentially inappropriately dosed medications (PIDM) among patients with CKD, and assess the characteristics of patients prescribed PIDM.

**METHODS:** This retrospective cross-sectional review involved the SinfoníaRx Medication Therapy Management (MTM) database including patients with serum creatinine data from one Medicare plan for the calendar year 2018. Glomerular filtration rate (GFR) was calculated using the CKD-EPI Creatinine equation. Stage of CKD was determined by the GFR. Patients with calculated GFR above 60 ml/min/1.73 m2 were excluded. Median and interquartile ranges and counts and percentages were utilized to describe patient characteristics and prevalence of PIDM. Odds ratios described relationship between CKD stage and PIDM. Exploratory forward stepwise logistic regression assessed relationship between patient characteristics and PIDM.

**RESULTS:** This analysis was comprised of 3,624 CKD patients: 2,856 (79%) with Stage 3, 548(15%) with Stage 4, and 220(6%) with Stage 5. Approximately, 33% of patients had at least one PIDM. Among patients with stage 3, stage 4, and stage 5 CKD, 583 (20%), 434 (79%) and 164 (75%), respectively, were prescribed at least one PIDM. In comparison to patients with stage 3 disease, patients with stage 4 or 5 presented with 13 times the odds of having a PIDM (OR 13.72, 95% Confidence Interval (CI) 11.31-16.64), $P<0.001$. After adjusting for patient characteristics, logistic regression revealed positive associations between PIDM with CKD stages, number of years qualified for MTM, and number of medications. Roughly, 15% of medications (2,835/19,274) were identified as PIDM including: canagliflozin (89/142, 63%), sitagliptin (591/1,743, 34%), dapagliflozin (43/129, 33%), spironolactone (103/397, 26%), and duloxetine (54/237, 23%).

**CONCLUSIONS:** One-third of Medicare MTM eligible patients with CKD presented with at least one PIDM. Worsening renal function, years qualified for MTM, and higher number of medications were positively associated with having a PIDM. Automated monitoring of prescription claims is warranted to avoid presence of PIDM among patients with CKD.

**SPONSORSHIP:** None

### N4 Demographic and Clinical Characteristics of Women with Diagnosed Endometriosis Initiating Therapy with Elagolix: Insights from a Real-World US Claims Database

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**BACKGROUND:** Elagolix, an oral gonadotropin releasing hormone antagonist, was approved in July 2018 for the management of moderate to severe pain associated with endometriosis in the US. To date, there exists no data on the characteristics of elagolix users in the real world.

**OBJECTIVE:** To characterize the demographic and clinical characteristics of women diagnosed with endometriosis who are initiating therapy with elagolix in the US.

**METHODS:** This was a retrospective cohort database analysis. Women aged 18 to 49 who had ≥1 pharmacy claim for elagolix between August 2018 and September 2019 in Source Healthcare Analytics claims database were initially selected. Date of earliest elagolix claim was deemed as the index date. Analysis was limited to women who had continuous medical and pharmacy health plan enrolment in the 12 months preceding the index date (baseline period) and had ≥1 medical claim with endometriosis ICD-9/10 code (617.x and N80.x) on or before the index date. Baseline demographics, comorbidities, ICD code-based endometriosis anatomic site, endometriosis-related treatments and pain symptoms were summarized descriptively

**RESULTS:** Final sample included 8,048 patients. At baseline, mean age was 32.6±7.7 years. The most prevalent age group among elagolix users was 30-39 years (41.8%). Most commonly recorded comorbidities were arthritis/joint pain (33.3%), anxiety (23.8%), back neck pain (21.3%) and mood disorders (19.7%). Most of the endometriosis diagnosis codes recorded referred to unspecified location (54.8%) and pelvic peritoneum (22.9%). Regarding treatments, 62.6% of the patients received a medical endometriosis-related treatment in the baseline period; most common of which were contraceptives (41.0%), progestins (33.1%) and gonadotropin-releasing hormone agonists (6.1%). Additionally, 25.8% of the patients received an endometriosis related surgery during baseline; the most common of which was laparoscopy (23.9%). Moreover, 61.0% of the patients have used opioids during the baseline period. For pain symptoms, 53.9%, 19.5% and 12.3% of the patients had claims for pelvic pain, dysmenorrhea, and dyspareunia; respectively.

**CONCLUSIONS:** A significant proportion of endometriosis patients initiating elagolix have used endometriosis therapies in the 12-month immediately preceding elagolix initiation. More than a quarter of the patients have initiated elagolix within one year of receiving a laparoscopy and almost two thirds of the patients have received opioids. Examining the potential impact of elagolix initiation on these treatment patterns longitudinally is warranted.

**SPONSORSHIP:** AbbVie

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

### Q1 Characteristics, Treatment Patterns, Healthcare Resource Use, and Costs Among Pediatric Patients Diagnosed with Neurofibromatosis Type 1 and Plexiform Neurofibromas: A Retrospective Database Analysis of a Medicaid Population

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**BACKGROUND:** Neurofibromatosis type 1 (NF1)-related plexiform neurofibromas (PN) can cause substantial morbidity by disfigurement and compression of vital structures. There are currently no drug therapies approved for the treatment of patients with NF1 and PN. Real-world data among pediatric patients with NF1 and PN is limited.

**OBJECTIVE:** The objectives of this study were to describe the characteristics, treatment patterns, healthcare resource use (HRU) and costs for these patients.

**METHODS:** This was a retrospective study of individuals enrolled in the MarketScan Multi-State Medicaid database from October 1, 2014-December 31, 2017 (study period). Patients aged ≤ 18 years at the index date with at least 1 ICD-10-CM diagnosis code for NF1 and PN were included. The index date was defined as the date of the first diagnosis of NF1 or PN during the study period, whichever occurred later. Continuous enrollment from the baseline period (12 months before the index date) was required. The follow-up period monitored patients from the index date up to the earliest date of end of data availability or end of continuous enrollment in a health plan. Descriptive analysis was conducted to describe baseline characteristics and follow-up treatment patterns. All-cause HRU (inpatient, outpatient, emergency room [ER], pharmacy, and other) and their associated costs during the follow-up period were calculated per patient per year [PPPY] in 2018 USD.

**RESULTS:** A total of 383 patients were included with a mean follow-up of 448 days. The mean age was 11.4 years and 52.0% of patients were male. Most diagnoses at index were done by a specialist (63.5%). During the follow-up period, pain medications were used by 58.5% of patients, 25.1% were treated with chemotherapy, 7.1% received surgery for PN, 1.6% received MEK inhibitors, and 0.8% received radiation. Mean PPPY HRU inpatient, outpatient, ER, pharmacy, and other visits were 1.4, 17.3, 1.6, 13.6, and 25.8, respectively. Mean ± SD [median] total PPPY healthcare costs were $17,275 ± $61,903 [$2,889], with total medical costs of $14,628 ± $56,203 [$2,334] and pharmacy costs of $2,646 ± $13,303 [$26]. Inpatient costs were the largest drivers of medical cost with mean PPPY costs of $6,739, followed by other costs ($4,289) and outpatient costs ($3,508).

**CONCLUSIONS:** This study showed that a proportion of pediatric patients diagnosed with NF1 and PN were treated with supportive care only, highlighting a substantial unmet medical need among these patients. This study also highlights the considerable economic burden among patients with NF1 and PN.

**SPONSORSHIP:** Merck & Co.

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

### R1 Vaccine Compared to Trivalent High-Dose Influenza

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**BACKGROUND:** Primary mitochondrial myopathy (PMM) is a genetic condition resulting from mutations of the nuclear or mitochondrial DNA, characterized by life-limiting symptoms such as muscle weakness, fatigue and pain.

**OBJECTIVE:** To develop a deeper understanding of the PMM patient experience and create a patient-reported outcome (PRO) tool capable of evaluating and monitoring those PMM symptoms.

**METHODS:** Qualitative concept elicitation interviews (CEIs) were conducted to identify the PMM signs and symptoms that best characterize the disease and explore which among them were most salient to patients. The open-ended patient input from the CEIs informed construction of the PMM Symptom Assessment (PMMSA) which was then tested in cognitive debriefing interviews (CDIs) to evaluate readability, relevance to patients' disease experience, and content validity. The PMMSA was implemented in a Phase 2 clinical trial. Psychometric performance was evaluated using trial data and guidelines for interpreting the clinical meaning of change were generated.

**RESULTS:** In the CEIs, the most frequently reported signs/symptoms were fatigue/tiredness, muscle weakness, muscle pain, impaired vision, memory problems, balance problems, numbness, and headache. The 10-item PMMSA was created using this patient input to assess the most frequently reported symptoms amenable to self-report. Results from CDIs supported patient comprehension and completeness of concepts contained in the PMMSA's items. Subjects reported that tiredness and muscle weakness represented the most salient symptoms of their condition. Through psychometric testing of the PMMSA in the Phase 2 clinical trial (n = 31), four items (assessing tiredness and muscle weakness both at rest and during activities) were found to characterize a "Total Fatigue" domain, which further demonstrated acceptable test-retest and internal consistency estimates, correlated as expected with reference measures, and differentiated between a priori defined patient severity groups.

**CONCLUSIONS:** Results confirmed PMM to be a debilitating and symptomatically bothersome condition, negatively impacting patient quality of life. To assess the most relevant of these symptoms, the PMMSA was developed in accordance with best measurement practices and regulatory guidelines. Results of the CDIs support the PMMSA as content-valid PRO assessment. Upon evaluation of its psychometric properties, the PMMSA, as well as the Total Fatigue domain, demonstrated reliability and construct-related validity. This evidence indicates that the PMMSA can be utilized to measure and monitor PMM patient symptom burden.

**SPONSORSHIP:** Stealth BioTherapeutics

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

### T1 Analysis of a Narcotic and Polypharmacy Case Management Program at a Health Plan

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**BACKGROUND:** Adverse drug events (ADEs) account for over 3.5 million physician office visits, 1 million emergency department visits, and 125,000 hospital admissions annually. Opioids can cause several ADEs that are detrimental to the health and quality of life of patients. Since 2015, Blue Shield of California has been dedicated to promoting medication safety by reducing overuse of opioids and polypharmacy amongst the health plan's members. The Patient Review and Coordination (PRC) Program is a new pharmacist-led case management program that is designed to improve patient safety through care coordination.

**OBJECTIVE:** To describe the number of commercial health plan patients who were enrolled into the PRC program and the resulting action of the cases.

**METHODS:** The PRC program is composed of a retrospective review of pharmacy claims data followed by active case management by health plan pharmacists. Patients were identified from outpatient prescription claims data collected between October 1, 2018 through September 30, 2019. Patients are eligible if they had persistent high opioid utilization or polypharmacy over a 90-day period and did not meet any exclusion criteria, such as a cancer diagnosis. Pharmacist intervention included faxing and speaking with prescribers to address medication concerns, counseling patients telephonically and performing medication reconciliation, and referring patients to nurse case managers to provide additional support.

**RESULTS:** The pharmacist team reviewed 210 cases and intervened on 123 (59%) cases. The pharmacists communicated with prescribers and patients to close 80 cases, of which 50 (63%) resulted in prescribers taking action to address medication concerns. Prescriber actions included conducting medication reconciliation (30%), tapering of opioid doses (26%), referral to nurse case management (24%), medication consolidation (16%), and referral to a specialist (4%). Of the cases where prescribers acted, 13 (26%) cases resulted in a decrease in opioid dose and 24 (48%) cases resulted in a decrease in the total number of prescriptions overall.

**CONCLUSIONS:** A pharmacist-led case management program at a health plan identified patients at high risk for ADEs associated with opioid overuse and polypharmacy. Pharmacists were able to improve care coordination and drug safety by facilitating referrals to specialists and nurse case managers as well as by engaging prescribers and patients in addressing medication concerns.

**SPONSORSHIP:** Blue Shield of California

## T2 Evaluating Medication-Related Risk Factors for Developing Opioid Use Disorder Post-Hospitalization

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**BACKGROUND:** Short-term opioid use in hospitals to manage pain is common. Studies suggest an association between inpatient opioid use and increased adverse clinical outcomes, mortality, and cost of hospitalization. Additionally, there are concerns that opioid use in the hospital may contribute to subsequent opioid use disorder (OUD) after discharge.

**OBJECTIVE:** To evaluate medication-related risk factors associated with developing opioid-related adverse events and chronic opioid use post-discharge after inpatient opioid use by an opioid-naive population.

**METHODS:** We linked outpatient and inpatient encounter data from a large integrated health plan of members ≥ 14 years old without any opioid claim 12 months prior to an inpatient opioid use (opioid-naïve). We compared patients who developed OUD with those who did not by specific medications using students t-test. We also assessed association between risk factors and OUD using multivariate logistic regression. Finally, we compared OUD patients' use of opioids up to 12-months post discharge. We defined OUD as a documented diagnosis in the electronic medical record and/or medication-assisted treatment (MAT) buprenorphine use 12-months post-discharge.

**RESULTS:** Our sample size included 23,352 opioid-naïve patients with prescribed inpatient opioids from September 2014 to July 2017. Three percent of the patients developed OUD by 12 months post-discharge. OUD Patients had statistical significantly higher usage (dose, days' supply, and number of prescriptions) of benzodiazepines, gabapentin, and skeletal muscle relaxants prior to admission, however only gabapentin remained statistically significant in a multivariate logistic regression controlling for patient demographics, diagnosis, family and area characteristics. OUD patients also had higher daily morphine equivalent doses at 30 days (4.8 vs. 3.2 $P=0.037$), 60 days (3.9 vs 1.5 $P=0.0007$), and 12 months (2.3 vs. 1.3 $P=0.003$) post-discharge.

**CONCLUSIONS:** Provider awareness of patient characteristics and medications associated with increased risk of OUD could serve to develop strategies to mitigate subsequent OUD.

**SPONSORSHIP:** None

# U00-U99 Codes for Special Purposes and AMCP Unclassified Abstracts *(e.g., Care Management, Specialty Pharmacy, Rare Diseases, Star Ratings, Pharmacist Services, MTM, Outcome Analyzers, Part D, Multidisease Studies, ACO, ACA)*

## U3 Pharmacy Benefit Carve-In Versus Carve-Out: Cost and Medical Events 2-Year Retrospective Cohort Study

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**BACKGROUND:** Pharmacy benefit can be purchased as an integrated total health package—a Carve-in model—or purchased as a separate benefit administered by an external pharmacy benefit manager—a Carve-out model.

**OBJECTIVE:** To compare the per member per year (PMPY) allowed total medical costs and health care utilization between commercially self-insured members receiving Carve-in to those receiving Carve-out pharmacy benefits overall and by 7 chronic condition sub-groups.

**METHODS:** This study utilized a limited dataset convenience sample of members who were continuously enrolled in a self-insured product from 2017 through 2018 with no major benefit changes from Cambia Blue plans covering 1.6 million members in Oregon, Washington, Utah and Idaho. The total medical PMPY comparison was made using a multivariate general linear model with gamma distribution to adjust for Optum Symmetry Risk Score (proxy for illness severity), age, gender, state of residence, 7 chronic diseases, insured group size, member enrollment in case or disease management, and plan paid to total paid ratio (proxy for benefit richness) between the 2 groups. Medical event objectives were statistically assessed using multivariate logistic regression models comparing the odds of hospitalization or emergency department (ED) visit adjusting for the same covariates. Sub-analyses for members with each of 7 chronic conditions including asthma, coronary artery disease, COPD, heart failure, diabetes, depression and rheumatoid arthritis were performed using the same methods.

**RESULTS:** 205,835 Carve-in and 125,555 Carve-out members met study criteria. Average age was 34.2 yrs (SD 18.6) and risk score 1.1 (SD 2.3) for Carve-in; and 35.2 yrs (SD 19.3) and 1.1 (SD 2.4) for Carve-out. Members were found to have 4% ($P<0.0001$) lower medical costs after adjustment, translating into an average $148 lower PMPY medical cost ($3,749 Carve-out versus $3,601 Carve-in). The Carve-in group had an adjusted 15% ($P<0.0001$) lower hospitalization odds and 7% ($P<0.0001$) lower ED visit odds, during the 2-years studied. Of 7 chronic conditions, 5 were found to have significantly lower costs, hospitalization and ED visits with Carve-in benefits.

**CONCLUSIONS:** These findings suggest members with integrated benefits had lower medical costs, fewer hospitalizations and ED visits. These results may be due to access to both medical and pharmacy data leading to improved care management and coordination. Further research is required to confirm.

**SPONSORSHIP:** Cambia and Prime Therapeutics

## U4 Impact of a High-Severity Drug-Drug Interaction Edit on Antibiotic Therapy in Commercial, Medicaid, and Medicare Members Prescribed Fluoroquinolones

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**BACKGROUND:** Drug-drug interactions are one of the most common causes of adverse drug events. While there are many adverse drug events that are unpredictable, most drug-drug interactions can be anticipated and prevented. Pharmacy benefit managers use point of sale edits to alert dispensing pharmacists of drug-drug interactions. Due to the concern for life-threatening drug-drug interactions, better understanding the impact of point of sale edits on appropriate medication use is warranted.

**OBJECTIVE:** To examine the impact of a high-severity drug-drug interaction edit on antibiotic therapy and trends in prescription override codes.

**METHODS:** A retrospective review was conducted utilizing pharmacy claims data between August 2018 and July 2019. Using a pharmacy benefit manager claims database, fluoroquinolone claims rejected due to a high-severity drug-drug interaction edit were identified and extracted. Duplicate claims were removed from the analysis. Prescription claims identified as having stayed rejected were manually reviewed and it was determined if the fluoroquinolone was switched to another antibiotic. Time between the initial claim rejection and paid claim for the new antibiotic was calculated. Override codes were determined for all fluoroquinolone rejected claims.

**RESULTS:** A total of 1,309 fluoroquinolone claims rejected and were included in the analysis, representing 952 distinct members. Demographics of the members were: mean age 54.9 years; 76.2% female. A total of 284 (22%) claims stayed rejected and were manually reviewed, with 67 of them being switched to a different antibiotic. Of those claims that were switched to a different antibiotic, most claims (15, 22.4%) were switched to sulfamethoxazole/trimethoprim, followed by 9 (13.4%) switched to levofloxacin, and 8 (11.9%) switched to nitrofurantoin. 58 (86.6%) rejected claims received a paid claim for a new antibiotic within 24 hours. Override codes were used with 1,170 of the rejected claims. Most claims (869, 74.3%) were overridden after prescriber consultation, followed by pharmacist consultation (238, 20.3%), and patient consultation (43, 3.7%).

**CONCLUSIONS:** The high-severity drug-drug interaction edit was shown to effectively prevent a significant drug-drug interaction. Additionally, the point of sale edit did not negatively impact the elapsed time for a patient to receive a paid claim for an antibiotic. Moving forward, pharmacy benefit managers should continue to be vigilant in their efforts to help guide safe and appropriate medication use.

**SPONSORSHIP:** Navitus Health Solutions

## U5 Assessing Changes in the Utilization and Costs Associated with the Non-Pharmacological Management of Back Pain in Oregon Medicaid Patients in the Setting of Increasingly Strict Opioid-Prescription Restrictions

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**BACKGROUND:** In response to an increase in overdose deaths and hospitalizations due to opioid prescriptions in Oregon, the Oregon Health Authority (OHA) lowered their recommended daily cumulative morphine milligram equivalent (MME) in line with guidance from the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services. In 2016, PacificSource Health Plans (PS) implemented a preauthorization policy to limit its Medicaid beneficiaries to 120 cumulative MME daily, which has been gradually lowered since.

**OBJECTIVE:** To assess how a PA on opioid medications may have impacted the utilization and cost of non-pharmacological pain management interventions for the treatment of back pain in our Medicaid population.

**METHODS:** Data-extraction was performed for claims via Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, and International Statistical Classification of Diseases and Related Health Problems 10 (ICD-10-CM) code, in accordance with Guideline-Note 56 of the 2019 Oregon Prioritized List of Health Services, which lists funded treatments for conditions of the back and spine. Monthly costs per member per month (PMPM) and utilization rates were assessed between April 2016 and July 2019, controlling for changes in membership, delays in medical-claims processing, and changes in costs of the services provided.

**RESULTS:** 183,676 claims were identified for analysis. Medical costs, medical costs PMPM, claims per month, and claims PMPM rose by 67.4% (slope 3.7%, $R2 = 0.614$), 85.3% (slope 0.71%, $R2 = 0.615$), 157.3% (slope 9.7%, $R2 = 0.559$), and 182.6% (slope 17.0%, $R2 = 0.508$), respectively, per linear regression. Costs tightly correlated with PMPM costs ($R = 0.994$), as did claims with PMPM claims ($R = 0.998$). Claims and PMPM claims were less tightly correlated with costs ($R = 0.866$ and $R = 0.847$, respectively) and PMPM costs ($R = 0.897$ and $R = 0.885$, respectively).

**CONCLUSIONS:** These results indicate a positive trend in medical costs associated with the treatment of PS Medicaid members suffering from back pain. This trend may be explained by a decrease in the utilization of opioid medications. Further research is required to strengthen this notion, but preliminary data for this purpose appears confirmatory. Known limitations to the data presented here include: a lack of comparison to the years prior to the implementation of a PA to opioid medications, inadequate sample size, and a lack of comparison to the costs and utilization rates associated with opioid prescriptions for the same set of diagnoses.

**SPONSORSHIP:** PacificSource Health Plans

## U6 A Descriptive Analysis of Healthcare Decision Maker Engagement Patterns in Pre-Approval Information Exchange

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**BACKGROUND:** Preapproval information exchange (PIE) is the communication of factual information (eg, clinical, pricing) between drug manufacturers and healthcare decision makers (HCDMs) prior to Food and Drug Administration (FDA) approval. The FormularyDecisions (FD) platform enables bidirectional information exchange between manufacturers and HCDMs. Despite availability of the FD platform and recent FDA guidance, a gap exists between information sought by HCDMs and that which is shared by manufacturers. Timing of HCDM interest in PIE is also unclear.

**OBJECTIVE:** To retrospectively evaluate patterns of HCDM engagement in PIE via the activity of registered users from the FD platform.

**METHODS:** New molecular entities (NMEs), biologics, biosimilars, and supplemental indications approved in a key therapeutic area (ie, hematology, oncology, central nervous system, and immunology) in 2018 to 2019 with a Product Page on FD were included. Product Page hits (i.e., HCDM clicks on the Product Page) and HCDM Watch List additions (i.e., product followed on the platform by HCDMs) from 10/15/10 to 10/01/19 were evaluated.

**RESULTS:** 82 products (41 NMEs, 41 non-NME approvals) were identified. HCDMs added products to their Watch List and first clicked on Product Pages 273 and 422 days prior to approval, respectively. There was no significant difference in the number of days prior to approval in which HCDMs began following products (added to Watch

List) between NME approvals and non-NME approvals. HCDMs first clicked on NME Product Pages significantly earlier than non-NME Product Pages (201 vs 556 days prior to approval; $P<0.05$). Analyses showed a significant upward trend in HCDM engagement as time to approval decreased, including a strong and moderate correlation with regard to Product Page hits ($r=-0.82$; $P<0.05$) and Watch List additions ($r=-0.49$; $P<0.05$). There was no difference in trends between Watch List additions and Product Page hits by approval type.

**CONCLUSIONS:** NMEs prompt greater HCDM interest than non-NMEs. Results show that HCDMs seek product information well in advance of FDA approval and increase engagement in PIE as the approval date nears. As the communication of PIE continues to evolve, further research should address potential shifts in HCDM PIE utilization and types of PIE.

**SPONSORSHIP:** None

## U7 Identifying the Root Cause of Intentional Medication Nonadherence

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**BACKGROUND:** Know anyone who intentionally fails to take their medication as directed? Suboptimal medication nonadherence can lead to worsened chronic condition management, amplified healthcare costs, and mortality. Pharmacists are invaluable in identifying barriers and offering creative solutions to increase medication adherence. The study aimed to identify reasons for intentional nonadherent to medications.

**OBJECTIVE:** The study objectives were to: assess patients' common reasons for intentional medication nonadherence; and categorize them based on sociodemographic factors.

**METHODS:** This retrospective review involved adult patient records from January 1 to December 31, 2018. Patients with suboptimal medication adherence [e.g., Proportion of Days Covered (PDC) rate less than 80%)] who received telephonic adherence intervention counseling from a pharmacy team member were included in the analysis. Reasons were categorized as: provider temporarily discontinued medication; insurance coverage issue; travel without medication; hospitalization; medication intolerance; forgot to refill; therapeutic regimen change; not taking as prescribed; never started therapy; lost medication; medical condition denial; caregiver misunderstanding; unable to pick up; or, patient did not understand indication.

**RESULTS:** A total of 270 patients included in the analysis, based on a PDC of less than 80%, received pharmacy team member-delivered interventions. Most were female (n = 178, 66%); and those aged 75-79 years (n = 120, 44%) were least adherent. Therapeutic regimen change was the most common reason identified for males (n = 51, 55%) and females (n = 75, 42%). Second most common were: travel (n = 13, 7%) and cost (n = 13, 7%); or not taking as prescribed (n = 15, 16%) and lack of refills (n = 4, 4%) for females and males, respectively. Other reasons, for males and females, included: lost medication (n = 1, < 1%); caregiver misunderstanding (n = 4, < 1%); denial of medical condition (n = 4, < 1%); unable to pick up (n = 2, < 1%); and patient did not understand medication purpose (n = 1, < 1%). Females (n = 60, 33.7%) and males (n = 41, 44.6%) with hypertension were least adherent.

**CONCLUSIONS:** This retrospective study provides new insight into reasons for intentional nonadherence. Therapeutic regimen change, the most common reason identified, lacked clarity and could have falsely identified patients as nonadherent. Future work investigating specific reasons for therapeutic regimen changes is warranted to better understand patient nonadherence.

**SPONSORSHIP:** SinfoniaRx

## U8 Payer Insight Mining on Rheumatoid Arthritis Disease Management: How Do US Payers Make Decisions?

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**BACKGROUND:** The expanding rheumatoid arthritis (RA) treatment landscape can be challenging for payers to manage to improve quality of care. With increasing RA drug options, payers are challenged to identify metrics to manage this class.

**OBJECTIVE:** To understand the payer mindset in approaching RA management, to gain insights on key clinical considerations on coverage policy, and to identify opportunities to improve RA care.

**METHODS:** Surveys were administered by a pharmaceutical manufacturer's payer-focused medical field team (MFT; July 2018-April 2019) to payers of various types of managed care organizations. Topics included key plan metrics, formulary decision making, disease management programs. Of 25 total questions, only those deemed relevant by the MFT were asked. An insight was defined as feedback gained from a respondent.

**RESULTS:** Over 950 insights were gathered from 38 respondents from US specialty pharmacies (SP; 58%), health plans (26%; majority regional), PBMs (11%), and ACOs/IDNs (5%). Criteria most often used to document time to switch/add therapy were suboptimal therapeutic response (76%), treatment intolerance/contraindication (73%), and/or disease progression (70%). Although not required, only 10% of those surveyed reported collecting data from physicians to measure RA outcomes. Dose escalation was monitored by 57% of respondents and focused mainly on TNF inhibitors (TNFi; 76%) and JAK inhibitors (29%). Efficacy, clinical guidelines, and safety were top factors guiding payer utilization management criteria for choice of non-TNFi after initial TNFi failure. RA disease management programs are offered by 90% of respondents, driven by the large population of SPs surveyed; programs mainly focus on adherence, disease/treatment education, and side effects, with SPs offering expanded patient care services. Clinical outcomes assessments (71%) and cost-effectiveness modeling (68%) were most often used for formulary decision making. ICER reports (47%) were most frequently used for RA drug value assessment. Information most likely to prompt a change in RA drug management decisions includes guideline recommendations (68%) and head-to-head comparator data (62%).

**CONCLUSIONS:** Sampled payers (mostly regional health plans and SPs) are eager to use clinical outcomes to assess the value of RA drugs; however, at this time, the majority of these payers do not capture outcomes data from physicians to inform their decisions. Payers and SPs should collaborate and focus on this gap to improve RA drug class management.

**SPONSORSHIP:** Sanofi

## U9 Development and Assessment of Real-World Evidence

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**BACKGROUND:** With the proliferation of real-world data (RWD) that supports growth in real-world evidence (RWE) generation and

publications alongside the recent FDA RWE Initiative, there is a need to build competency in RWE research concepts across stakeholders to optimize the use of RWE for decision-making in healthcare.

**OBJECTIVE:** To describe the process and outcomes related to developing a novel RWE training program customized for pharmaceutical company field medical professionals.

**METHODS:** Researchers at the Texas Center for Health Outcomes Research and Education (TxCORE) and members of Pfizer Medical Affairs collaborated over a 6-month period to customize the content of an RWE training program. Knowledge gaps were assessed, and 11 content categories addressing these gaps and the variability of knowledge depth were prioritized based on relevance to the medical role. Final program format included 22 hours of self-directed web-based modules, live didactic presentations, and case study workshops. Pre- and post-program testing (30 items each) was conducted that followed a matrix of content categories and complexity levels to gauge competency change. Pre-testing was completed on a sample of 5 participants and finalized prior to launch of the modules and live workshop, which participants completed over a 1-month period.

**RESULTS:** A total of 71 field medical professionals completed the training program. Example content topics included RWD sources, RWE designs, medication adherence, multivariable regression, use of propensity scores, and RWE method tools/checklists. Mean post-program assessment scores increased significantly compared to baseline, 83.2% (SD 11.8) versus 67.6% (SD 11.2), respectively; $P<0.001$. Post program scores increased from baseline in 10 of the 11 content categories, with multivariable regression and propensity score topics having the lowest post program scores, representing more complex topics. Participants expressed high satisfaction with the RWE training program.

**CONCLUSIONS:** Results revealed a positive impact of designing/implementing an RWE training program to improve knowledge across a pharmaceutical field medical team. Review of pre-post scores by content category indicated areas for additional training in multivariable regression and propensity score matching. Key to facilitating success of the RWE training program was an assessment of knowledge gaps prior to designing content and customizing program content to specifically address those gaps. Similar educational programs may optimize generation and use of RWE for stakeholders in healthcare.

**SPONSORSHIP:** Pfizer

## U10 Cost-Savings Analysis of a Pharmacist-Led Transitions of Care Program in a Managed Care Setting

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**BACKGROUND:** Evidence suggests that 20% of patients discharged from the hospital to home will experience an adverse event during this transition and that approximately 66% to 71% of these events are associated with medications. The majority of transition of care studies focus on pharmacists improving patient outcomes in the inpatient setting and literature is limited on the pivotal role pharmacists play post discharge.

**OBJECTIVE:** To evaluate the impact pharmacists have on reducing healthcare costs post discharge.

**METHODS:** This retrospective cost analysis was conducted between January 2018 and October 2019. A transitions of care program was comprised of pharmacists, pharmacy technicians, and pharmacy students for high risk members of the Sunshine Health Managed Medicaid and Health Insurance Marketplace populations. A daily inpatient census report is reviewed by pharmacy technicians to identify eligible members who must have a hospital discharge, medication list, and a relationship with a provider. All members included were 18 years and older and were stratified according to their readmission risk score, which was based on a number of variables including but not limited to: LACE score, authorization service type, and number of ER visits in the last 12 months. Members were excluded if they were admitted for behavioral health diagnoses, substance abuse, suicidal ideation, hospice, or active malignancies. After completing medication reviews, pharmacists completed patient/caregiver education via telephone. Cost savings were calculated for each member by determining the difference in projected total costs had the member not been engaged, and actual costs after the intervention. This calculation of cost savings was based on the total cost of medical and pharmacy claims up to 3 months prior to the intervention, and total actual costs up to 6 months after the intervention.

**RESULTS:** A total of 317 members were included. A summative total $15,190,369 was saved based on medical and pharmacy claims cost—$12,173,758 and $3,016,611 for Medicaid and Health Insurance Marketplace respectively—for an average of $47,919 per member.

**CONCLUSIONS:** The results of this analysis show that the role of a pharmacist post discharge is vital in improving patient care outcomes. These results may motivate other managed care organizations to evaluate their current process and justify the need for a pharmacist to be involved throughout the continuum of care. As a result, this initiative is being considered for adoption for the entire Centene Corporation; consisting of more than 15 million managed care lives.

**SPONSORSHIP:** Sunshine Health

## U11 Specialty Drug Managed Care Pharmacist Clinical Review Program Savings Among 1.5 Million Commercially Insured Lives

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**BACKGROUND:** Specialty drugs are the fastest growing expense within the pharmacy benefit and are an increasing component of medical benefit expenditures. Because specialty drugs have high unit costs, are found on both the medical and pharmacy benefits, have complex dosing/treatment regimens, and the potential for fraud/waste/abuse (FWA), they require close oversight and review by managed care specialty pharmacists.

**OBJECTIVE:** Determine savings from a full-time pharmacist dedicated to reviewing specialty drug utilizers using integrated medical and pharmacy claims, as well as, prior authorization (PA) data to optimize drug therapy and make drug saving recommendations.

**METHODS:** August 2018 to September 2019 (12 months) integrated medical and pharmacy claims and PA data for 1.5 million commercially insured members within a Blue Cross Blue Shield (BCBS) plan were queried to identify patterns and opportunities from individual member complete claim review by a pharmacy benefit manager pharmacist in collaboration with the BCBS plan pharmacy department. Savings were defined as direct or plan approved due to changes in drug dosing units, therapy changes, PA process changes, or FWA recovery/future claims avoidance.

**RESULTS:** A dedicated pharmacist for 1.5 million commercial members reviewed comprehensive member level specialty claims for 365 members and compared PA approvals to claims dispensing patterns over 12 months. The pharmacist in collaboration with the BCBS plan pharmacy department made improvements to the Hepatitis C PA detailing process to ensure only 56 days of therapy was dispensed resulting $1,034,505 savings. A pharmacy FWA investigation resulting in $696,065 savings. A single patient over using hereditary angioedema acute treatments provider intervention resulted in

$462,285 savings and dosing optimization for secukinumab $327,770 (9 members), selexipag $71,456 (1 member), adalimumab $56,225 (1 member), ibrutinib $31,408 (1 member), and all others $29,478 (7 members) totaled $2,709,192 in savings.

**CONCLUSIONS:** A single dedicated pharmacist conducting specialty drug comprehensive member claim review working in collaboration with a 1.5 million member BCBS plan pharmacy department resulted in $2.7 million or $0.15 per member per month savings. These savings were due to pharmacist to provider recommended dosing optimization/therapy modification, identification of a pharmacy conducting FWA activities, and drug PA detailing changes that would not have occurred without a dedicated pharmacist with access to PA review documentation and member level integrated medical and pharmacy claims data.

**SPONSORSHIP:** Prime Therapeutics and Blue Cross Blue Shield Alabama

## U12 Variation in Subcutaneous Allergy Immunotherapy Billing Practices in the United States: A Claims Analysis of Allergic Rhinitis Patients

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**BACKGROUND:** Allergy immunotherapy (AIT) is an effective treatment for reducing symptomatic relieving medication use and symptoms in people with allergic rhinitis by modifying the underlying cause of disease. Medical coding practices for the reimbursement of AIT, in particular subcutaneous allergy immunotherapy (SCIT), have been known to vary, partly driven by the discrepancies in accepted code usage across health insurance plans.

**OBJECTIVE:** To examine the extent and patterns of real-world variation in SCIT reimbursement at the point of therapy initiation.

**METHODS:** Allergic rhinitis patients receiving SCIT were identified in the IBM MarketScan database between 1/1/2014-3/31/2017. SCIT claims were identified using current procedural terminology codes, with the earliest SCIT claim serving as the index date. To be eligible for inclusion into the study, all patients must have met the following criteria: at least 12 months of pre- and post-index continuous enrollment; absence of AIT during the pre-index period; and an absence of venom immunotherapy. The total number of SCIT administrations were assessed, along with the distribution of paid amounts for the initial SCIT claim segmented by the nine distinct non-venom AIT procedure codes currently in use. Initial SCIT claim costs were segmented into categories of increasing $100 increments based on initial distribution diagnostics. Means ± standard deviations (SD) are presented for all continuously measured outcomes, while frequencies and proportions are presented for categorical outcomes.

**RESULTS:** A total of 102,447 patients receiving SCIT were included in the analysis. Patients were 34.2 ± 17.3 years of age, and 58.0% were female. 20.4% of patients received just a single AIT claim in the one-year follow-up period after the index date; 50.5% presented <20 AIT claims. The mean paid amount for the initial SCIT claim was $674 ± $831. 18.0% of paid amounts for the initial SCIT visits were in the lowest cost segment of $0.00-$100, while 21.1% were >$1,000. The remaining 60.9% of claims were evenly dispersed between $200 and $999.

**CONCLUSIONS:** Results demonstrate significant variability in the initial treatment costs for SCIT, along with a high mean cost value. The observed spread in paid amounts may be reflective of physicians' willingness and ability to bill for allergen extracts which would be administered over multiple successive office visits. This may contribute to healthcare waste, particularly as 1 in 5 patients were observed to discontinue after a single treatment.

**SPONSORSHIP:** ALK-Abelló

## U13 Payer Perceptions on the Use of Real-World Evidence and Economic Models in Oncology-Based Decision Making: Results from an Online Survey and Modified Delphi Panel

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**BACKGROUND:** While clinical trials are regarded as the gold standard of evidence to demonstrate a medicine's safety and efficacy, they are conducted in select populations that may not mirror the general population. As such, decision makers have unaddressed questions surrounding appropriate use of new treatments. This may be more pronounced in oncology due to accelerated regulatory approvals. Real-world evidence (RWE) and economic models may help address knowledge gaps to inform formulary decision making.

**OBJECTIVE:** To assess payer perceptions regarding use of RWE and economic models to inform oncology decision making.

**METHODS:** A pilot survey was developed and fielded to a small group of national and regional US payers. Results of the pilot were discussed during an in-person meeting. Payers provided feedback on the questionnaire, in a modified Delphi approach, to inform the development of a larger national survey that will validate these preliminary results.

**RESULTS:** Five national and regional payers participated in the pilot survey representing over 53 million lives. In the pre-meeting survey, 80% of payers reported having oncology expertise in evaluating observational studies and 60% reported having oncology expertise in evaluating economic models on their P&T committees. During the in-person discussion, payers confirmed the value of product-specific RWE at every stage of a product's life cycle. Interest in RWE studies assessing comparative effectiveness, adverse event rates, and duration of therapy were viewed as most useful for informing formulary decisions, negotiating contracts, creating clinical pathways, and assessing off-label usage. The majority of payers (80%) reported that RWE is used to supplement clinical trials. Payers indicated that barriers to widespread use of RWE included lack of RWE at launch and difficulties in accessing relevant data. Cost-effectiveness models (CEMs) were perceived as more useful than budget impact models by majority of participants. Payers expressed skepticism around manufacturers' sponsored models due to perceived lack of transparency; however, they expressed interest in partnering on model development to increase the utility of CEMs. Results from the larger survey will validate these preliminary results and will be presented.

**CONCLUSIONS:** Payers are interested in RWE and economic models to support oncology-based decision making. Collaboration between manufacturer and payer to overcome barriers in RWE generation and to increase transparency in modeling may increase the utility of these resources among payers.

**SPONSORSHIP:** Pfizer

## U14 Determinants of Prescription Unaffordability in the Insured Population of Ohio

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**BACKGROUND:** Prescription drug costs present challenge with respect to access. Insurance coverage alleviates the burden of prescription drug costs to a certain extent. However, with increasing out-of-pocket spending, prescriptions are unaffordable for many individuals. Little is known about prescription unaffordability in the insured population, its predictors and its association with health services utilization.

**OBJECTIVE:** 1. Identify patient-level determinants of prescription unaffordability amongst the insured population in the state of Ohio. 2. Determine association between ER utilization and inability to afford prescriptions amongst the insured population in the state of Ohio

**METHODS:** Retrospective, cross-sectional study was conducted using the 2015 Ohio Medicaid Assessment Survey (OMAS) responses dataset. Respondents who reported having prescription insurance were included in this study. Multiple logistic regression was conducted to identify predictors which include socioeconomic variables, patient reported health status, insurance type and comorbid conditions. Another multiple logistic regression model was used to evaluate the association of ER utilization and inability to afford prescriptions using the above-mentioned covariates.

**RESULTS:** Approximately 81% of the respondents (n = 34,753/42,876) were insured. Of these, 13% (n = 4,758/34,753) reported inability to afford prescriptions. Predictors of prescription unaffordability identified were: female (OR 1.476, 95% CI 1.378-1.581), elderly (OR 0.354, 95% CI 0.303-0.413), low income (OR 1.544, 95% CI 1.365-1.747), having Medicare (OR 1.437, 95% CI 1.244-1.661) and having Medicaid (OR 0.779, 95% CI 0.673-0.903). Poor health status and having diagnosis of cancer, cardiovascular disease (CVD) or diabetes was associated with increased odds of prescription unaffordability. ER utilization was associated with low/middle income status, females, cancer, CVD and prescription unaffordability (OR 1.566, 95% CI 1.457-1.682).

**CONCLUSIONS:** Prescription unaffordability is still a concern amongst insured population in Ohio. Prescription unaffordability has been associated with socioeconomic factors, insurance type, and perceived health status. Prescription unaffordability is also associated with ER utilization. While insurance could improve access, the questions around affordability persists.

**SPONSORSHIP:** None

## U15 Motivational Interviewing for Behavior Change to Improve Adherence Rate and Stars in a Medicare Plan

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**BACKGROUND:** The 5-star quality rating system was designed to drive improvements in Medicare quality and to increase accountability among Medicare plans. As the Medicare Star Ratings System matures and plans are held more accountable for improving adherence measures, high Star Ratings become more difficult to attain. This MI continuous feedback training program for pharmacists allows for rapid cycle change in response to these challenges.

**OBJECTIVE:** This project covers best practices and evaluates the impact of implementing a pharmacist-lead, patient-centered program incorporating motivational interviewing (MI) on patient adherence and star ratings.

**METHODS:** Envolve Pharmacy Solutions' adherence program incorporates MI for member-driven behavior change. The program utilizes didactic learning, skills assessments, and continuous feedback coaching. An automated system records all pharmacists' calls so that they are available in real-time for scoring. Call monitoring/scoring is conducted by 3 MTM technicians with customer service call audit background. The technicians, along with the managers and program director, meet monthly for calibration calls to ensure each pharmacist is scored and coached in a consistent manner. For scoring, UCSF consultants worked with the pharmacy management team to revise a standardized MITI evaluation tool and rubric to objectively assess pharmacist effectiveness on the calls. The rubric is based on the global concepts of MI as follows: Empathy, Collaboration, Autonomy & Support, Direction and Evocation. For training, the management staff reviews MI techniques and conducts role-play sessions. Pharmacists attend a call review session for baseline scoring within the first 90 days of training.

**RESULTS:** The program increased adherence rates 5-9 percentage points (Chi-square for all plans and drug classes measured, $P < 0.05$) over 5 years and improved Medicare Star Ratings by 1-2 stars.

**CONCLUSIONS:** This study demonstrates that an adherence program that includes rigorous training in MI and continuous quality improvement can positively impact adherence rates and CMS Star Ratings. Furthermore, health plans that dedicate to providing targeted and ongoing coaching to MTM staff can further improve adherence rates over time. While programs that include MI training alone may improve adherence rates, this study indicates that additional improvements can be achieved if MTM staff have individual skill development plans that are continuously evaluated, acted upon and updated.

**SPONSORSHIP:** Envolve Pharmacy Solutions and the University of California, San Francisco

## U16 Change in Opioid Utilization Across Multiple Lines of Business in a Managed Care Organization

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**BACKGROUND:** In 2016, the Centers for Disease Control and Prevention (CDC) published its Guideline for Prescribing Opioids for Chronic Pain to improve communication between clinicians and patients in regards to the following: the risks and benefits of opioid therapy for chronic pain, the safety and effectiveness of pain treatment, and the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. In support of the CDC guidelines, an enhanced Opioid Program to reduce opioid overutilization through coordination of care between prescribers was implemented in 2018. Prescribers were provided educational tools and patient-specific profiles, and patients were sent a general flier about opioids.

**OBJECTIVE:** To determine the impact of provider and patient education on opioid utilization and cost in the commercial and Medicaid population.

**METHODS:** Pharmacy claims data were used to identify patients meeting the following criteria: use of opioids with a morphine milligram equivalent (MME) of ≥ 90 mg for ≥ 90 days; > 3 opioids/> 3 prescribers/> 3 pharmacies or > 5 prescribers; use of benzodiazepines, carisoprodol, ± gabapentinoids and ≥ 90 MME/day of opioids; overlapping use of opioids and opioid dependence medications for ≥ 30 days. Patients with pharmacy benefits 5 months pre/post intervention were evaluated. Utilization outcomes measured included change in average MME and opioid costs. A paired t-test was performed to compare the difference.

**RESULTS:** A total of 1985 patients met program eligibility criteria for evaluation. Reduction in average MME was 28 mg (95% CI 25, 31). Reduction in average opioid pharmacy claims cost was $271.03 (95% CI $216.10, $325.95). A total of 581 (30%) patients no longer met program criteria of > 90 mg of MME. The number of patients utilizing multiple pharmacies and prescribers dropped from 98 at baseline to 14 post intervention.

**CONCLUSIONS:** Provider outreach and coordination across prescribers and patients reduced opioid utilization and cost. A future enhancement to the program may entail case management of patients continuing to meet high MME utilization.

**SPONSORSHIP:** Envolve Pharmacy Solutions

## U17 Clinical Trial Versus Real-World Utilization of As-Needed Acute or Rescue Medications

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**BACKGROUND:** Acute and rescue medications are used on an as-needed basis to manage various conditions. To establish formulary quantity limits or assess the budget impact of new as-needed acute or rescue medication, payers often must make predictions on utilization. For new market entries, information from analogs or randomized controlled trials (RCTs) may be scarce. For novel treatments, no suitable analogs may exist. Furthermore, RCT utilization may not directly translate to real-world utilization. Limited research exists to compare RCT vs real-world utilization rates of acute and rescue medications.

**OBJECTIVE:** To evaluate how utilization differs in the real world compared to RCT setting for as-needed acute or rescue medications.

**METHODS:** A literature review was conducted using PubMed and conference abstract databases across five therapeutic areas including respiratory diseases, diabetes, attention-deficit/hyperactivity disorder (ADHD), migraines, and pain with opioid use, to identify RCTs and real-world retrospective studies (RWS) that reported utilization data. As various metrics of utilization exist (e.g., dose/day, fills/year, etc.), analogous metrics were matched by disease state, medication class, or specific medications. Utilization from RCTs was compared against RWS using descriptive statistics.

**RESULTS:** A total of 100 studies were identified which provided utilization data. After matching for analogous utilization metrics, nine outcomes were identified across 62 RCTs and 38 RWS. Median utilization of RCTs was higher compared to RWS for asthma (1.62 vs 1.35 puffs/day; +20%) and COPD (2.25 vs 1.31 puffs/day; +72%). RCT daily doses were higher for both glargine (54 vs 29.9 U/day; +80%) and detemir (76.5 vs 40.0 U/day; +91%) vs RWS. In ADHD, median methylphenidate doses were lower (32.0 vs 47.0 mg/day; -32%) while median amphetamine doses were higher (32.2 vs 17.5 mg/day; +84%) in RCT vs RWS. Median triptan use for migraines was similar, but slightly higher in RCTs (3.2 vs 3.0 tabs/month; +7%). Median opioid use was lower in RCTs for both chronic non-cancer pain (76.8 vs 109.4 MME/day; -30%) and post-surgery pain (29.4 vs 106.5 MME/day; -72%).

**CONCLUSIONS:** Our analysis suggests that for many therapeutic areas, medication utilization in RCTs may be higher than observed in the real-world setting, ranging from 7% to 91% higher. In contrast, opioid utilization for both chronic non-cancer and post-surgery pain was higher in the real world compared to RCTs. Additional analyses are needed to confirm these findings.

**SPONSORSHIP:** Curta

## U18 Assessing Interventions to Improve Patient Care Conducted by Pharmacists at an Outpatient Renal Transplant Clinic Within a Collaborative Pharmacy Practice Agreement

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**BACKGROUND:** A collaborative pharmacy practice agreement (CPPA) permits pharmacists to perform clinical services under the guidance of a supervising physician without direct physician intervention. A CPPA has been in use within the Vanderbilt Renal Transplant Clinic since March 2017.

**OBJECTIVE:** We aimed to quantify and categorize interventions performed by two clinical pharmacists with a CPPA at an academic renal transplant clinic and determine the impact of interventions on patient care.

**METHODS:** Clinic notes were reviewed to collect pharmacist interventions (defined as an encounter with one or more actions to improve patient outcomes), performed between 1/01/2019-06/30/2019, for adult patients prescribed immunosuppressant or non-immunosuppressant medication. Interventions were categorized by type (medical record assessments, medication counseling, or resolution of barriers to medication continuation), then further classified into subcategories. The number and type of interventions performed were summarized with frequency distributions. We also calculated the number of prescription orders entered by the clinical pharmacists during this time.

**RESULTS:** During the 6-month window, clinical pharmacists under a CPPA placed 2,997 prescription orders and performed 1,821 clinical chart reviews for 958 patients. Five percent of all orders were audited by the attending physician with a zero percent error rate. Within all clinical chart reviews, 3,852 interventions were performed: 2,695 medical record assessments, 734 medication counseling, and 423 resolutions of barriers to medication continuation.

**CONCLUSIONS:** Pharmacists practicing under a CPPA were able to reduce provider burden and improve patient care by managing the prescribing of transplant medications. The most common intervention performed was medical record assessment, which facilitates prescribing of appropriate medication and dosage. Pharmacist interventions ensured treatment adherence and persistence in patients that were evaluated.

**SPONSORSHIP:** None

## U19 Evaluation of Payer-Manufacturer Collaborations: Priorities, Barriers, and Characteristics of Successful Partnerships

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**BACKGROUND:** In the context of rising expenditures and shift from volume-based to value-based healthcare payment and delivery, payers are focused on improving member outcomes and decreasing costs. Manufacturers also play key roles in supporting the industry's shift to increasing and capturing value. Aligning these priorities allows stakeholders to engage in mutually beneficial collaborations. There is a need to characterize these experiences to identify best practices and assess opportunities for future engagement.

**OBJECTIVE:** To understand the themes and key steps to establish successful, non-contractual collaborations between payers and biopharmaceutical manufacturers.

**METHODS:** An online survey was fielded November-December 2019 to a panel of managed care professionals from Xcenda's Managed Care Network. Respondents with direct involvement in at least one collaboration with manufacturers were asked about their experiences, including barriers to implementation, elements of successful partnerships, and priorities for future opportunities.

**RESULTS:** A total of 31 respondents completed the survey, comprising mostly pharmacy directors (74%) and representing health plans (49%). 45% had a significant role in 3 or more collaborations with manufacturers. Respondents indicated often collaborating with manufacturers on patient education materials (55%), clinician education resources (52%), quality measure improvement programs (52%), and formulary pull-through resources (52%). Most collaborations focused on a single disease state (84%), and 32% focused on a single medication. For future collaborations, oncology was most commonly selected as a high-priority disease area (71%), followed by cardiovascular diseases (65%) and endocrinology (61%). Over half (58%) of respondents indicated that their organization's interest in collaborating with

biopharmaceutical manufacturers has increased over the past 5 years. Respondents were very interested in programs focusing on reducing unnecessary healthcare expenditures (90%). For future collaborations, respondents indicated research projects as the most valuable (68%) and having the highest likelihood of implementation (61%). For barriers to collaboration, 74% of respondents identified lack of funding as a very obstructive primary obstacle.

**CONCLUSIONS:** Payers are increasingly interested in collaborations, especially ones focusing on disease-related research and reducing healthcare expenditures. By aligning priorities, payers and manufacturers can collaborate to improve patient outcomes, lower costs, and increase patient access.

**SPONSORSHIP:** None

## U20 Medical Benefit (Part B) Drug Step Therapy and the Utilization Management Implications for Medicare Advantage Plans

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**BACKGROUND:** For Medicare Advantage (MA) plans, implementing utilization management (UM) of medical drugs (Part B) has been challenging prior to 2019. MA plans had to adhere to nonrestrictive Medicare guidance in order to manage medical drugs. Even in the presence of a lower cost clinically equivalent drug alternative, plans were required to provide coverage for high cost Part B drugs since Medicare guidance allowed it. This changed when The Centers for Medicare and Medicaid Services (CMS) issued a memorandum for plan year 2019, allowing MA plans to implement step therapy on Part B drugs. As the medical drug spend continues to rise, step therapy presents as a valuable UM strategy for MA organizations.

**OBJECTIVE:** To evaluate the impact of step therapy on utilization management of Part B drugs.

**METHODS:** Starting January 1, 2019, step therapy (ST) was implemented on 27 Part B drugs for Blue Cross Blue Shield of Michigan Medicare Advantage members. Prior authorization drug request information and medical claims for these drugs were analyzed for a 9-month period pre (1/1/18-9/30/18) and post (1/1/19-9/30/19) implementation of ST. Clinical interventions for these drugs in 2019 were compared against 2018. A clinical intervention was performed by a pharmacist and defined as a successful stepping of a part B drug to a lower cost clinically equivalent alternative.

**RESULTS:** A total of 372 step therapy (ST) based interventions were made across the board. Our top three drugs for ST intervention were Prolia (denosumab), Eylea (aflibercept), and Lucentis (ranibizumab). The number of clinical interventions increased 3 to 5 times for some of the highly utilized Part B drugs. For denosumab, the number of clinical interventions in 2019 were 225 vs. 89 in 2018; aflibercept was 63 vs. 12 and ranibizumab 40 vs. 7. Aflibercept and ranibizumab were stepped with Avastin (bevacizumab) eye injection. In the category of retinal anti-VEGF injections, utilization of bevacizumab increased from 41% to 45%, ranibizumab decreased from 25% to 21% and aflibercept stayed the same at 34%. Actuarial data showed incremental savings of $43,231 attributed to denosumab in second quarter of 2019 compared to second quarter of 2018 due to updated ST criteria.

**CONCLUSIONS:** Clinical pharmacists were able to make more interventions and generate more savings by implementation of a Part B step therapy program. Increased use of lower cost similar efficacy alternatives lead to reduced drug spend on Part B specialty medications.

**SPONSORSHIP:** Emergent Holdings for Blue Cross Blue Shield of Michigan

## U21 Evaluating Perceptions of Social Determinants of Health and Part D Star Performance of Medicare Advantage-Contracted Primary Care Physicians Serving a South Texas Market

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**BACKGROUND:** Socioeconomic factors can have a significant impact on a patient's health status, and could be responsible for as much as 70-80% of a patient's overall health. These factors, called the social determinants of health (SDoH), define a patient's day-to-day experiences. While the influence of such factors is well-recognized, there remains a debate regarding who is ultimately responsible for addressing SDoH in healthcare. Physicians and other clinicians are suitably placed to assess SDoH factors that can impact clinical decision making. Understanding Medicare Advantage (MA)-contracted primary care provider (PCP) SDoH perceptions, and their relationship to Part D performance, has yet to be fully explored.

**OBJECTIVE:** To understand MA-contracted PCP perceptions of SDoH and to investigate the correlation between their perceptions and their CMS Part D Star performance.

**METHODS:** Survey data was collected from MA-contracted PCPs serving a South Texas market during the 2019 year. An 8-item survey consisting of short answer, ranking, and multiple-choice questions was deployed at attendance-mandatory provider meetings from August-October. Differences in beliefs toward patients' overall health and beliefs towards patients' medication adherence practices were assessed using chi-square and t-tests. Spearman's correlation coefficient was used to examine the correlation between responses in beliefs towards patients' medication adherence practices and CMS Star ratings. A logistic regression model was applied to examine associations of physician characteristics and views with Star ratings (5 vs. less).

**RESULTS:** The response rate for returned surveys was 89%. Analysis revealed that the top three SDoH barriers included financial insecurity (24.87%), low health literacy (18.65%), and social isolation (15.03%). Safety (0.52%) and food insecurity (1.55%) were ranked among the least important barriers. About 36% of PCPs felt that they should be the primary addressor of SDoH, while 28.57% felt that it is the job of insurers. Furthermore, there was no statistically significant correlation between how PCPs answered regarding medication adherence and their CMS Part D Star ratings. Racial differences in physician views may exist, but larger samples are needed to fully ascertain.

**CONCLUSIONS:** Safety and food insecurity were not among the top SDoH barriers in our survey, but previous literature recognizes them as key SDoH factors. Future research should examine patient perceptions of SDOH in this population to identify ways providers and payers can better serve and interact with their patients.

**SPONSORSHIP:** None

## U22 A Systematic Comparison of Status Quo and Future Expectations for Novel Drug Financing Strategies Across Managed Care Organizations

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**BACKGROUND:** The category of high-cost specialty pharmaceuticals is rapidly growing, leading to a severe cost burden. Innovative and alternative payment strategies are often discussed as solutions, though the actual level of implementation in managed care organizations (MCOs) is unclear.

**OBJECTIVE:** To assess both the status quo of novel payment strategies across Commercial and Medicare lives, and opportunities for future expansion within three years.

**METHODS:** Data were collected from an online survey of 12 pharmacy and 8 medical directors as active voting members of their organization's Pharmacy & Therapeutics Committee. Respondents were responsible for a total of 178 million (M) lives across the United States (148.2M Commercial, 29.6M Medicare). Payer archetypes included national and regional health plans, pharmacy benefit managers (PBMs) and integrated delivery networks (IDNs).

**RESULTS:** Increased cost-sharing is the leading 'financing' strategy across 50% of Commercial and 30% of Medicare lives overall. Mid-sized plans (≥920,000 and <3,400,000 covered lives) draw on increased cost-sharing for 70-90% of commercial lives, while regional plans are nearly twice as likely as larger national plans to expand it further. Different types of outcomes-based agreements (OBAs) are used in <10% of lives, contract renewals are expected in national plans. Only IDNs are moderately confident to expand OBA use beyond pilots. Amongst potential alternative models of subscription pricing, risk pooling, annuity payments and stop loss for high-cost members, only the latter is currently employed for roughly 20% of Commercial lives, being the one model all MCO types are somewhat likely to expand in the future. Overall, IDNs are somewhat optimistic on the implementation of various novel strategies whereas PBMs and small plans overwhelmingly prefer 'tried and tested' cost-sharing.

**CONCLUSIONS:** Despite heightened excitement around innovative financing models, MCOs in the US see comparatively little to no current use and narrow plans of future implementation. We see few immediate opportunities for the adoption of alternative solutions. Additional qualitative feedback also indicates why the current types of OBA have seen limited scale, frequently citing a lack of resources and lack of manufacturer commitment to more meaningful areas of implementation. One 1 in 3 MCOs with OBA experience today is satisfied with what has been put in place. Following our results, there is still an opening to further adopt alternative models – but it remains restricted to IDN archetypes in the near future.

**SPONSORSHIP:** Certara

## U23 Payer Health Economic and Outcomes Research Data Needs: An Evaluation of Value

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**BACKGROUND:** Shifting market dynamics in the US have increased the role of health economics and outcomes research (HEOR) data in payer evaluations of product value and coverage decisions. HEOR can be described as a field that complements traditional clinical development programs and information (eg, efficacy, safety, appropriate use, and administration) in order to further guide healthcare decision makers (eg, payers) regarding coverage, reimbursement, and patient access to specific drugs, devices, and services.

**OBJECTIVE:** To assess which components of HEOR evidence are important when evaluating a product's value and whether HEOR evidence needs differ across therapeutic areas as well as the competitive landscape.

**METHODS:** An online 30-minute, double-blinded quantitative survey was completed by healthcare decision makers in Xcenda's Managed Care Network from April 19 to May 5, 2019.

**RESULTS:** Payers (n=41) represented 78 million covered lives from national (34%) and regional (66%) health plans (68%), integrated delivery networks (22%), and pharmacy benefit managers (10%). Respondents indicated that clinical outcomes and cost/medical offset data are considered the most important components of HEOR data packages. 93% of respondents agree that HEOR evidence needs differ across therapeutic areas and is especially important for "me-too" therapies and products receiving fast-track Food and Drug Administration (FDA) approval. Across oncology, rare/orphan diseases, and cell/gene therapy, clinical trial data (≥97% importance) and direct comparisons (≥93% importance) of efficacy were the HEOR components rated as most important. The survey also highlighted that HEOR evidence is important when evaluating a product based on a surrogate endpoint with unproven clinical benefits (86% of payers agree). More than 90% of payers agree that the existence of generic alternatives and the unmet need for new therapies are considered the most important factors when reviewing a new FDA-approved product entering a crowded market, and that product price for payers is considered the most important economic consideration when evaluating a new FDA-approved product.

**CONCLUSIONS:** Payer HEOR data needs for the evaluation of a product's value differ based on therapeutic area and competitive landscape. Manufacturers should pursue customized HEOR evidence-generation activities based on their product's disease state and market position.

**SPONSORSHIP:** Xcenda

## U24 Use of Digital Prescription Management and Reminder Tools Is Associated with Increased Medication Adherence Among Patients at a Large Chain Pharmacy

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**BACKGROUND:** Taking medication as prescribed is often critical to managing chronic conditions. Medication non-adherence is linked to adverse health outcomes including complications and worsening of the condition. Digital tools may help improve medication adherence through digital prescription management and refill reminders.

**OBJECTIVE:** The objective of this study was to examine the differences in medication adherence between patients who used pharmacy-based digital prescription management and reminder tools and those who did not use these tools.

**METHODS:** Digitally active patients who filled prescriptions from top therapeutic drug groups between March and June of 2018 were selected and followed for 12 months. Those with only one medication fill were excluded. Patients were separated into three groups: those with confirmed use of the online or mobile tool to manage and refill prescriptions, those who activated the online or mobile tool but used email or SMS reminders to refill instead, and those who did not activate the online or mobile tool but did use email or SMS reminders to refill. Non-digital control patients were selected using the same criterion and matched with each digitally engaged group. A 1:1 propensity score match was used to minimize differences in age, gender, chronic condition score, copay, household income, and urban locality between the groups. Adherence was measured by calculating the proportion of days covered (PDC). Results were reported for all therapeutic groups combined, as well as by individual therapeutic group.

**RESULTS:** Patients who used the online or mobile tool to manage and refill prescriptions (n=1,016,490), were on average 52 years old, and 58.9% female. These participants had an average PDC of 79.4, compared to 77.5 for the control group ($P<0.0001$). Patients who could use the online or mobile tool but instead used email or SMS reminders to refill (n=800,673) were on average 53 years old, and 59.2% female. These participants had an average PDC of 81.2, while the non-digital control group had an average PDC of 78.4 ($P<0.0001$). The last group did not activate the online or mobile tool but did use email or SMS reminders to refill (n=305,618). They had an average age of 55 and were 59.7% female. This group also had a higher average PDC compared to the control, 80.6 vs 78.0 ($P<0.0001$).

**CONCLUSIONS:** Patients who used digital prescription management and reminder tools were consistently more adherent than those who were not digitally engaged.

**SPONSORSHIP:** None

## U26 A Multilevel Analysis of Medication Nonadherence in a Medicare Advantage Population in Philadelphia

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**BACKGROUND:** Medication adherence is a public health priority and its improvement is a policy goal of the Center for Medicare and Medicaid Services (CMS). Medication nonadherence is associated with both adverse health outcomes and higher medical expenditure. Leveraging a unique data source from a large commercial insurer in Philadelphia, Pennsylvania this study examines associations between medication adherence for a Medicare Advantage (MA) and individual, neighborhood, and health system variables.

**OBJECTIVE:** To understand the association between individual, neighborhood, and health system factors and medication nonadherence among MA members in Philadelphia, PA.

**METHODS:** Claims from a large commercial insurer are used to calculate medication nonadherence (proportion of days covered [PDC] < 80%) for 37,387 MA members taking antidiabetic, antihypertensive, or antilipidemic medications in 2018. Descriptive statistics and multivariable logistic regression analyses were used to assess the associations between the individual, neighborhood, and health system levels factors and medication nonadherence.

**RESULTS:** Adjusted and unadjusted models revealed several significant associations. In multivariable analyses, those receiving prescriptions via mail order (OR = 0.40, $P < 0.001$) or in a 90-day supply from their pharmacy (OR = 0.58, $P < 0.001$) had significantly lower odds of being nonadherent relative to members not receiving prescriptions through the mail or in a 90-day supply. Additionally, members with Alzheimer's or dementia (OR = 1.21, $P < 0.001$) and members residing in North Philadelphia (OR = 1.46, $P < 0.001$) had significantly higher odds of being nonadherent. Members who commuted to pharmacies outside of their neighborhood to get prescriptions were less likely to be nonadherent (OR = 0.86, $P = 0.001$). Measures such as pharmacy benefit structure (open vs closed) or type of insurance (PPO vs HMO) were not found to be significantly associated with nonadherence.

**CONCLUSIONS:** This study brings together unique sources of data to gain a comprehensive look into medication nonadherence for MA members. The presence of chronic conditions, receiving prescriptions through mail or in a 90-day supply, and a member's neighborhood were all significantly associated with medication nonadherence. Integrating this information into outreach efforts by health plans and policymakers could significantly reduce medication nonadherence and improve member health.

**SPONSORSHIP:** Independence Blue Cross

## U27 Application of the Pharmacy Quality Alliance Medication Therapy Problem Categories Framework to In-home Medication Verification After Hospital Discharge in Complex and High-Risk Patients

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**BACKGROUND:** Patients discharged from acute-care settings often have difficulty reconciling medication changes. Additionally, social determinants of health (SDOH) can further compromise access and adherence. We hypothesized that using a pharmacy technician to perform verification and assess SDOH in the home would be more informative than in the hospital or clinic setting.

**OBJECTIVE:** To describe medication therapy problems and SDOH identified through in-home medication verifications for medically complex and high-risk patients discharged from the hospital.

**METHODS:** High-risk patients with complex medication regimens were identified prior to discharge by hospital staff and referred for home medication verification. Referral criteria included high-risk medication regimens (anticoagulation, new insulin) or complexity (6 or more chronic medications). A technician performed the patient interview in the home following discharge. Medication related problems, defined by Pharmacy Quality Alliance Medication Therapy Problem Categories Framework (PQA), and SDOH, were subsequently documented by the supervisory clinical pharmacist.

**RESULTS:** During a 5-month period [Jul-Dec 2019], 144 pharmacy technician home visits were conducted and the initial 51 visits were analyzed. The majority (70.6%) of patients were age 65 years or older, and 11.8% received Spanish translation services. At the time of the home visit, the patients were taking on average 11 medications and nearly two-thirds (62.7%) of the patients had medications prescribed by 3 or more providers. Adherence problems were identified in 45.1% of the patients. SDOH impacting care were noted for 86.3% of the patients, and in 91.3% of the subset of patients with adherence problems. Ultimately 140 drug-related problems using the PQA Framework (average 2.75 per patient) were recorded by the clinical pharmacist. The most common drug-related problems were needing additional therapy and adherence. Expired medications were discovered in 19.6% of the patients' homes, and 30% of these patients utilized the medication disposal service provided by the pharmacy technician.

**CONCLUSIONS:** Our pharmacy technician played an important early role that resulted in the identification of nearly 3 drug therapy problems on average per high risk discharged patient. Moreover, we identified important social determinants of health that affected patients' access and adherence to medications. There is an unmet need for comprehensive in-home pharmacy care services in the post-acute care setting.

**SPONSORSHIP:** None

## U28 Supporting Patients with NVAF Outside of the Clinic: Improving Patient Physical and Behavioral Outcomes with a 12-Week Digital Health Coaching Intervention

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**BACKGROUND:** A person's health is a combination of many factors including social, economic, physical, and behavioral. A patient-centered and holistic approach to care is needed in individuals with chronic illness in order to help them overcome barriers, promote health literacy, and improve outcomes. Receiving a diagnosis of non-valvular atrial fibrillation (NVAF) can be overwhelming, especially for those without a strong social network. To support patients outside of the clinic, a high-touch, digital coaching, patient-centered engagement intervention can help those with chronic conditions develop positive behaviors, increase medication adherence, and improve overall well-being.

**OBJECTIVE:** Primary care clinicians are the frontline providers seeing patients at risk for NVAF and play an integral role in screening and initiating care for NVAF, often in collaboration with a cardiologist. However, clinicians can't do it all and patients often need support outside of their HCPs office.

**METHODS:** Given that, CME Outfitters partnered with Pack Health, a digital health coaching company that assigned a dedicated health advisor to each enrolled patient (n = 75) with NVAF. Patients learned about the digital health coaching from their HCPs, who completed NVAF education with CME Outfitters. The health advisor established weekly and on-demand contacts with the patient via phone, text, email, and events. A retrospective analysis was performed using patient-reported outcomes collected during the 12-week health coaching intervention.

**RESULTS:** Of the patients completing the 12-week program, 88% were female and 12% male with 12% living in rural areas with limited access to care. Patients are taking an average of 10 prescription medications. Before beginning coaching, 23% thought the risk goes away once they begin treatment, 16% struggle to pay for their medical care, and 10% reported difficulty scheduling appointments with their HCP. After the 12-week program, 72% felt confident in discussing their treatment plan with their HCP. Mental health improved in these patients from 34% to 50% based on PROMIS scores. There was a reduction from 89% to 35% of patients with above average stress and an increase from 11% to 67% in health self-efficacy. The top 3 goals for patients participating in the digital health coaching were maintaining a healthy weight, adhering to medications, and eating healthy.

**CONCLUSIONS:** This poster will illustrate improvements and barriers reported in patients' physical health, mental health, medication adherence, and self-efficacy in the management of their NVAF.

**SPONSORSHIP:** Bristol Myers Squibb and Pfizer Alliance

## U29 ICER's Influence on Health Care Delivery: How Managed Care Organizations Use ICER Reports in Decision Making

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**BACKGROUND:** The influence of the Institute for Clinical and Economic Review (ICER) on drug pricing and reimbursement decisions has been increasing over the last few years. In particular, managed care organizations (MCOs) are interested in ICER reports as they are charged with delivering quality care while controlling costs. It is unclear how, and to what extent, MCOs are utilizing reports to inform their formulary reviews.

**OBJECTIVE:** To understand how managed care is using ICER reports to make decisions and to examine the advantages and limitations of ICER evaluations from this perspective.

**METHODS:** Data from payers and other health care decision makers in the United States were collected from FormularyDecisions. FormularyDecisions is an online platform with over 2,100 registered and active formulary decision makers, including MCOs, pharmacy benefit managers, hospitals, and government payers who access ICER reports through the platform. Syndicated surveys were completed between December 1, 2018 and December 1, 2019.

**RESULTS:** MCOs represented 39% of active users that accessed ICER reports within the FormularyDecisions platform. Of the MCO users that provided responses, 74.0% indicated they used ICER evaluations for decision-making, spending an average of 12.5 minutes per user session (vs the overall average of 10.9) reviewing ICER reports. A majority (61.2%) of MCO respondents indicated they have used or will use an ICER report in their formulary review. Of those MCOs who used ICER assessments to support clinical decision-making, 35.0% indicated they were used as a primary source of evidence to support their evaluation and P&T preparations, 52.2% as a secondary source of evidence, 44.6% to assist in determining product affordability, and 42.0% to inform or validate their own research and analysis. Respondents rated the executive summary, the comparative clinical effectiveness section, and the incremental value per outcomes achieved as the most useful components of ICER reports. The primary limitations included length, complexity, and model methodology. Of those who have not used ICER reports, 57.9% indicated that it was because the report was not available in time to prepare for P&T decisions.

**CONCLUSIONS:** ICER reports are actively being used by MCOs as part of their formulary review process for determining patient access to therapies. Clinical effectiveness and incremental value are key elements utilized from these reports; however, this information is not always available at the time when organizations convene for decision-making.

**SPONSORSHIP:** Xcenda

## U30 Systematic Literature Review on Value Assessment Criteria Used in MCDA Frameworks Evaluating Orphan Drugs

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**BACKGROUND:** Multi-criteria decision analysis (MCDA) is a structured decision-making process that offers greater flexibility to incorporate multiple objectives and criteria, than traditional cost-effectiveness analysis.

**OBJECTIVE:** To perform a systematic literature review on the criteria and scoring functions used in MCDA value frameworks, relevant to evaluate pharmaceuticals used to treat rare diseases. The aim is to gain a better understanding on the measurement of MCDA attributes with the help of the scales and scoring functions applied in published value frameworks.

**METHODS:** MCDA or value framework articles relevant for pricing and reimbursement decision making of pharmaceuticals, and structured review papers on orphan drug specific MCDA articles were reviewed. Information sources included Scopus, Medline, Embase, and 26 other grey literature sources (databases of universities, health technology assessment agencies, etc.). Title and abstract screening and full text screening was conducted by two independent researchers. Data extraction emphasized study criterion descriptions (name, definition, scoring function details). Value frameworks were included in final selection if they contained explicit scoring functions for the included criteria and were orphan drug specific or were considered impactful general frameworks (appeared or were referenced more than once in the search and/or a previous literature reviews).

**RESULTS:** Preliminary results found 2913 independent publications. Title and abstract screenings narrowed our search to 434 publications. Of the 434 publications, 50 peer review articles published some kind of value attributes. However, only 11 papers satisfied inclusion criteria. Additionally, 74 conference abstracts were found, resulting in 12 relevant posters, with one being included alongside screened peer review articles. Final screening identified 12 unique MCDA value frameworks. Initial findings suggest the most frequently identified criteria in these frameworks were addressing "Unmet Needs", included in 11 Frameworks, "Comparative Clinical Effectiveness" included in 10 Frameworks, and "Comparative Safety" included in 9 Frameworks

**CONCLUSIONS:** Findings presented at the conference will include evaluating framework specific criterion, criterion specific scoring functions, and categorizing criterion based on if they fall within the scope of traditional or non-traditional value assessment. The published scales and measurement methods of MCDA attributes will support future recommendation in the evaluation of treatments for rare diseases

**SPONSORSHIP:** Center for Excellence PhRMA Foundation Grant

## U31 Case Simulations in OSA and Narcolepsy: Patients That Keep You Up at Night

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**BACKGROUND:** For a significant number of patients with narcolepsy or obstructive sleep apnea, residual excessive daytime sleepiness persists despite treatment. The effect of residual EDS is far-reaching, impacting quality of life, levels of fatigue, cognitive and daily functioning, as well as increasing morbidity and mortality. To optimize clinical outcomes, clinicians must be aware of the efficacy of current and emerging therapies, as well as strategies to engage patients in shared decision-making regarding treatment.

**OBJECTIVE:** 3 CME interventions used online case simulations to facilitate the recognition of residual EDS in patients with narcolepsy and OSA and to improve decision-making when developing strategies for long-term management of residual EDS.

**METHODS:** Outcomes data were obtained from 3, 30-minute case simulations on residual EDS. Surveys assessing knowledge, confidence, and behavior were administered pre- and post-activity. A separate evaluation provided demographics and other variables used in the model. Data from a 2-month follow-up survey were analyzed to determine performance effects on the learner population (n = 30) compared to matched controls (n = 30). Statistical comparisons of data from baseline to post-intervention were made using McNemar's tests and paired t-tests. Additionally, predictive modeling was applied to evaluate variables predictive of evidence-based decisions. A longitudinal analysis of results was conducted to evaluate knowledge and performance changes in sleep-related initiatives between 2016-2019.

**RESULTS:** Learners outperformed controls in utilizing the Epworth Sleepiness Scale (ESS) and are more likely to interpret ESS scores to confirm EDS diagnosis and select appropriate treatment options in managing patients with EDS. Further, learners are more likely than controls to engage in shared decision-making with patients. When given a real-world case, learners are more likely than controls to identify symptoms and order correct tests. Learners were also more likely to select best treatment options for the patient more often than non-learners. Continued education needs to focus on treatment options for patients with narcolepsy.

**CONCLUSIONS:** Follow-up assessments were conducted to understand lasting performance in learners attributable to this education. Using data from learners compared to matched controls, we found the education had an effect size of 23% (Cohen's d = 0.33). This indicates that for every 100 clinicians exposed to this education, 23 will perform more according to evidence than if they were not exposed.

**SPONSORSHIP:** Jazz Pharmaceuticals

## U32 A Survey-Based Analysis of Formulary Decision Making and Utilization Management Trends Across Managed Care Organizations

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**BACKGROUND:** The number and prices of specialty products continue to rise, leading to a severe cost burden for key stakeholders. From the perspective of managed care organizations (MCOs), many strategies are employed to manage specialty drug utilization though it is often unclear what is currently implemented and the likelihood of expansion in the future.

**OBJECTIVE:** To assess the current and future formulary decision and utilization management (UM) for specialty products in Commercial and Medicare lives

**METHODS:** An online survey was conducted among active members of Pharmacy & Therapeutics Committees in MCOs. Of 20 respondents, 12 were pharmacy directors and eight were medical directors, covering a total 148.2 million Commercial and 29.6 million Medicare lives. Respondents consisted of national and regional health plans, pharmacy benefit managers (PBMs) and integrated delivery networks (IDNs). Health plans were also categorized by size based on the number of covered lives.

**RESULTS:** Overall, there was limited use of quality-adjusted life year (QALY) based analyses to guide formulary decisions with an estimated implementation across ≤ 10% of Commercial and Medicare lives. In the next 3 years, MCOs anticipate expanding use of these to at least 30% of lives in both channels. The incorporation of clinical effectiveness analyses saw an implementation for about 40% and ≤10% of Commercial and Medicare lives, respectively. Respondents anticipate increased use of these analyses for coverage decisions to about 60% of Commercial and 30% of Medicare lives. Quantity limits are the most used UM strategy across both Commercial and Medicare, in an estimated ≥ 90% and 70% of lives, respectively. Small plans (< 920,000 lives), regional plans and PBMs have the highest use of coverage strategies. The near future will see more UM expansion across all archetypes, especially for the Commercial segment. Product preference and exclusions for medical benefit drugs and more restrictive PA and reauthorization criteria for physician-administered drugs are just a few strategies that will be used for at least 50% and 30% of Commercial and Medicare lives, respectively.

**CONCLUSIONS:** Thus far clinical effectiveness and QALY-based analyses like ICER have not been key influencers of formulary decisions, however it is safe to say that such frameworks should not be ignored and may have a pronounced impact on decisions in the future. The specialty category will be managed more stringently moving forward with MCOs expanding restrictive strategies to more covered lives among their membership, especially for physician-administered products.

**SPONSORSHIP:** Certara

## U33 Efficacy of Using Artificial Intelligence to Determine Whether Adding Pharmacy-Based Interventions in Addition to Call Center Interventions Will Improve Patients' Refill Rates

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**BACKGROUND:** Medication adherence interventions to prompt medication refills are often executed by centralized call centers and are also often executed by retail pharmacies. It is important to evaluate which patients will achieve the greatest uplift in Rx refill rates by receiving both call center and pharmacy provided interventions.

**OBJECTIVE:** This study evaluated the effectiveness of using artificial intelligence (AI) to target which patients would benefit most from receiving pharmacy-based interventions in addition to call center interventions.

**METHODS:** In this randomized controlled trial (RCT) study, data was sourced from a pharmacy chain and from a call center that provides medication adherence interventions.

Patients who were had a fill due soon or were late for RAS antagonists, non-insulin anti-diabetics and/or statin medications and were high risk were selected for medication adherence interventions via AI. Two intervention options were available for this population. One option was a reminder call from a centralized call center. The other option was to receive both the call center intervention as well as an intervention from the patient's retail pharmacy. Patients were independently randomized to either receive the call center intervention alone or to receive both interventions. Patients were further predicted as to

whether adding the retail pharmacy outreach to the centralized call center outreach would have a high impact (Group A, n=4,011) or a low impact (Group B, n=8,026) on their likelihood of filling within 14 days.

**RESULTS:** Patients placed into Group A by the AI and randomized to receive both interventions were 51.9% more likely to refill within 14 days than patients placed into Group A by the AI and randomized to only receive the call center intervention ($P<0.001$). Patients placed into Group B by the AI and randomized to receive both interventions were 24.5% more likely to refill within 14 days than patients placed into Group B by the AI and randomized to only receive the call center intervention ($P<0.001$).

**CONCLUSIONS:** AI can effectively select which patients will achieve greater uplifts in refill rates by adding a pharmacy-based intervention to a call center intervention.

**SPONSORSHIP:** AllazoHealth

## Z00-Z99 Factors Influencing Health Status and Contact with Health Services

### Z2 Key Informant Perceptions of Telephonic Comprehensive Medication Review Services in the US

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**BACKGROUND:** Medicare Advantage Part D and stand-alone Part D prescription drug plans are required by the Centers for Medicare & Medicaid Services (CMS) to have qualified providers, including pharmacists, offer annual comprehensive medication reviews (CMRs) for eligible beneficiaries. Although CMRs have been shown to provide value, little is known about service uniformity. As such, variation in and quality of CMR services are not well understood.

**OBJECTIVE:** To characterize CMS-mandated telephonic CMR services from diverse stakeholder perspectives.

**METHODS:** Semi-structured interviews were conducted with a purposive sample of subject matter experts to assess CMR perceptions. Topics included scope of CMR content, frequency, eligibility, and perceived strengths/weaknesses of telephonic CMRs. Transcripts were analyzed using the inductive saturation model and phenomenological approach to code emergent themes, which were iteratively refined until saturation was achieved. Two researchers independently coded each transcript and intercoder reliability (IR) was estimated using Krippendorf's alpha.

**RESULTS:** Interviewees included CMR providers (n=5), payers (n=3) and standard-setting organizations (n=2). More than half (n=6, 60%) had >10 years of MTM experience. IR was 0.92 (high agreement). CMR content descriptions were consistent across perspectives. Interviewees described scenarios appropriate for expanded CMR eligibility criteria, though none were consistently applied. In the current delivery model, providers emphasized patient CMR acceptance rates whereas payers and standard-setting organizations emphasized completion rates. Completion rates and adherence to CMS standards were characterized as a core organizational goal (n=8), while patient satisfaction was not (n=4). Lack of incentive for CMR providers to follow up with patients was a barrier to expanded services. Overall, interviewees were dissatisfied with the CMR completion rate measure and would prefer measures focused on service quality and outcomes.

**CONCLUSIONS:** CMR services largely met minimum CMS guidelines, with variation in value-add services. Incentivization of CMR completion has shifted organizational focus to quantity, yet completion rates do not measure drug-related outcomes or changes in disease management. Interviewees desired adoption of a quality measure that is actionable and non-redundant. To inform a measure of quality, future research should include analysis of completed CMRs to determine the extent of variation in content and delivery.

**SPONSORSHIP:** Merck Sharp & Dohme, a subsidiary of Merck & Co.

### Z3 Family Caregiver Burden of Patients with Acute Myeloid Leukemia and Other Hematologic Malignancies Receiving Stem Cell Therapy

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**BACKGROUND:** Caregivers, defined as "those with close social/familial ties to patient", experience family caregiving burden (FCB). FCB of patients with acute myeloid leukemia (AML), other hematologic malignancies (HMs), or patients receiving stem cell therapy (SCT) is attributable to the threat to survival, long and costly hospitalizations, and significant treatment side effects experienced by patients. FCB manifests in the form of direct medical impact leading to worsened health-related quality of life (HRQOL) and financial impact due to copays/coinsurance, income loss, travel, and/or lodging.

**OBJECTIVE:** To review FCB of patients with AML, HM, and SCT. To explore instruments that measure and interventions that address FCB.

**METHODS:** We identified studies published in 2010 or later in English through PubMed, Embase, Medline, and Ovid databases. Two reviewers independently determined eligibility based on pre-specified PICOS criteria that included as population caregivers of patients with AML, HM, and SCT; as interventions, tools to quantify or address FCB; as outcomes, humanistic and economic burden with no restriction on study design or comparator.

**RESULTS:** We found 524 publications of which 87 met eligibility criteria; only 3 reported AML-specific FCB. Fatigue, sleep problems, post-traumatic stress, anxiety, and depression impacted caregivers. Annual mean out-of-pocket (OOP) costs reached 25% of the household income after SCT. Within the year before SCT, reported median household income reduction was $15,690 (range: $3,500-$70,000). Three months after SCT, the median OOP was $2,440 (range, $199-$13,769). Patients/caregivers who had to travel had higher lodging expenses than those who did not (median, $5,247 vs. $716). Annual pharmaceutical OOP was $12,400-$16,000 after SCT. FCs faced job loss, work disruptions, and inability to secure a full-time position after diagnosis (2-6 years). 51% of FCs were full-time employed before vs 27% during caregiving. The proportion of caregivers on leave increased from 2% to 25%. We found 16 FCB-specific, 15 generic and 6 symptom-specific instruments to measure FCB, and interventions to address it (education, expression, self-adjustment, digital health). Systematic interventions to guide FCs for treatment-related symptomatic burden were lacking.

**CONCLUSIONS:** Caregivers of patients with AML, HM, and SCT face humanistic burden due to medical symptoms that worsen HRQOL and psychosocial challenges, and economic burden due to copays and work loss. Systematic and structured interventions offering respite help are needed.

**SPONSORSHIP:** Amgen

## Z9 Integration of a Collaborative Practice Agreement to Manage Medication Adherence

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**BACKGROUND:** Medicare Star Rating performance thresholds continue to rise amidst primary care physician shortages. Medication reconciliation and clinical management are often required in managing chronic use of statin, renin-angiotensin system, and oral diabetes medications. Pharmacist expertise can be applied to optimize medication management in Medicare measures of Medication Adherence (ADH) and Medication Therapy Management (MTM).

**OBJECTIVE:** To describe the establishment and utilization of a Collaborative Pharmacy Practice Agreement (CPA) between pharmacists and physicians to impact Medicare Stars within an integrated health system.

**METHODS:** A novel CPA was created and approved by the Northern California Regional Pharmacy and Therapeutics Committee to allow authorized pharmacists to directly manage medication therapy for Medicare patients for up to three years. The Medicare Protocol broadly covers ADH, MTM, polypharmacy, and additional medication-related CMS measure that may be forthcoming. Authorized functions of the pharmacist include initiating, adjusting, or discontinuing medications and ordering of drug related laboratory tests.

**RESULTS:** An eligible patient list consisting of Medicare beneficiaries on statin, blood pressure, or oral diabetes medications was generated and used to track physician CPA approval and documentation of authorization into each patient's electronic medical record. Ambulatory care pharmacists are authorized to work under the CPA and were matched to manage complex patients in ADH. This included patients with low adherence (as calculated by proportion of days covered [PDC]) or with a refill pattern half of what it should be based on the directions for use. Common use of prescriptive authority in ADH included prescription sig updates, authorization of refills, maximizing medication quantity to 100-day supply, changing dose or drug (i.e. due to intolerance or drug shortages), and ordering and monitoring labs. The same CPA authorizations are applied to patients also meeting eligibility for Medicare Part D MTM comprehensive medication reviews. There is a proposal to adopt the Medicare CPA nationally within the integrated health system. Protocol workflow and details from the integration playbook will be shared with the poster.

**CONCLUSIONS:** The Medicare CPA establishes pharmacist prescriptive authority to provide timely and clinically appropriate care for Medicare patients.

**SPONSORSHIP:** None

## Z12 Real-World Daily Average Consumption of Tacrolimus Extended-Release After Conversion from Tacrolimus Immediate-Release Among Kidney Transplant Patients

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**BACKGROUND:** Envarsus XR (LCPT), a calcineurin inhibitor approved for the prevention of rejection in kidney transplant recipients, shows improved bioavailability and a lower dose requirement than tacrolimus immediate release (IR-TAC). The prescribing information for LCPT recommends a 20% total daily dose reduction upon conversion from IR-TAC.

**OBJECTIVE:** To identify the actual daily average consumption (DACON) patterns of kidney transplant recipients converted from IR-TAC to LCPT and to calculate the associated differences in drug acquisition costs

**METHODS:** Symphony Health Solutions claims data from January 2015 to December 2018 were analyzed. Patients with prescription claims for both IR-TAC and LCPT were identified. Identified patients were required to have a stable dosage of IR-TAC for a minimum of 90 days and at least 2 claims for LCPT. The first fill of LCPT was identified as the switch date. The IR-TAC dose immediately preceding the switch date was compared with the dose of LCPT from the 2nd fill after the switch date. DACON were compared across patient demographics and initial tacrolimus dose. Wholesale acquisition costs and national average drug acquisition costs were used to calculate costs based on the weighted average daily dose.

**RESULTS:** 1618 patients were identified. After switching to LCPT, 9% of patients were on the same and 66% were on a lower daily dose. The mean stable IR-TAC dose prior to conversion was 5.8 mg/day and 4.1 mg/day of LCPT after conversion. Results were similar across gender, age, ethnicity, and payer type (40% commercial, 36% Medicare, 13% Medicaid). Patients in the highest initial daily IR-TAC dose quartile (IR-TAC dose >8 mg/day, mean 12.6 mg/day) were most likely (89%) to convert to a lower dose of LCPT and had an average dose decrease of 56%. Patients in the lowest quartile (IR-TAC<1 mg/day, mean 0.9 mg/day) were most likely (63%) to require a higher dose of LCPT. Based on DACON, drug costs for hi-dose patients switching from branded IR-TAC to LCPT would decrease from $75.98 to $40.32 per day (-47%).

**CONCLUSIONS:** Most patients who convert from IR-TAC to LCPT have a decreased DACON with patients on the highest initial daily doses experiencing the greatest dose reduction. The acquisition cost of LCPT is 47% less than the cost for branded IR-TAC. The impact of dose decrease on patient and payer drug costs should be examined in future studies.

**SPONSORSHIP:** Veloxis Pharmaceuticals

## Z13 Evaluation of Adherence to Behavioral Health Medications and STARS Adherence Medications

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**BACKGROUND:** There are limited studies demonstrating the relationship in adherence between behavioral health (BH) medications and the Star adherence classes.

**OBJECTIVE:** Determine the relationship between adherence to BH medications and Star adherence classes.

**METHODS:** Retrospective claims analysis of Medicare Advantage (MAPD) and Prescription Drug Plan (PDP) members continuously enrolled in the health plan between 2017 and 2018. Members had to have been in at least once triple weighted Star adherence measure (RASA, Diabetes, or Statin) and had at least 2 fills of an antidepressant and/or antipsychotic medication. Adherence was calculated using the proportion of days covered (PDC) calculation with adherence defined as ≥80%.

**RESULTS:** There were 702,881 and 202,454 members included in the antidepressant and antipsychotic analysis, respectively. The composite antidepressant Odds Ratio (OR) in 2017 was 3.61 (CI 3.52-3.70) and 2.92 (CI 2.87-2.97) in 2018. The composite antipsychotic OR in 2017 was 3.17 (CI 3.03-3.32) and 2.69 (CI 2.57-2.75) in 2018.

**CONCLUSIONS:** Members adherent to their BH medication are 2-3 times more likely to be adherent to any Star adherence class.

**SPONSORSHIP:** None

## Z14 Evidence of Peanut Allergy Management in Healthcare Resource Utilization Among Commercially Insured Individuals with Peanut Allergy Despite Practicing Peanut Avoidance

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**BACKGROUND:** Current options for individuals with peanut allergy (PA) are limited to allergen avoidance and treatment of allergic reactions with emergency medicines including epinephrine auto-injectors (EAI). There is a paucity of real-world data assessing healthcare resource utilization (HRU) and costs in the US associated with the peanut avoidance practice.

**OBJECTIVE:** To evaluate HRU and costs associated with current PA management practice.

**METHODS:** Individuals with PA were identified from a large US administrative claims database (1999-2017). Continuous enrollment was split into episodes of 12-month study periods (patient-years). PA-related HRU, indicated by PA-related codes or EAI prescription fills in medical and pharmacy claims, respectively, and all-cause direct healthcare costs were described on a patient-year basis. Comorbidities frequently associated with PA (asthma, atopic dermatitis/eczema, other food allergies, and allergic rhinitis) were identified using diagnosis codes in medical claims.

**RESULTS:** Of 55,193 patient-years (from 10,959 individuals with PA), 15.8% were aged 0-3 years, 50.2% 4-11 years, 17.4% 12-17 years, and 16.6% ≥18 years. Higher HRU was observed in younger individuals (aged ≤17 and ≥18 years, respectively); particularly PA-related outpatient (OP) visits (23.9% and 11.8%), food challenges (3.2% and 1.1%), peanut-specific IgE blood tests (14.7% and 5.9%), skin prick tests (20.1% and 8.2%), and EAI prescription fills (59.6% and 25.9%). Overall, mean cost of individuals with PA was $2,806 per patient per year (PPPY). They had on average 0.3 PA-related OP visits PPPY; 78.1% had no visits and, among those with ≥1 visits, 5.2% had ≥3 visits over 1 year. Those with ≥3 visits had a mean cost of $3,854 PPPY. 54.1% of individuals had ≥1 EAI prescription fills over 1 year and, among these, 11.3% had prescription fills for ≥6 EAIs; those with ≥6 EAIs had a mean cost of $3,038 PPPY. Individuals with ≥1 comorbidity (53.1%) had a mean cost of $3,365 PPPY; those with ≥3 comorbidities (5.4%) had a mean cost of $4,446 PPPY. 2.3% of individuals had ≥1 PA-related ED or inpatient (IP) visit over 1 year with a mean cost of $9,006 PPPY; those with ≥1 IP visit had a mean cost of $17,936 PPPY.

**CONCLUSIONS:** Allergen avoidance is the only option currently available for individuals with PA and is associated with significant HRU across all age groups. Among the commercially insured population, greater HRU was observed in children and adolescents and those with intensive HRU accrued substantial healthcare costs related to PA management. There is a need for an effective therapy for individuals with PA.

**SPONSORSHIP:** Aimmune Therapeutics

# Student Poster Titles and Presenters

**A2 A Retrospective Analysis to Assess the Discontinuation of Amikacin Liposome Inhalation Suspension Therapy Among Patients Treated for Refractory Mycobacterium Avium Complex Lung Disease**
*Marissa J. Puc, PharmD, Pamela Koerner, PharmD, BCPS, Austin Russian, PharmD, Richard Faris, PhD, RPh, Gordon J. Vanscoy, PharmD, MBA, CACP, mpuc@pantherxrare.com*

**B5 Antiretroviral Therapy Adherence Initiative for Members of Aetna Better Health of Pennsylvania**
*Augusta George, PharmD, MBA, Natalie Nkurunziza, PharmD, Lindsay Carvalho, PharmD, Andrew Lester, PharmD, georgea1@aetna.com*

**B6 Prescribing Rates and Characteristics of Users of Tenofovir-Containing Regimens Before and After Market Entry of New Formulation**
*Anna Hung, PharmD, PhD, MS, Matthew Sinclair, MD, Marion Hemmersbach-Miller, MD, Daniel Edmonston, MD, Christina Wyatt, MD, anna.hung@duke.edu*

**B7 HIV Pre-Exposure Prophylaxis: Adherence, Retention, and Discontinuation Rates Between Single and Multiple Tablet Regimens**
*Amber Reinert, PharmD, Ted Williams, PharmD, BCPS, Patrick Roberts, PharmD, reinertrx@gmail.com*

**B9 Study of Penicillin Tolerance Group B Streptococci Strains**
*Irfan Khan, PharmD, Aya Hammouda, PharmD, Paramita Basu, PharmD, ahammoud@student.touro.edu*

**C6 Identifying Patient and Clinical Factors that Impact Overall Survival Among Patients with Metastatic Colorectal Cancer Who Received Chemotherapy**
*Chinelo C. Orji, MS, Carolyn M. Brown, PhD, John R. Hoverman, MD, PhD, Kristin M. Richards, PhD, neloorji@gmail.com*

**C10 Evaluation of Real-World Effectiveness and Safety of Bevacizumab Versus Bevacizumab-Awwb in Patients with Metastatic Colorectal Cancer or Advanced Non-Squamous Non-Small Cell Lung Cancer in a US-Integrated Healthcare Delivery System**
*Catherine Pham, PharmD, MPH, Kim N. Le, PharmD, Timothy Chiu, PharmD, Fang Niu, MS, Amarylis C. Gutierrez, PharmD, Rita Hui, PharmD, MS, catherine.x1.pham@kp.org*

**C26 Review of CDK 4/6 Inhibitors in the Treatment of Advanced or Metastatic Hormone Receptor Positive, Human Epidermal Growth Factor Receptor 2 Negative Breast Cancer: A Retrospective Study to Evaluate the Efficacy, Safety, and Utilization of Treatment**
*Lakyn Husinka, PharmD, Pamela Koerner, PharmD, Francis Staskon, PhD, Richard Miller, MS, MBA, RPh, CSP, William Trombatt, PharmD, Melanie Radi, PharmD, lakyn.husinka@alliancerxwp.com*

**C37 Real-World Duration of Treatment Evaluation and Development of a Predictive Model for Patients with Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma at a Specialty Pharmacy**
*Michelle L. Shahbol, PharmD, Steven Schwartz, PhD, Millie Mo, PharmD, Joseph Cremaldi, PhD, Stephanie LaPointe, PharmD, mshahbol@diplomat.is*

**D6 Age-Related Healthcare Service Utilization in Sickle Cell Disease Management**
*Nidhi Shukla, MS, MBA, Jamie Barner, PhD, Karen Rascati, PhD, Kenneth A. Lawson, PhD, nidhi.shukla@utexas.edu*

**D7 The Impact of Erythropoiesis-Stimulating Agent Toolkit and Targeted Payer Communication on the Utilization and Reimbursement of Biosimilar Epoetin Alfa-epbx**
*Daniel M. Winslow, PharmD, Bradley Bruce, PharmD, Carol White, PharmD, Ty Elders, MS, Edward Murray, PharmD, Agatha Nolen, PhD, dmwinslow2@gmail.com*

**D18 Utilization and Prescribing Patterns of Biosimilars and Their Reference Products**
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**D19 Conversion to Biosimilars of Pegfilgrastim in Outpatient Settings from an Integrated Delivery Network Perspective**
*Andrew Osterland, PharmD, Paul Godley, PharmD, FASHP, Andrew.Osterland@BSWHealth.org*

**D24 Comparative Effectiveness of Second-Line Tumor Necrosis Factor Inhibitors (TNFi) Versus Other Second-Line Immunological Therapies (non-TNFi) Following First-Line TNFi**
*Kori Asante, PharmD, Phil Schwab, PhD, Patrick Racsa, MS, Andrea Bloomfield, PharmD, kasante@humana.com*

**E14 Comparative Effectiveness of Analog Insulin and Neutral Protamine Hagedorn Insulin in Providing Guideline-Directed Glycemic Control in a Medicare Patient Population**
*Angelica Asadi, PharmD, Qingqing Xu, MS, PhD candidate, Kirti Gandhi, Lin Guan, Kristine Lopez, Hannia Qureshi, Denise Jonathan, Donnie Aga, Patrick Carter, Sujit Sansgiry, PhD, angelica.asadi@kelsey-seybold.com*

**E15 Reducing Rates of DPP-4i and GLP-1RA Co-Prescribing Using an Educational Letter Program**
*Kelsey Lockwood, PharmD, Ted Williams, PharmD, BCPS, Anne Kangethe, PharmD, MPH, PhD, Alissa Johnson, PharmD, MBA, BCPS, Stephen Kim, PharmD candidate, lockwoodk@magellanhealth.com*

**E16 HbA1c Variability and Risk of Microvascular Complications Among Patients with Type 1 Diabetes in T1D Exchange Clinic Registry**
*Qingqing Xu, MS, PhD candidate, Sujit S. Sansgiry, MS, PhD, qxu11@Central.UH.EDU*

**E17 Retrospective Review of the Impact of a Basal Insulin Formulary Change on a Medicaid Population**
*Taylor E. Akers, PharmD, Ashley Modany, PharmD, Molly McGraw, PharmD, akerst@upmc.edu*

**E18 Impact of Pharmacy Intern Outreach on Statin Adherence in Patients with Type 2 Diabetes Within an Integrated Healthcare System**
*Holly A. Edison, PharmD candidate, Nadia Hason, PharmD, BCPS, CDE, rxhols15@gmail.com*

**E19 Basal Insulin Persistence of Patients Who See an Endocrinologist Compared to a Primary Care Physician**
*Meredith A. Diamond, PharmD, Kevin Leung, PharmD, MS, BCPS, John Sendzik, BS, Rosalia Alcoser, MS, Harry Lee, PharmD, MS, mdiamond426@outlook.com*

**E20 Clinical Outcomes and Costs Associated with the Utilization of Continuous Glucose Monitors in a Medicaid Population**
*Casey L. O'Brien, PharmD, Devon Trumbower, PharmD, BCPS, Calla Vodoor, PharmD, Erika Kaplan, PharmD, cobrien1@performrx.com*

**E21 Impact of a New Prior Authorization on Adherence to Guideline-Directed Therapy in Type II Diabetes Mellitus**
*Kristen N. Patti, PharmD, Kevin Leung, PharmD, MS, BCPS, John Sendzik, BS, Rosalia Alcoser, MS, Harry Lee, PharmD, MS, kristen.patti@ingenio-rx.com*

**E22 Impact of Intranasal Glucagon Administration on Total Cost of Care in a Managed Medicaid Diabetic Population**
*Allison N. Enghauser, PharmD, allison.enghauser@caresource.com*

**E23 Impact of Continuous Glucose Monitoring on Total Cost of Care**
*Jennifer Chapin, PharmD, jennifer.chapin@caresource.com*

**E24 Type 2 Diabetes and Mental Health: A Retrospective Analysis of Glycemic Control Among Commercial Health Plan Members with Comorbid Depression or Anxiety**
*Emma Casteel, PharmD, Amanda Bain, PharmD, MPH, MBA, Tasneem Motiwala, PhD, MPH, SMBA, emma.casteel@osumc.edu*

**E25 Analyzing the Impact of a Telephonic Outreach from a Pharmacist Addressing Health Belief Gaps to Increase Refills of a Statin Medication**
*Trey Ingram, PharmD, Katy Collins, PharmD, BCACP, Matthew Parker, MS, MBA, rogeringram@uabmc.edu*

**E29 Development and Analysis of a Novel Digital Health App Designed for Cystic Fibrosis**
*Alexandre H. Watanabe, PharmD, Connor Willis, PharmD, Russell Ragsdale, BSPharm, Karlene Moore, Prateek Kukreja, BS, MS, Saluka Amarasinghe, BS, MS, Alex Klein, BS, MS, Diana Brixner, RPh, PhD, FAMCP, David C. Young, PharmD, Alexandre.Watanabe@pharm.utah.edu*

**F7 Impact on Utilization when Prior Authorization Is Removed from Medication-Assisted Treatment**
*Heather Lee, PharmD, Tosan Isemede, PharmD, Robert Coalson, PharmD, MBA, Donna Obra, PharmD, leeh4@aetna.com*

**F8 Coverage and Utilization of Abuse-Deterrent Formulation Opioid Analgesics in Medicare Part D**
*John R. Brown, PharmD, MBA, Patricia R. Freeman, RPh, PhD, Tracy McDowd, PharmD, Kosali Simon, PhD, john.brown1@uky.edu*

**F9 Healthcare Resource Utilization and Costs Among Patients at Risk for Opioid Overdose Who Were Prescribed Naloxone Versus Those Not Prescribed Naloxone**
*Gabriel Johnson, PharmD, MHI, Ashley Sluis, MHI, Jacob Zillhardt, MS, Sara Alvarez, PharmD, MS, Josephine Tran, PharmD, MS, gabriel.johnson@uhc.com*

**F18 Evaluation of Outcomes Among First-Generation Versus Second-Generation Long-Acting Injectable Antipsychotics**
*Kelli C. Goo, PharmD, Anne Tran-Pugh, PharmD, FCSHP, Fang Niu, MS, Leanne Watanabe-Leung, PharmD, BCPS, Kim N. Le, PharmD, Amarylis C. Gutierrez, PharmD, Nolan Thompson, MD, James Moore, MD, Louai Bilal, MD, MSc, Rita Hui, PharmD, MS, kelli.c.goo@kp.org*

**F19 Clinical and Financial Implications of Promoting Atypical LAIs in High Utilizers of the Medical Benefit**
*Jenny Qiu, PharmD, Jennifer Dijaili, PharmD, Robert Coalson, PharmD, MBA, Faren French, PharmD, MBA, Donna Obra, PharmD, qiuj@aetna.com*

**G8 Initial Insights into Costs of Care for Patients with Spinal Muscular Atrophy on Nusinersen**
*Josephine Tran, PharmD, MS, Ashley Sluis, MHI, Erik Schindler, PharmD, BCPS, josephine.tran@uhc.com*

**G13 Assessment of Primary Medication Nonadherence for Newly Referred Valbenazine Patients and Corresponding Barriers to Receiving Therapy**
*Brittany Albert, PharmD, Pamela Koerner, PharmD, BCPS, Timothy Mizak, PharmD, MS, MBA, Richard Faris, PhD, RPh, Chuck Yonan, PharmD, Gordon J. Vanscoy, PharmD, MBA, CACP, balbert@pantherxrare.com*

**G17 Comparison of Medication Adherence Among Multiple Sclerosis and Oncology Patients in High-Deductible Health Plans and Non-High Deductible Health Plans Dispensed at Specialty and Retail Pharmacies**
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**G18 Factors Associated with Diagnoses of Alzheimer's Disease and Related Dementias Among Older Adults in the US**
*Xiaomo Xiong, MS, Minghui Li, PhD, Kevin Lu, PhD, xxmcpu@gmail.com*

**G24 Implementation of a Health Plan-Driven Outreach Program for Patients Without Therapy for Treatment of Multiple Sclerosis**
*Michael Formica, PharmD, Sital Patel, PharmD, MBA, Danielle Massie, PharmD, Tina Mody, PharmD, MPH, michael.formica@modahealth.com*

**G25 Adherence to Disease-Modifying Therapies for Multiple Sclerosis in the Medicare Population**
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**G40 Evaluation of Persistence, Switch Patterns, and Costs Among Migraine Patients Utilizing Calcitonin Gene-Related Peptide Inhibitors in a U.S. Medicaid Population**
*Kayla M. Thompson, PharmD, Majid Mirzai, PharmD, Jessica Zhang, PhD, Timothy Crabtree, PharmD, Jeramie Thomas, PharmD, Leigh Anne Kustra, MHA, MBA, kthompson@gatewayhealthplan.com*

**G41 Migraine Total Cost of Care and Outcomes: Comparison of Calcitonin Gene-Related Peptide Inhibitors, OnabotulinumToxinA, and Traditional Therapies Among a Commercially Insured Population**
*Alyssa M. Guest, PharmD, Alexandra Lin, PharmD, Jake Chaffee, PharmD, aguest14@midwestern.edu*

**G42 Impact of Prior Authorization Criteria on CGRP Antagonist Utilization in the Prevention of Migraine Headache**
*Stephanie Byrne, PharmD, Natalia Ruiz-Negron, PharmD, Casey Koch, PharmD, Curtis Wander, PharmD, stephanie.byrne@selecthealth.org*

**G43 Characteristics and Treatment of Migraine Cases in the Emergency Department Setting in the United States**
*Tri M. Van, PharmD, Grant H. Skrepnek, PhD, Bethany P. Holderread, PharmD, Melissa M. Abbott, PharmD, Ashley J. Teel, PharmD, Tri-Van@ouhsc.edu*

**G44 A Retrospective Claims Analysis of Calcitonin Gene-Related Peptides: Adherence, Persistence, Switch Rate, and Impact on Acute Migraine Therapy Among 4 Million Commercial Lives**
*Julie Lai, PharmD, Marleen Wickizer, PharmD, AE-C, CDE, Julie Olson, DNP, MS, RN, CQIA, Colleen Hickman, Jennie Chou, RPh, PhD, Tina Patel, PharmD, Amy Torgerson, Robert Topp, PhD, RN, Julie.Lai@navitus.com*

**G45 Incidence of Abortive Migraine Medication Fills After Initiation of a Calcitonin Gene-Related Peptide Inhibitor for Migraine Prophylaxis**
*Leslie Shumlas, PharmD, Eric Abanquah, PharmD, Nancy Archila, PharmD, Emily Rossi, MPH, Henry Zeringue, PhD, Ellen Feeney, PharmD, BCPS, leslie.shumlas@highmark.com*

**G53 A Cost-Effectiveness Analysis of Galcanezumab Use Preventative Treatment of Chronic Migraines**
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**I3 Health Behaviors Among Myocardial Infarction Survivors in the United States: A Propensity Score Matched Study**
*Zufan Yegezu, BS, Lea Mollon, PharmD, Dhfer Alshayban, PhD, Jawad Bilal, MD, Sandipan Bhattacharjee, BPharm, MS, PhD, zyegezu@email.arizona.edu*

**I8 Cost-Benefit Analysis of Sacubitril/Valsartan Among Patients with Heart Failure with Reduced Ejection Fraction in a Medicaid Population**
*Alan Gabot, PharmD, Pavel Lavitas, PharmD, Rachel Bacon, PharmD, Thomas Pomfret, PharmD, MPH, BCPS, Mckenzie Taylor, PharmD, Karen Stevens, PharmD, Andrew Coelho, PharmD, Tasmina Hydery, PharmD, Bonnie Greenwood, PharmD, Caroline Alper, MD, Karen Clements, ScD, Kimberly Lenz, alan.gabot@umassmed.edu*

**I9 Understanding Risks and Time to Heart Failure Following Incident Atrial Fibrillation**
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**I11 Clinical Outcomes Comparison of Ticagrelor and Clopidogrel or Prasugrel in a Medicaid Population**
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**J8 Real-World Outcomes of Biologic Therapies for the Treatment of Asthma Within an Employer Group Population**
*Amina H. Bensami, PharmD, Stephen Lott, PharmD, MS, bensamia@med.umich.edu*

**J9 Evaluating the Impact of a Chronic Obstructive Pulmonary Disease Transitions of Care Program in a Managed Care Setting**
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**J10 Evaluating the Outcomes of a COPD/Asthma Prescribing Guidance Within the VA Heart of Texas Health Care Network**
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**J11 Reflecting the Patient's Voice in Treatment Attributes and Outcomes for Value Assessment**
*Karen Nguyen, PharmD candidate, Jea Kyong Hwang, PharmD candidate, Megidelawit Yirefu, PharmD candidate, Susan dosReis, PhD, Julia Slejko, PhD, kvnguyen@umaryland.edu*

**K3 Comparison of Annual All-Cause Healthcare Costs Associated with Biologic-Naive Crohn's Disease Patients on Adalimumab Versus Vedolizumab and Adalimumab Versus Ustekizumab**
*Kristen Tripicchio, PharmD, Stephanie Yu, PharmD, MS, Rosalia Alcoser, MS, John Sendzik, BS, Kevin Leung, PharmD, MS, BCPS, kristen.tripicchio@ingenio-rx.com*

**K4 Real-World Effectiveness and Safety of Infliximab and Biosimilar in Patients with Inflammatory Bowel Disease**
*Joshua T. Smith, PharmD, Fang Niu, MS, Vincent Liu, MD, MS, Fernando Velayos, MD, Suresh Pola, MD, Xian Ning, MS, Rita Hui, PharmD, MS, joshua.t.smith@kp.org*

**K5 Trends in IBD: Medication Utilization, Disease Progression, and Healthcare Costs in a Commercial Health Plan Population**
*Sterling A. Harpst, PharmD, Amanda Bain, PharmD, MPH, MBA, sterling.harpst@osumc.edu*

**L11 A Systematic Review of Ixekizumab for the Treatment of Moderate to Severe Chronic Plaque Psoriasis**
*Aderinola Omoniyi, PharmD candidate, Juanita Andoh, PharmD candidate, Jennifer Kippling, PharmD candidate, F. Ellen Loh, BPharm, MBA, PhD, aomoniyi@student.touro.edu*

**L12 Effect of Digital Adherence Outreach in Under-Adherent Patients with Psoriasis**
*Christine L. Albatal, PharmD, Kayla E. Friend, PharmD, BCGP, Kathryn D. Johnson, PharmD, Cristina Sotelo, RPh, christine.albatal@cvshealth.com*

**M11 Rheumatoid Arthritis Monitoring at an Integrated Delivery Network: An Assessment of Disease Activity Score Documentation Rates and Adherence to Provider Recommended Schedule for Follow-up Visits**
*Marie Yasuda, PharmD, Paul Godley, PharmD, FASHP, marie.yasuda@bswhealth.org*

**M12 Impact of a Pharmacist-Led Program on the Initiation of Disease-Modifying Anti-Rheumatic Drugs in Medicare Beneficiaries with Rheumatoid Arthritis**
*Xiang Ding, PharmD, Ettien Awofiranye, PharmD, Erika Kaplan, PharmD, xding@performrx.com*

**M22 Effectiveness of a New Jersey Osteoporosis Prevention Program in the Community Setting**
*Amy Hu, PharmD candidate, Mary M. Bridgeman, PharmD, Dennis McGowan, BA, Mary L. Wagner, PharmD, MS, hu.amy09@gmail.com*

**M23 Effect of Awareness of Osteoporosis on Osteoporosis Medication Use and Adherence: A Systematic Review**
*F. Ellen Loh, BPharm, MBA, PhD, feng-hua.loh@touro.edu*

**M24 Impact of Hip Fracture Surgery Versus Non-Surgical Intervention on Hospital Costs and Length of Stay for Medicare Patients from 2012-2013**
*Aliza K. Matusevich, PhD, Suzanne L. Hunt, MS, MA, Rana S. Zalmai, PharmD, Nahid Rianon, MD, DrPH, rafia.rasu@unthsc.edu*

**N3 Economic Burden of Endometriosis: A Systematic Literature Review**
*Claire King, PharmD, Eric Hsiao, PharmD, Karishma Shelley, PharmD, clairenichols38@gmail.com*

**O1 Effect of Dispensing Higher Quantity of Oral Contraceptive Pills on the Incidence of Unintended Pregnancies in a Commercially Insured Cohort**
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**O2 Progesterone (17-alpha Hydroxyprogesterone Caproate) Utilization and Adherence in Women with a High-Risk Pregnancy: A Study of Two Databases**
*Shiyu Zhang, MS, Karen Rascati, PhD, Jamie Barner, PhD, Kristin M. Richards, PhD, shiyuserene@gmail.com*

**R2 Factors Associated with Prescription Tramadol Use Among Patients Prescribed Opioids in Rhode Island**
*Eric P. Borrelli, PharmD, MBA, Rouba Youssef, PhD, Blake Morphis, BS, Stephen J. Kogut, PhD, MBA, RPh, ericborrelli@my.uri.edu*

**R3 Utilization Evaluation of Centers for Disease Control and Prevention Recommended Nonopioid Treatment Alternatives in Response to Pharmacy Benefit Opioid Strategies Within a Commercially Insured Patient Population**
*Loralee Phillips, PharmD, Ahmed Guhad, PharmD, Alvah Stahlnecker, PharmD, Rafia Rasu, PhD, loralee.phillips@CVSHealth.com*

**R4 Predicting Risk of Long-Term Opioid Use for Opioid-Naive New Starts Using Pharmacy Claims**
*Kathy L. Nguyen, PharmD, Sara E. Carruth, PharmD, Janice Jin, MS, Wenyi Qiu, MS, Jim Burgdorf, PhD, Scott Leslie, MS, PhD, kathy.nguyen@medimpact.com*

**T3 Effects of Concurrent Opioid and Gabapentin Therapy in an Integrated Managed Care Health System**
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**U34 Operational and Financial Implications of Implementing a State-Mandated Preferred Drug List in a Medicaid Managed Care Plan**
*Katie Y. Tam, PharmD, Vivi Tran, PharmD, Brenda J. Burke, PharmD, Vanessa Smith, PharmD, tamk@aetna.com*

**U35 Impact of Real-Time Pharmacy Benefit Information on Prescribing Behavior in a Primary Care Clinic**
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**U36 Impact of a Medical Device Utilization Management Strategy on the Utilization and Cost of Medical Device Products Within a Commercial Population**
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**U37 Adherence and Economic Outcomes of a Therapeutic Interchange Program**
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**U38 Analysis of Adherence Outcomes in Specialty Patients Receiving Clinical Secure Messaging**
*Mandeep Sohal, PharmD, Sarah McLarty, PharmD, Christine Sawicki, RPh, MBA, LSSMBB, Kathryn D. Johnson, PharmD, Jason R. Merritt, PhD, Nitin Vallapuneni, MS, Kayla E. Friend, PharmD, BCGP, Mandeep.Sohal@CVSHealth.com*

**U39 Impact of State-Legislated Step-Therapy Limitations on Prior Authorization Approval Rates for Prescription Medications**
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**U40 Evaluating Clinical Outcomes Following Fentanyl Patch Prior Authorization Drug Review Across Seven Health Care Systems in the Department of Veterans Affairs Heart of Texas Health Care Network**
*Connor Medernach, PharmD, David Jacob, PharmD, Jennifer Gunter, PharmD, BCPS, connor.medernach@gmail.com*

**U41 Impact of Manufacturer Coupons on Utilization and Spend of Specialty Autoimmune Biologics: A Retrospective Analysis**
*Anna Burns, PharmD, MBA, Iuliana Mihu, PharmD, BCPS, MPH, Chris Campbell, PharmD, BCPS, BCOP, Joseph Bauer, PhD, Maria Michael, anna_burns@bcbsil.com*

**U42 Evaluating the Effect of Proactive Interventions for Prior Authorization Recertifications on Continuity of Care in a Specialized Medicaid Population**
*Soumya Vishwanath, PharmD, Stephanie Tran, PharmD, Thomas Pomfret, PharmD, MPH, BCPS, Kaelyn Boss, PharmD, Mark Tesell, PharmD, BCPS, Mylissa Price, MPH, RPh, Caroline Alper, MD, Lorean Muchnik, RPh, Karen Clements, ScD, Kimberly Lenz, PharmD, Soumya.Vishwanath@umassmed.edu*

**U43 Changes to the Exchange: The Effect of State Initiatives in Stabilizing the Health Insurance Marketplace**
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**U44 The Impact of a Pharmacist Review of Medical Drugs on the Utilization of Drugs Covered Under the Medical Benefit**
*Avani Patel, PharmD, MBA, Anthony Sandoval, PharmD, Donna Obra, PharmD, Elsa Tchakoute, PharmD, CSP, AAHIVP, patela6@aetna.com*

**U45 Stakeholders Disagree on When, Not How, to Implement Step Therapy**
*Taruja Karmarkar, PhD, MHS, Jennifer Graff, PharmD, Robert Dubois, MD, PhD, tkarmarkar@npcnow.org*

**U46 Retrospective Review of Appropriate Antipsychotic Utilization Between Behavioral Health and Physical Health Medical Providers**
*Brittany Bailey, PharmD, Sellers D. Alisha, PharmD, Cadmus Kyrala, PharmD, MBA, baileyb4@aetna.com*

**U47 Relationship Between Telepharmacy Care and Health Quality**
*Mitchell Haynes, PharmD candidate, Shweta Pathak, MPH, PhD, Benjamin Y. Urick, PharmD, PhD, haynesmi@email.unc.edu*

**U48 Clinical Impact of a Multidisciplinary Team-Based Program Utilizing Data-Driven Healthcare on a High-Risk Patient Population**
*Amy Pham, PharmD, Donnie Aga, Denise Jonathan, Kirti Gandhi, Kristine Lopez, Hannia Qureshi, Patrick Carter, Lin Guan, Ani Altounian, PharmD, Amy.Pham@kelsey-seybold.com*

**U49 Understanding Healthcare Decision Maker Perspectives on AMCP Format Dossier Content**
*Isabell Kang, PharmD, Aishani Patel, PharmD, Bridgette Schroader, PharmD, MPA, BCOP, Elaine Mak, BA, Bridget Olson, PharmD, MS, Evelyn Sarnes, PharmD, MPH, Lorie Mody, PharmD, isabell.kang@xcenda.com*

**U50 Opioid Use and Prescribing Trends Following 2019 CMS Opioid Policies in a Medicare Patient Population**
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**U51 Improving Access to Medication Therapy Management Programs by Completing Comprehensive Medication Reviews in a Medicare Population that Prefers to Speak a Language Other than English Despite Identifying as an English Speaker with their Health Plan**
*Emily Ragland, Bita Farrokhroo, PharmD, Arianna Rosales, Patrick Tracy, earagland23@gmail.com*

**U52 To Evaluate the Effect of a Medication Delivery Program on Adherence Among a Health Plan's High Risk Medicare Population**
*Eric Sohn, PharmD, Helen Kourlas, PharmD, esohn@healthfirst.org*

**U53 An Analysis of the Optimal Technician to Pharmacist Ratio for Increasing Telephonic Medication Review Completion Rate While Maintaining Patient Safety and Quality**
*Tiffany Iwamura, PharmD, Teresa Roane, PharmD, tiwamura@cop.ufl.edu*

**U54 Analysis of an Opioid-Based Pharmacy Lock-In Program in a Medicaid Managed Care Population**
*Ustina A. Mikhiel, PharmD, Kevin McCloy, PharmD, BCPS, ustina_mikhiel@horizonblue.com*

**U55 Promote Utilization of a 12-Month Supply of Hormonal Contraceptives Within the Medicaid Population**
*Jenny Nguyen, PharmD, Jessica Shost, PharmD, Kaitlin Hawkins, PharmD, Lisa Ghotbi, PharmD, Jenna Heath, PharmD, jnguyen1289@gmail.com*

**U56 Implementation of Select Care Drugs Zero-Dollar Copay Tier in a Health Plan and Its Impact on Member Adherence Rates in the Medicare Population**
*Bianca London, PharmD, Kim Moon, PharmD, BLondon@bcbsm.com*

**U57 Identifying Trend Drivers in High-Cost Members and Assessing Impact of Pharmacist-Led Interventions**
*Jackie Lolos, PharmD, Timothy O'Shea, MS, PharmD, Rana Abdeljabbar, PharmD, Saira Jan, MS, PharmD, jackieklolos@gmail.com*

**U59 Drug Policy and Formulary-Related Job Postings: Current Skills and Qualifications**
*Dorothy Liu, PharmD, Patrick D. Meek, Pharm D, MSPH, James R. Hopsicker, MBA, dorothy.liu@acphs.edu*

**U60 Implementation of a Community Pharmacy Value-Based Program in a Medicaid Patient Population**
*Andy Han, PharmD, ahan@lacare.org*

**U61 The Impact of Custom Formulary Edits Designed for Self-Insured Employers in a Group Purchasing Organization**
*Kelsey Dieters, PharmD, kdieters@employershealthco.com*

**U62 Identifying Trend Drivers in Acute Opioid Utilization and the Impact on Subsequent Pain Management**
*Cassidy L. Delaney, PharmD, Hannah Jang, PharmD, Saira Jan, MS, PharmD, Keri Farber, CPhT, MBA, cassidyldelaney@gmail.com*

**U63 Analysis of Opioid and Medication-Assisted Treatment Trends in a Medicaid Managed Care Population**
*Maryam Rowneki, PharmD, Kevin McCloy, PharmD, BCPS, Maryam_rowneki@horizonblue.com*

**U64 Impact of 1992 FDA Stereoisomer Statement on Global Drug Trends**
*Nicholas Senne, Claire Caschetta, Mahsa Salsabili, PharmD, Stephen Schondelmeyer, PharmD, PhD, senne025@umn.edu*

**U65 Role of Social Determinants of Health in Health Plans' Decision Making: A Review of the Literature**
*Elham Heidari, PharmD, MSc, C.M. Brown, PhD, Yogesh Vohra, PharmD, Chinyere M. Okoh, BPharm, heidarie@utexas.edu*

**U66 Impact of Implementing Limited Specialty Pharmacy Networks on Plan Costs and Medication Adherence**
*Christopher A. Fung-On, PharmD, chris.fung-on@southernscripts.net*

**U67 Impact of Life Coaching Services on Medication Utilization in a Managed Medicaid Population**
*Kylee L. Dickey, PharmD, KyleeLDickey@gmail.com*

**U68 Overcoming Doxorubicin-Induced Cardiotoxicity with Micellar Phytochemicals**
*Max Lee, PharmD candidate, Arthur Nguyen, PharmD candidate, Deepa Rao, PhD, lee7829@pacificu.edu*

**U69 Economic Outcome Evaluations of a Medication Therapy Management Program in a Medicare Advantage Plan Population**
*Mary A. Hunt, PharmD, Katy Collins, PharmD, BCACP, Matthew Parker, MS, MBA, Chris Presley, Katrina Pronath, BSHCM, CPhT, maryhunt@uabmc.edu*

**U70 Evaluating the Use and Perception of E-Cigarettes/Vaping Among College Students at Rutgers University**
*Serena Lam, PharmD candidate, Lois Ko, PharmD candidate, Joelle Jo, PharmD candidate, serenalam08@gmail.com*

**U71 Impact of Implementing a Narrow 90-Day Pharmacy Network Within an Integrated Delivery System on Maintenance Medication Adherence**
*Rachael K. Lai, Curtis Wander, PharmD, Natalia Ruiz-Negron, PharmD, Lori Blackner-Brown, PharmD, rachaelklai@gmail.com*

**U72 A Retrospective Analysis of Prescription Opioid Claims and Expenditures by Metropolitan Statistical Area Status and County Using Texas Medicaid Pharmacy Claims Data**
*Waverly Yang, BS Biology, waverlyyang@utexas.edu*

**U73 Impact of Deductible-Exempt, Low or No Cost High Deductible Health Plan Preventive Care Coverage on Medication Adherence**
*Mindy Huynh, PharmD, mindy.huynh@crxspecialty.com*

**U74 Identifying Barriers to Medication Adherence Among Latinxs in New Brunswick, NJ**
*Daniel Mesa, Congjian Zhou, Ashley Tang, Serena Lam, PharmD candidate, Palna Mehta, Mohil Trivedi, daniel.a.mesa42@gmail.com*

**U75 Clinical and Financial Impact of Downsizing Refill Care Coordination in Specialty Pharmacy**
*Devin DeNofio, PharmD candidate, Paul Yoon, David Gross, PharmD, devingreen@utexas.edu*

**U76 Self-Awareness and Management of Chronic Conditions with a Focus on High Blood Pressure, Cholesterol, Diabetes, and Epilepsy in Underserved Community Health Clinics in Narkwa, Ghana**
*Richard Lee, PharmD candidate, richwlee@uw.edu*

**Z1 Real-World Outcomes Related to Self-Administered Hormonal Contraceptives Within an Integrated Healthcare System**
*Jasmine Cornelius, PharmD, Fang Niu, MS, Natalie Aboubechara, PharmD, Kim N. Le, PharmD, Amarylis C. Gutierrez, PharmD, Anne Tran-Pugh, PharmD, FCSHP, Rita Hui, PharmD, MS, jasmine.x.cornelius@kp.org*

**Z4 Retrospective Analysis of Pharmacoeconomic Impact of Pharmacist-Led Medication Therapy Management at a Medicaid Managed Care Organization**
*Andrew Wherley, PharmD, Kin-Sang (Jason) Lam, PharmD, Jose Diaz Luna, PharmD, La'Marcus Wingate, PhD, PharmD, Miranda Law, PharmD, Tamara McCants, PharmD, andrew.wherley@gmail.com*

**Z5 Statewide Opioid-Prescribing Restrictions and Their Impact on Opioid Prescribing Rates**
*Jake Hayes, PharmD candidate, Kaitlin Moy, PharmD candidate, Justin-Theodore H. Gondeck, PharmD candidate, Devon J. Lash, Leon E. Cosler, RPh, PhD, jhayes3@binghamton.edu*

**Z6 Descriptive Analysis of a Specialty Pharmacy Workflow with Electronic Health Record Access**
*Matt Glasow, PharmD, MBA, Daniel Rehrauer, PharmD, glasowmatthew@gmail.com*

**Z7 Analyzing Methods to Improve Provider Response Rates to Pharmacist-Led Recommendations**
*Sarah R. Hopseker, PharmD, Stephanie Englert, PharmD, James Notaro, RPh, PhD, Karen Mlodozeniec, PharmD, hopses18@dyc.edu*

**Z8 Are Expanded Prescribing Practices Enough? Impact of Naloxone Standing Orders and Good Samaritan Laws on Opioid Overdose Deaths in Appalachian States**
*Urouge Akhtar, Jennifer Nguyen, PhD, urouge.akhtar@live.mercer.edu*

**Z10 Assessing Prescribing Trends of Opioids, Non-Opioid Adjuvants, and Opioid Combination Medication Therapy in Outpatients with a Diagnosis of Nonmalignant Chronic Pain**
*Rana S. Zalmai, PharmD, Nistha Srestha, BPharm, MPH candidate, Meredith Howard, PharmD, rafia.rasu@unthsc.edu*

**Z15 Can Intervention Tools with Better Message Framing Lead to Better Intention: A Case of Chemoprevention for Breast Cancer**
*Andre Obimah, Ravi Goyal, Archita Bhansali, PhD, Sujit Sansgiry, PhD, andreobimah@gmail.com*

**Z16 The Importance of Measuring Medication Adherence Periodically Among End-Stage Renal Disease Patients Taking P2Y12 Inhibitors**
*Elina Lee, PharmD candidate, rafia.rasu@unthsc.edu*

# Encore Poster Titles and Presenters

**B8 Ridinilazole for *Clostridium difficile* Infections Results in Improved Sustained Cures While Sparing the Microbiome Compared with Vancomycin: Results from the CoDIFy Phase 2 Clinical Trial**
*Anh N. Singhania, PharmD, Richard J. Vickers, PhD, Kevin W. Garey, PharmD, MS, FASHP, anh.singhania@summitplc.com*

**C12 Cost per Outcome Analysis of Nivolumab Compared with Dabrafenib+Trametinib as Adjuvant Therapy for Patients with Stage IIIB/C BRAF-Mutant Cutaneous Melanoma**
*Tayla M. Poretta, PharmD, MPH, Ella Du, MS, Yan Wang, ScD, Keith A. Betts, PhD, Sumati Rao, PhD, tayla.poretta@bms.com*

**C32 Real-World Outcomes with Taxane Monotherapy Following Platinum and Anti-Programmed Death 1/Death-Ligand 1 Therapy in Locally Advanced or Metastatic Urothelial Carcinoma**
*Zsolt Hepp, PharmD, MS, Sonali Shah, RPh, MBA, MPH, Katherin Tan, PhD, Shreya Balakrishna, BA, zhepp@seagen.com*

**C33 Quality of Life of Metastatic Urothelial Cancer Patients Treated with Enfortumab Vedotin Following Platinum-Containing Chemotherapy and a Checkpoint Inhibitor: Data from EV-201 Cohort 1**
*Zsolt Hepp, PharmD, MS, Peter H. O'Donnell, MD, Arjun Balar, MD, Daniel P. Petrylak, MD, Jonathan E. Rosenberg, MD, Evan Y. Yu, MD, David I. Quinn, MD, PhD, Sonali Shah, RPh, MBA, MPH, Juan Pinelli, PA-C, MMSc, Zsolt Hepp, PharmD, MS, Matthew D. Galsky, MD, zhepp@seagen.com*

**C34 Budget Impact Analysis of Avelumab plus Axitinib for the First-Line Treatment of Patients with Advanced Renal Cell Carcinoma**
*Frank Liu, PhD, Kristin Heinrich, MPH, Catarina Neves, MSc Economics, BSc Economics, Ying Zheng, MHSA, MS, Adam Kasle, BA, frank.liu@emdserono.com*

**C35 Real-World Treatment Patterns and Overall Survival Among Medicare Fee-for-Service Beneficiaries Newly Diagnosed with Peripheral T-Cell Lymphoma**
*Allison Petrilla, MPH, Mayvis Rebeira, PhD, Joseph Feliciano, PharmD, MS, Thomas LeBlanc, MD, Julie Lisano, PharmD, apetrilla@avalere.com*

**D8 Gene Therapy for Hemophilia B Patients: Development of a Flexible Cost-Effectiveness Model**
*Nanxin (Nick) Li, PhD, Eileen K. Sawyer, PhD, Konrad Maruszczyk, MSc, Marta Slomka, PhD, Tom Burke, MSc, Antony P. Martin, PhD, Matt Stevenson, PhD, Greg Guzauskas, PhD, Jamie O'Hara, MSc, n.li@uniqure.com*

**D9 Emicizumab Demonstrates Long-Term Efficacy and Tolerability in a Broad Population of Persons with Hemophilia A with or Without Factor VIII Inhibitors: Pooled Data from Four HAVEN Studies**
*Michael U. Callaghan, MD, Claude Negrier, MD, Ido Paz-Priel, MD, Sammy Chebon, MSc, Michaela Lehle, PhD, Johnny Mahlangu, BSc, MBBCh, Guy Young, MD, Tiffany Chang, MD, MAS, Jin Xu, PhD, Rebecca Kruse-Jarres, MD, Maria Mancuso, MD, Markus Niggli, PhD, Peter Kuebler, PhD, Midori Shima, MD, Victor Jimenez Yuste, MD, Elina Asikanius, MSc, Gallia Levy, MD, Steven Pipe, MD, Johannes Oldenburg, MD, mcallagh@med.wayne.edu*

**D16 Patients' Experience with Sickle Cell Disease: Treatment Patterns, Management of Vaso-Occlusive Crises, and Barriers to Care**
*Avery A. Rizio, PhD, Xiaochen Lin, PhD, MSc, Kristen McCausland, PhD, MPH, Michelle K. White, PhD, Menaka Bhor, PhD, Jincy Paulose, MD, Savita Nandal, MD, Rashid Halloway, MSc, MPH, Lanetta Bronté-Hall, MD, MPH, MSPH, arizio@qualitymetric.com*

**D20 Oral Prophylaxis with Berotralstat Reduces Hereditary Angioedema Attack Rates and Is Well Tolerated: APeX-2 Study Results**
*Melanie Cornpropst, PharmD, William Lumry, MD, Aleena Banerji, MD, Emel Aygören-Pürsün, MD, Jonathan A. Bernstein, MD, Douglas Johnston, DO, FAAAAI, FACAAI, Sandra Christiansen, MD, Marc Riedl, MD, MS, Sylvia Dobo, MD, Heather Iocca, PhD, Eniko Nagy, MD, Sharon C. Murray, PhD, Phil Collis, PhD, William P. Sheridan, MD, Marcus Maurer, MD, mcornpropst@BIOCRYST.com*

**E1 The Onduo Virtual Type 2 Diabetes Clinic: Coaching, Endocrinology Consultations, and Continuous Glucose Monitoring**
*Jennifer Layne, PhD, Howard Zisser, MD, David Miller, MS, Nathan Barleen, BS, Daniel Moloney, PhD, Amit Majithia, MD, Robert A. Gabbay, MD, PhD, Josh Riff, MD, Ronald Dixon, MD, jennifer.layne@onduo.com*

**E26 Analysis of Healthcare Resource Use and Time to Resource Use in US Patients Experiencing Pulmonary-Related Clinical Manifestations Associated with Severe Versus Non-Severe Alpha-1 Antitrypsin Deficiency**
*Ernesto Mayen Herrera, MSc, Corey Joseph, MPH, Emily Brouwer, PhD, Michael Czorniak, MD, MS, Ernesto.Mayen@gmail.com*

**E27 Cost-Effectiveness of Icosapent Ethyl in REDUCE-IT**
*Sarahfaye Dolman, MPH, William Weintraub, MD, Deepak Bhatt, MD, MPH, Zugui Zhang, PhD, Cheng Zheng, PhD, Adam Bress, PharmD, MS, Jordan King, PharmD, MS, Gabriel Steg, MD, Michael Miller, MD, Eliot Brinton, MD, Jean-Claude Tardif, MD, Christie Ballantyne, MD, Paul Kolm, PhD, sarahfaye.f.dolman@medstar.net*

**F10 Dementia-Related Psychosis: Real-World Patient Characteristics and Healthcare Utilization from a Large US Administrative Claims Database**
*Benjamin Skoog, PharmD, Rachel Halpern, PhD, MPH, Eleena Koep, MSc, Vic Abler, MD, Nazia Rashid, PharmD, bskoog@ACADIA-pharm.com*

**F11 Burden of Disease Associated with Dementia-Related Psychosis and Dementia-Related Agitation and Aggression Using a National Long-Term Care US Database**
*Sherry Andes, PharmD, Vic Abler, MD, Leslie Citrome, MD, MPH, sandes@ACADIA-pharm.com*

**F12 A National Comprehensive Survey Study of Parkinson's Disease Psychosis Patients and Caregivers Regarding Time to Parkinson's Disease Psychosis Diagnosis and Treatment Initiation**
*Sherry Andes, PharmD, Candace Andersson, PhD, Nazia Rashid, PharmD, Vic Abler, MD, sandes@ACADIA-pharm.com*

**F26 Open-Label Dose-Optimization of an Amphetamine Extended-Release Oral Suspension in Children with Attention-Deficit/Hyperactivity Disorder**
*Lisa K. Strouss, PharmD, Andrew Cutler, MD, Antonio Pardo, MD, Judith Kando, PharmD, BCPP, Barry Herman, MD MMM, lstrouss@trispharma.com*

**G4 Assessment of Cost-Effectiveness Results from Institute for Clinical and Economic Review Cell and Gene Therapy Reviews**
*Anish Patel, PharmD, Deepa V. Venkitaramani, PhD, Thomas Wiesner, BA, Benit Maru, MD, PhD, Omar Dabbous, MD, PhD, APatel509@avexis.com*

**G5 How Does Risdiplam Compare in Infantile Onset Spinal Muscular Atrophy? Preliminary Indirect Treatment Comparisons Based on FIREFISH Part 1 Data**
*Monica Daigl, MSc, Er Chen, MPP, Anna Kotzeva, MD, PhD, Ksenija Gorni, MD, PhD, Rachel Evans, MSc, Neil Hawkins, MSc, PhD, MBA, CStat, David Scott, MA, MSc, Anadi Mahajan, MPharm, monica.daigl@roche.com*

**G14 Patterns of Genetic Testing in Huntington's Disease**
*Alex Exuzides, PhD, Karina Raimundo, MS, Ruoding Tan, PhD, Tu My To, PhD, Jonathan de Courcy, BSc, Umang Ondhia, MSc, Huu Phuc Nguyen, MD, Martha Nance, MD, exuzides.alex@gene.com*

**G15 Patient and Physician Perspectives on the Care and Assistance Needs in Huntington's Disease**
*Ruoding Tan, PhD, Tu My To, PhD, Jonathan de Courcy, BSc, Umang Ondhia, MSc, Hugh Rickards, MD, Martha Nance, MD, tan.ruoding@gene.com*

**G19 The Implications of Suboptimal Treatment Outcomes with Disease-Modifying Drugs in Employees with Multiple Sclerosis**
*Amy L. Phillips, PharmD, Richard A. Brook, MS, MBA, Ian A. Beren, Nicholas J. Rohrbacker, PhD, Lori Lebson, PhD, Christian Henke, PhD, Amy.Phillips@emdserono.com*

**G26 Acute Treatment Patterns Among New Triptan Treatment Users and Potential Triptan Insufficient Responders**
*Anand R. Shewale, MS, PhD, Steven C. Marcus, PhD, Richard B. Lipton, MD, David W. Dodick, MD, Hema N. Viswananthan, PhD, Jalpa A. Doshi, PhD, Anand.Shewale@allergan.com*

**G27 Higher Healthcare Resource Utilization and Costs Among Patients with Potentially Insufficient Response to Triptans**
*Steven C. Marcus, PhD, Anand R. Shewale, MS, PhD, Stephen D. Silberstein, MD, Richard B. Lipton, MD, William B. Young, MD, Hema N. Viswananthan, PhD, Jalpa A. Doshi, PhD, marcuss@healthstatistics.com*

**G28 Annual Costs Associated with Patients with Migraine by Intensity of Treatment-Seeking Behavior**
*Ruslan Horblyuk, PhD, Oth Tran, MD, Philip Chan, PhD, MS, Gilwan Kim, PharmD, MS, David M. Smith, PhD, Chad Patel, PhD, Ruslan@aesara.com*

**G29 Safety of Valtoco (NRL-1; Diazepam Nasal Spray) in Patients with Epilepsy: Interim Results from a Phase 3, Open-Label, 12-Month Repeat Dose Study**
*James W. Wheless, MD, Michael R. Sperling, MD, Eric Segal, MD, R. Edward Hogan, MD, Daniel Tarquinio, DO, Enrique Carrazana, MD, Adrian L. Rabinowicz, MD, for the DIAZ.001.05 Study Group, jwheless@uthsc.edu*

**G30 Ubrogepant Achieves Pain Relief at 1 Hour for the Acute Treatment of Migraine**
*Joel Trugman, MD, David W. Dodick, MD, Peter Goadsby, MD, PhD, Kaifeng Lu, PhD, Abhijeet Jakate, PhD, Michelle Finnegan, MPH, Armin Szegedi, MD, PhD, Joel.Trugman@Allergan.com*

**G46 Assessment of Next-Morning Residual Effects of Lemborexant: Results from Three Randomized Studies**
*Norman Atkins, MBA, PhD, Dinesh Kumar, PhD, Kate Pinner, MSc, Norman_Atkins@eisai.com*

**G47 Long-Term Effectiveness and Safety of Lemborexant in Adults with Insomnia**
*Margaret Moline, PhD, Mikko Kärppä, MD, PhD, Yuichi Inoue, MD, Kate Pinner, MSc, Carlos Perdomo, MS, Kohei Ishikawa, MSc, Gleb Filippov, MD, PhD, Naoki Kubota, MPharm, Margaret Moline, PhD, margaret_moline@eisai.com*

**G48 Impact of Lemborexant Treatment on Insomnia Disease Severity and Fatigue over 12 Months: Results from SUNRISE-2**
*Jane Yardley, PhD, Mikko Kärppä, MD, PhD, Dinesh Kumar, PhD, Kate Pinner, MSc, Carlos Perdomo, MS, Gleb Filippov, MD, PhD, Norman Atkins, MBA, PhD, Jane_Yardley@eisai.net*

**G49 Indirect Comparison of the Efficacy of Fremanezumab Versus Erenumab in Episodic Migraine Patients Who Had Failed 2-4 Prior Migraine Preventive Treatments**
*Oscar Patterson-Lomba, PhD, Stephen Thompson, BS, MS, Sanjay Gandhi, MS, PhD, Ronghua Yang, PhD, Joshua M. Cohen, MD, MPH, FAHS, Fan Mu, PhD, MS, MBBS, Joshua Young, BS, Oscar.Patterson-Lomba@analysisgroup.com*

**G50 Burden of Comorbid Depression and Anxiety on Migraine-Specific Health-Related Quality of Life in Adult Migraine Patients in the United States**
*Richard B. Lipton, MD, Ravi Iyer, PhD, Joshua M. Cohen, MD, MPH, FAHS, James Jackson, BA, Verena Ramirez-Campos, MD, Sarah Cotton, MA, Gary Milligan, BS, Dawn C. Buse, PhD, richard.lipton@einstein.yu.edu*

**G51 Burden of Comorbid Depression and Anxiety on Work Productivity in Adult Migraine Patients in the United States**
*Richard B. Lipton, MD, Ravi Iyer, PhD, Joshua M. Cohen, MD, MPH, FAHS, James Jackson, BA, Verena Ramirez-Campos, MD, Sarah Cotton, MA, Gary Milligan, BS, Dawn C. Buse, PhD, richard.lipton@einstein.yu.edu*

**H2 Pooled Analysis of OTX-101, a Novel Nanomicellar Cyclosporine Formulation, on Corneal Fluorescein Staining in Individual Zones over 3 Months in the Worse Eye**
*Bridgitte Shen Lee, OD, Ranjan Malhotra, MD, FACS, Abayomi Ogundele, PharmD, BCMAS, Charles Darby, MS, Alan Kabat, OD, FAAO, bshenlee@sbcglobal.net*

**H5 Healthcare Resource Utilization and Costs Related to Ocular Hypertension and Open-Angle Glaucoma by Disease Severity**
*Vanessa Shih, PharmD, MS, Mousam Parekh, MS, Jasjit K. Multani, MPH, Catherine B. McGuiness, MA, MSc, Chi-Chang Chen, PhD, MsPharm, Joanna Campbell, PhD, Mildred Olivier, MD, vanessa.shih@allergan.com*

**J12 Persistence and Adherence of Antifibrotic Medication in Patients with Idiopathic Pulmonary Fibrosis in a Commercially Insured Patient Population**
*Mitra Corral, MS, MPH, Kathryn DeYoung, MS, Amanda Kong, DrPH, corral.mitra@gene.com*

**J13 Impact of Antifibrotic Use on Healthcare Resource Use and Cost in Patients with Idiopathic Pulmonary Fibrosis in a Commercially Insured Patient Population**
*Mitra Corral, MS, MPH, Kathryn DeYoung, MS, Amanda Kong, DrPH, corral.mitra@gene.com*

**J14 Omalizumab Improves Quality of Life in Patients with Chronic Rhinosinusitis with Nasal Polyps and Comorbid Asthma**
*Theodore Omachi, MD, Claus Bachert, MD, PhD, Philippe Gevaert, MD, PhD, Joaquim Mullol, MD, PhD, Joseph K. Han, MD, Randall Ow, MD, Sanna Toppila-Salmi, MD, PhD, Isam Alobid, MD, PhD, Derrick Kaufman, PhD, Jessica Braid, BSc (Hons), Monet Howard, MSc, Bongin Yoo, PhD, Monica Ligueros, MD, Lutaf Islam, DVM, MS, omachi.theodore@gene.com*

**L1 The Economic Burden of Mild to Moderate Atopic Dermatitis in the United States: Analyses of the National Health and Wellness Survey**
*Jonathan I. Silverberg, MD, PhD, MPH, David Gruben, PhD, Timothy W. Smith, BA, Selwyn Fung, MBBS, BSc (Med), Daniela E. Myers, MPH, jonathanisilverberg@gmail.com*

**L2 The Clinical and Humanistic Burden of Mild to Moderate Atopic Dermatitis in the United States: Analyses of the National Health and Wellness Survey**
*Jonathan I. Silverberg, MD, PhD, MPH, David Gruben, PhD, Maureen P. Neary, MS, PhD, Timothy W. Smith, BA, Selwyn Fung, MBBS, BSc (Med), Daniela E. Myers, MPH, jonathanisilverberg@gmail.com*

**L7 Cost per Responder Analysis of Guselkumab Versus Secukinumab in Obese Patients Using Efficacy Results from the ECLIPSE Head-to-Head Clinical Trial**
*Amanda M. Teeple, MPH, Timothy Fitzgerald, PhD, ateeple@its.jnj.com*

**L8 Bimekizumab Provides Rapid and Sustained Improvements in Quality of Life That Correlate with Clinical Outcomes in Patients with Moderate to Severe Plaque Psoriasis: 60-Week Post Hoc Results from a Randomized, Double-Blinded, Phase 2b Extension Study**
*Robert Low, PharmD, Joseph F. Merola, Alice B. Gottlieb, Christopher E. M. Griffiths, OBE, MD, FMedSci, Kristina K. Harris, DPhil, MSc, Nancy Cross, Luke Peterson, MS, Christopher Cioffi, PhD, Andrew Blauvelt, robert.low@ucb.com*

**M1 Comparison of Real-World Persistence of Subcutaneously Administered Biologic Disease-Modifying Antirheumatic Drug Therapies Among Patients with Rheumatoid Arthritis Switching from Another Biologic**
*Lenore Tominna, PharmD, Ibrahim Abbass, RPh, PhD, tominna.lenore@gene.com*

**M15 Earlier Treatment of Non-Radiographic Axial Spondyloarthritis with Certolizumab Pegol Results in Improved Clinical and Patient-Reported Outcomes**
*Robert Low, PharmD, Lianne S. Gensler, MD, Atul Deodhar, MD, MRCP, Walter P. Maksymowych, MD, FRCP (C), FRCP (UK), FACP, Nigil Haroon, MD, PhD, Simone E. Auteri, MSc, EMS, PhD, Natasha de Peyrecave, PhD, Thomas Kumke, PhD, Bengt Hoepken, PhD, Lars Bauer, MD, Martin Rudwaleit, Prof. Dr (Med), robert.low@ucb.com*

**M16 Certolizumab Pegol Improves Work and Household Productivity and Social Participation over One Year of Treatment in Patients with Non-Radiographic Axial Spondyloarthritis**
*Robert Low, PharmD, Lianne S. Gensler, MD, Jonathan Kay, MD, Walter P. Maksymowych, MD, FRCP (C), FRCP (UK), FACP, Nigil Haroon, MD, PhD, Robert Landewe, MD, PhD, Martin Rudwaleit, Prof. Dr (Med), Stephen Hall, MBBS, MMSc, FRACP, Lars Bauer, MD, Bengt Hoepken, PhD, Natasha de Peyrecave, PhD, Thomas Kumke, PhD, Desiree van der Heijde, MD, PhD, DMFM, robert.low@ucb.com*

**M18 Eteplirsen Delays Time to Loss of Walking Ability in Patients with Duchenne Muscular Dystrophy Compared with Patients Receiving Standard of Care**
*Joel Iff, Charles Gerrits, Gautam Sajeev, ScD, James Signorovitch, PhD, Edward Tuttle, Erica Birk, PhD, Intekhab Hossain, Zhiwen Yao, Courtney Ng, Nathalie Goemans, MD, PhD, slewis@sarepta.com*

**M25 Improved Efficacy and Safety Outcomes of Gene Therapy with Eladocagene Exuparvovec in Children with AADC Deficiency: Results from Three Clinical Trials**
*Paul Wuh-Liang Hwu, Yin-Hsiu Chien, Ni-Chung Lee, Sheng-Hong Tseng, Chun-Hwei Tai, Anne Marie Conway, Mark Pykett, hwuwlntu@ntu.edu.tw*

**M26 Eladocagene Exuparvovec Gene Therapy of Children with AADC Deficiency Leads to Sustained Improvements in Motor and Developmental Milestones: 5 Years Follow-Up**
*Yin-Hsiu Chien, Ni-Chung Lee, Sheng-Hong Tseng, Chun-Hwei Tai, Anne Marie Conway, Mark Pykett, Paul Wuh-Liang Hwu, chienyh@ntu.edu.tw*

**M27 Pulmonary Function in Nonambulatory Patients with DMD from the STRIDE Registry and the CINRG Duchenne Natural History Study: A Matched Cohort Analysis**
*Andrés Nascimento Osorio, Már Tulinius, Filippo Buccella, Isabelle Desguerre, Janbernd Kirschner, Eugenio Maria Mercuri, Francesco Muntoni, Joel Jiang, Allan Kristensen, Panayiota Trifillis, Claudio Santos, Craig McDonald, anascimento@sjdhospitalbarcelona.org*

**M28 Systemic Gene Transfer with rAAVrh74.MHCK7.Micro-Dystrophin in Patients with Duchenne Muscular Dystrophy**
*Kathrin Kucharski, PharmD, Zarife Sahenk, MD, PhD, Kelly Lehman, FNP, Carrie Nease, CPNP-AC, Linda Lowes, PT, PhD, Natalie Miller, DPT, Megan Iammarino, DPT, Lindsay Alfano, DPT, Jordan Vaiea, PhD, Samiah Al-Zaidy, MD, Sarah Lewis, PhD, Kathleen Church, PhD, Richard Shell, MD, Rachael Potter, PhD, Danielle Griffin, PhD, Eric Pozsgai, PhD, Mark Hogan, PhD, Louise Rodino-Klapac, PhD, slewis@sarepta.com*

**M29 Systemic Gene Transfer with AAVrh74.MHCK7.SGCB Increased β-Sarcoglycan Expression in Patients with Limb Girdle Muscular Dystrophy Type 2E**
*Leslie Zanetti, PharmD, Eric Pozsgai, PhD, Sarah Lewis, PhD, Danielle Griffin, PhD, Aaron Meadows, FNP, Kelly Lehman, FNP, Kathleen Church, PhD, Linda Lowes, PT, PhD, Jerry Mendell, MD, slewis@sarepta.com*

**N2 Vibegron Demonstrates Statistically Significant Improvement in Secondary Efficacy Measures in Overactive Bladder: EMPOWUR Study**
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**U1 Unmet Needs Exist in Payer Communications: Are Digital Solutions the Answer?**
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