Making the Way for Innovation

NEX:US 2020
VIRTUAL • WEEK OF OCT. 19

Poster Abstracts
AMCP Abstracts Program

The AMCP NEXUS 2020 VIRTUAL will be held online the week of October 19, 2020. The AMCP abstracts program provides a forum through which authors can share their insights and outcomes of advanced managed care practice.

For NEXUS 2020 VIRTUAL, abstract posters are scheduled to be presented Wednesday, October 21, from 1:00 pm EDT to 2:30 pm EDT. At that time, poster presenters will be available for live chats and will also share 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 (JMCP) Poster Abstracts supplement.

Abstract Review Process

Sixty-seven reviewers and 4 JMCP editorial reviewers were involved in the abstract review process for AMCP NEXUS 2020 VIRTUAL. 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 AMCP NEXUS 2020 VIRTUAL were as follows:

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K5 Cost per responder and cost per remitter analysis of ustekinumab versus adalimumab among patients with moderate to severe ulcerative colitis that have failed conventional therapy in the United States

K7 Economic impact of vedolizumab IV versus adalimumab SC for moderately to severely active ulcerative colitis

K8 Relationship between hospitalization and achievement of clinical remission or clinical response in moderate to severe ulcerative colitis patients: results from the UNIFI trial

K11 Differences in clinical characteristics and patient-reported outcomes of recently hospitalized versus non-hospitalized Crohn’s disease patients: real-world data from the Corrona Inflammatory Bowel Disease Registry

K12 Healthcare resource utilization increases with disease severity in Crohn’s disease in the United States: the National Health and Wellness Survey

K13 Characterizing prior healthcare resource utilization by disease severity in Crohn’s disease: real-world data from the Corrona Inflammatory Bowel Disease Registry

K14 Healthcare resource utilization and costs associated with a biologic versus its biosimilar in inflammatory bowel disease

K15 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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K17 A review of patient-reported outcomes for irritable bowel syndrome with constipation

K18 An analysis of healthcare utilization and costs associated with patients with acute hepatic porphyria (AHP) in ENVISION: a phase 3 study of safety and efficacy of givosiran

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L7 Efficacy and safety of bimekizumab in patients with moderate to severe plaque psoriasis: results from BE VIVID, a 52-week phase 3, randomized, double-blinded ustekinumab and placebo-controlled study

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M10 Effect of awareness of osteoporosis on osteoporosis medication use and adherence: a systematic review

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M16 Demographics and safety data from patients with nonsense mutation Duchenne muscular dystrophy receiving ataluren in the STRIDE Registry

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U11 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

U12 Clinical and financial impact of downsizing refill care coordination in specialty pharmacy

U13 Understanding healthcare decision-maker perspectives on AMCP Format dossier content
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U25 Impact of a value-based program on the utilization and adoption of oncology biosimilars

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U29 Savings analysis of a Medicaid medication reconciliation post-discharge program

U30 Healthcare economic information and patient experience information in immuno-oncology: is the research being conducted and communicated effectively to U.S. payers?

U31 Evaluation of providers’ response to polypharmacy program outreach

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U38 Patient-related factors: a prevalent barrier dimension in adherence to oral oncology treatments literature review

U39 Impact of electronic-directly observed therapy (eDOT) on medication adherence: results of a systematic literature review

U40 Analyzing trends in new molecular entities and biologics approved by the FDA from 2015 through 2019

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U43 A retrospective analysis of outpatient prescription claim trends during the COVID-19 pandemic

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U51 2016 to 2019 trend in integrated total pharmacy plus medical benefit drug spend: doubling of members with extremely high annual drug cost within a 17 million commercially insured population

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U53 Overcoming biosimilar barriers: stakeholder perspectives on strategies to overcome challenges: a cross-sectional study

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Z1 Pharmacists as accessible healthcare providers: quantifying the opportunity

Z2 Physical health-related quality of life among older women with breast cancer and patient satisfaction with medical and pharmacy services
Z3  Knowledge and attitudes towards human immunodeficiency virus (HIV) and pre-exposure prophylaxis (PREP) among pharmacy students in Indiana.

Z4  Changes in utilization patterns for pre-exposure prophylaxis to HIV after recommendation from U.S. Preventive Services Task Force.


Z6  Pharmacoeconomic impact of face-to-face medication therapy management at a Medicaid managed care organization.

Z7  Effects of the pilot volume-based procurement program in China on drug uses and costs: real-world evidence from atorvastatin prescription claims in Guangzhou.

Z8  COVID-triggered effects from telehealth, unemployment, and coverage changes on treatment costs and volumes.

Z9  The number of falls per faller varies with the annual incidence of having at least one fall.

Z10 Naloxone prescribing trends in New Jersey during the COVID-19 pandemic from a managed care perspective.
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.

**POSTER AWARD**

**PLATINUM**

James P. Burke, PhD, [I9] Sacubitril-valsartan real-world assessment of total cost of care and resource utilization pre/post initiation among commercially insured members with reduced ejection fraction heart failure

Justin Gatwood, PhD, [J2] The role of social determinants of health in adult influenza vaccination: a nationwide claims analysis

Christopher V. Quenelle, PharmD, [B8] Assessment and characterization of U.S. government funding decisions for COVID-19 vaccine and treatment development programs and manufacturing

Benjamin Y. Urick, PharmD, PhD, [U35] Structure and implementation environment of performance-based pharmacy payment models

**POSTER AWARD**

**GOLD**

Joseph Biskupiak, PhD, MBA, [U52] United States payer perceptions on the use of economic models in oncology formulary decision making: results from an online survey and payer panel

Brenna L. Brady, PhD, [C22] The impact of chemotherapy-induced peripheral neuropathy in metastatic breast cancer patients treated with paclitaxel or Abraxane

Andrew P. Brogan, PhD, [U30] Healthcare economic information and patient experience information in immuno-oncology: is the research being conducted and communicated effectively to US payers?

Ze Cong, PhD, [D5] Beyond pain: symptom burden of adolescents and adults with sickle cell disease

Jill Davis, MS, [R1] Characteristics, medication use, and outcomes of inpatients with heart failure and hyperkalemia

Kemi R. Ibrahim, MSc, [T1] Opioid analgesic use among Texas Medicaid enrollees: trends in potential inappropriate prescribing practices from 2013 to 2016

Anjana Mohan, MPharm, [I2] Impact of motivational interviewing intervention in Texas Medicare advantage patients with hypertension

Rayna Y. Shah, BS, [U38] Patient-related factors: a prevalent barrier dimension in adherence to oral oncolytic treatments literature review

Greg Smith, [C6] An evaluation of the efficacy and safety of second-line (2L) treatments in metastatic colorectal cancer (mCRC)

Kevin J. Sundquist, MS, [U28] AWP and NADAC price trends from 2015 to 2020: a retrospective analysis

Elizabeth Tinoco, BS, [E10] Cost-effectiveness analysis of amputation risk and cardiovascular benefits with canagliflozin in patients with type 2 diabetes

Yimin Wu, PhD, [U22] Forecast pharmacy cost using demographics, therapeutic conditions, and historical pharmacy cost
Medal-Winning Abstracts

Beilei Cai, PhD, [C11] Budget impact of capmatinib in adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to MET exon 14 skipping in the United States

Justin Gatwood, PhD, [B1] Impact of a clinical “nudge” on herpes zoster vaccine dose completion in community pharmacies

Patrick P. Gleason, PharmD, [U23] Is Medicare star category medication adherence associated with lower total cost of care and medical events?

Feng Lin, PhD, [C27] Workplace productivity loss and associated indirect costs among patients with HER2+ metastatic breast cancer in the United States

Nazia Rashid, PharmD, MS, [F4] Healthcare resource utilization and associated costs for dementia patients with psychosis: a Medicare database study

Rebecca L. Robinson, MS, [M5] Factors associated with poor clinical outcomes and costs following total hip replacement for patients with osteoarthritis

Soham Shukla, PharmD, [C1] Real-world evidence-based patient profiles and treatment patterns among patients with recurrent or metastatic squamous cell carcinoma of the head and neck (R/M HNSCC) from 2016-2019

Kaylin Braekevelt, PharmD, [E6] Impact of short-acting insulin non-medical switching and utilization among commercially insured members with diabetes

James Chambers, PhD, MPharm, MSc, [U32] Characterizing health plan evidence review practices: an empirical analysis

Laura Clark, [F17] Comorbid medical conditions, outpatient healthcare resource use, and charges associated with diagnosis of chronic insomnia in the U.S.

Susan Gabriel, PhD, [I4] Major adverse cardiovascular events and associated costs following acute myocardial infarction: a 90-day perspective

Zahra Majd, PharmD, [E11] Predicting future adherence to statins using previous adherence to antihypertensive drugs

Erik Muser PharmD, MPH, [K8] Relationship between hospitalization and achievement of clinical remission or clinical response in moderate to severe ulcerative colitis patients: results from the UNIFI trial

Ajay Sharma, DO, [G17] Patient characteristics and comorbidities in patients with MS with commercial insurance or Medicare Advantage in a large health plan

Neal Shore, MD, FACS, [C36] Major adverse cardiovascular events: number needed to treat analysis for the phase 3 randomized controlled trial (HERO) of relugolix versus current standard of care (leuprolide) in men with advanced prostate cancer

Sohul A. Shuvo, MS, MBA, [L2] The role of social determinants in timely herpes zoster vaccination among older U.S. adults

Kenneth H. Yu, MD, [C3] Hospitalizations and real-world clinical outcomes of liposomal irinotecan in a NAPOLI1-based regimen among patients with metastatic pancreatic ductal adenocarcinoma (mPDAC): a multi-center chart review

Samantha Valliant, [Z1] Pharmacists as accessible healthcare providers: quantifying the opportunity
OBJECTIVE: To characterize U.S. government funding decisions for COVID-19 vaccine and treatment development programs and companies awarded acceleration grants.

METHODS: U.S. Department of Health and Human Services documents detailing funding decisions for COVID-19 vaccine and treatment programs were gathered and reviewed. The therapeutic platforms and the assessments of manufacturing capacity of companies the U.S. government partnered with were documented and compared. BARDA funding awards were analyzed and described.

RESULTS: As of June 2020, BARDA had entered into six significant funding agreements with biopharmaceutical research organizations to advance the development of vaccines and nine agreements for therapeutic agents for COVID-19. The BARDA Medical Countermeasure Portfolio consisted of over $2.8 billion in investment and funding for COVID-19 vaccine research and manufacturing. More than $1.7 billion (60.8%) was awarded to programs that adapted previously used vaccine platforms to be used for COVID-19. Nearly $500 million (17%) was awarded for a novel mRNA vaccine platform with the goal of FDA licensure. More than $628 million (22.1%) was awarded to commit manufacturing capacity and pave the way for biotechnology innovators to ensure stable supply. Over $350 million was awarded by BARDA for development and testing of a variety of therapeutic agents which consisted of several new antibodies, two FDA approved drugs, immune globulins, and interleukin inhibitors.

CONCLUSIONS: Key factors leading to U.S. government funding for COVID-19 vaccines and therapeutics included programs utilizing previously approved vaccine platforms, products being rapidly deployable, companies having significant domestic and global manufacturing capacity and scalability, and companies having established U.S. development and manufacturing supply chains. Enhanced development and regulatory pathways will have to be matched with reimbursement and access decisions.

SPONSORSHIP: Apperture Health.
**J2 The role of social determinants of health in adult influenza vaccination: a nationwide claims analysis**

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**BACKGROUND:** The health and economic benefits of the annual influenza vaccine are well defined, yet vaccination rates in the United States are below the Healthy People 2020 goal and multiple factors are likely contributors. By identifying underlying reasons for low annual influenza vaccination, social elements that need targeting may be identified and could guide future interventions or policy development, to achieve vaccination goals and improve overall public health.

**OBJECTIVE:** To determine the influence of certain social determinants of health on adherence to annual influenza vaccination in American adults.

**METHODS:** This was a retrospective cohort analysis of American adults (18 years and older) who were continuously enrolled in employer-sponsored, Medicare Advantage, or traditional fee-for-service Medicare coverage between 2013-2016. Receipt of the influenza vaccine was counted over three consecutive influenza seasons and select social determinants were extracted from publicly-available sources. Patient characteristics, health resource utilization, and social determinants of health were included in bivariate and logistic regression analyses to determine their association with annual influenza vaccination.

**RESULTS:** A total of 7,816,421 adults across employer-sponsored and Medicare coverage groups were analyzed, of which 9.2% received an influenza vaccine in all three seasons. Higher proportions of vaccine adherence (i.e., all 3 seasons) were observed among females (9.6%), the immunocompromised (10.8%), rural residents (9.9%) (all P < 0.0001), and those enrolled in a high-deductible health plan (10.3%). Multivariable models indicated the odds of vaccinating in all 3 years were somewhat more likely in areas of higher health literacy (AOR: 1.035; 95% CI: 1.035-1.036), in individuals with more prescription fills (AOR: 1.006; 95% CI: 1.006-1.006), in communities with lower rates of Internet access (AOR: 1.011; 95% CI: 1.010-1.013), and among those who did not relocate during the observation period (AOR: 1.05; 95% CI: 1.03-1.06). Slightly lower odds were observed in more liberal voting areas (AOR: 0.998; 95% CI: 0.997-0.999).

**CONCLUSIONS:** Key social determinants of health are important factors of vaccine adherence and can guide policy and intervention efforts toward addressing potential hesitancy. A deeper assessment of other contributing social factors is needed in seasonal influenza and other vaccines to better interpret the vaccine-seeking behaviors of adults.

**SPONSORSHIP:** None.

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**U35 Structure and implementation environment of performance-based pharmacy payment models**

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**BACKGROUND:** There has been a recent shift in the United States (US) towards value-based health care models which seek to improve patient outcomes while reducing health care spending. As a part of this trend, many payers have implemented performance-based pharmacy payment models (PBPPMs) which incentivize pharmacists to improve patient care by tying reimbursement to performance measures. However, the design and implementation of PBPPMs in pharmacy lacks transparency and has not been described in the literature.

**OBJECTIVE:** To (1) describe the current structure of PBPPMs in the US and (2) identify the contextual and motivational influences that need to be considered when implementing these models.

**METHODS:** A literature search of peer-reviewed and grey literature on value-based care, pay-for-performance, and performance-based models in pharmacy settings was conducted. Additionally, semi-structured stakeholder interviews were conducted with a convenience sample of 17 individuals who were selected to ensure representation across the socio-ecological model. Participants included community pharmacists, payers, quality measure developers and vendors, academics, and pharmacy advocacy organization leaders. Data were analyzed to facilitate a greater understanding of PBPPMs and how they can be improved in the US, as well as the contextual conditions and motivational pressures of the environments in which the PBPPMs are currently implemented.

**RESULTS:** Four major components of PBPPMs in the US were found: 1) performance and quality measures; 2) incentive structures; 3) patient care services; and 4) attribution. The analysis highlighted major barriers (e.g., lack of alignment) and interviewees made recommendations to improve current structures of PBPPMs. When implementing PBPPMs it is important to consider individual and relational factors (e.g., conflicting interests), organizational factors (e.g., organizational culture, information technology, and workflow operations), broader contextual factors, and other motivations and pressures. Notable implementation considerations included: 1) having a quality driven, innovative, and flexible organizational culture; 2) ensuring engagement of pharmacists, payers, and patients; and 3) utilizing necessary workflow and IT infrastructure (e.g., data sharing through use of EQuIPP).

**CONCLUSIONS:** To better develop and implement PBPPMs, it is first critical to understand their key components and needed changes, as well as the contextual and motivational influences that impact their implementation.

**SPONSORSHIP:** PharmAlliance.
A5 Higher healthcare burden in patients with urinary tract infections by carbapenem-resistant gram-negative pathogens in U.S. hospitals (2014 to June 2019)

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BACKGROUND: Urinary tract infections (UTIs) are the most frequent infections caused by Gram-negative bacteria (GNB) in the USA.

OBJECTIVE: Characterize the healthcare burden of UTIs caused by carbapenem-resistant (CR) or -susceptible (CS) GNB in hospitalized patients.

METHODS: We conducted a retrospective analysis of the U.S. Premier Healthcare Database (2014-June 2019) in hospitalized adults to estimate the healthcare burden of CR-Gram-negative UTIs. We defined UTIs as positive urine culture and receipt of GN antibiotics within -2 to 3 days of the index urine culture during the hospitalization. The pathogen was CR if it was resistant or intermediate susceptible to any carbapenem (excluding ertapenem for Acinetobacter baumannii and Pseudomonas aeruginosa), or it is Stenotrophomonas maltophilia. The pathogen was CS if it was susceptible to all carbapenems tested.

RESULTS: Among the 47,496 patients with UTI analyzed, 2,076 (4.4%) of them had CR infections. Mean age was 69 years for both CR and CS groups. Females accounted for 46.6% of CR and 67.1% of CS. E. coli was the most frequent pathogen (61.9%). However, Pseudomonas aeruginosa was the most frequent CR pathogen (49.4), followed by Klebsiella pneumoniae (14.2%) and Stenotrophomonas maltophilia (11.3%). CR patients had longer overall LOS (median: 8 vs. 6 days), infection-associated LOS (median: 7 vs. 6 days), a slightly lower rate of ICU stay (32.3% vs. 34.7%) but a longer infection-associated ICU LOS (6.5 days vs. 4.9 days), less likely to be discharged home (38.4% vs. 51.0%), higher average LOS-associated charges ($91.7K vs. $66.0K) and infection-associated LOS charges ($19.8K vs. $17.4K). CR patients also had a higher rate of readmission with the same pathogens (22.6% vs. 13.5%, P < 0.001), and readmitted within 30 days (6.9% vs. 2.7%) than CS patients.

CONCLUSIONS: Our analysis demonstrates the increased burden associated with the presence of CR pathogens in UTI patients. Early identification and effective treatment of CR pathogens in patients UTIs might reduce this burden for hospitals and patients.

SPONSORSHIP: Shionogi.

B1 Impact of a clinical “nudge” on herpes zoster vaccine dose completion in community pharmacies

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BACKGROUND: The recombinant herpes zoster vaccine has advanced efforts to prevent shingles in adults 50 years of age and older, however, the multi-dose regimen introduces potential barriers to full protection that must be managed by community pharmacies. To address this potential patient management challenge, a pharmacy records tool was developed to assist pharmacy staff in managing multi-dose herpes zoster vaccinations.

OBJECTIVE: To assess the impact of a clinical decision support tool within a pharmacy records system to improve the odds of herpes zoster vaccine completion.

METHODS: Beginning in November 2018, a large community pharmacy chain implemented a clinical decision support tool in all of its locations. The system alerts pharmacists to place patients in “queue” when their second herpes zoster vaccine dose is due, facilitating the management of vaccine supply. This “nudge” then prompts pharmacy staff to encourage dose completion among those for whom alerts were provided. Initial and second doses were followed over two, overlapping, 10-month periods prior to and after system launch. Differences in vaccine completion rates before and after the system was operational were assessed by chi-squared tests and predictors of completion, controlling for store- and patient-level characteristics, were analyzed by multivariable logistic regression and generalized linear models.

RESULTS: Across 2,200 pharmacies, the proportion of patients completing both doses increased slightly after system implementation (pre: 74.2%; post: 76.1%; P < 0.0001). Changes in completion were realized in half of the states with pharmacies, among which 50% saw improvements, with most increases observed in western states. The system was comparatively more effective in stores with lower prescription (B: 0.657 vs 0.644; P = 0.0247) and influenza vaccine (B: 0.657 vs 0.617; P = 0.0001) volume as well as in areas with lower health literacy (B: 0.657 vs 0.654 per unit increase in health literacy; P = 0.0003). Dramatic improvements in time to dose completion were observed (pre: 120.2 days; post: 97.8 days; P < 0.0001), and changes were significant in stores in all but 4 states. Among stores with higher influenza vaccine volume, the system significantly decreased average time to completion compared to those with lower vaccine volume (B: 15.93 [low] vs 38.29 [high]; P < 0.001).

CONCLUSIONS: Results suggest that use of a clinical “nudge” can improve the occurrence of and time to herpes zoster vaccine dose completion in adults across the United States; however, patient-focused interventions may be needed to achieve greater completion rates.

SPONSORSHIP: GlaxoSmithKline.
Background: Herpes zoster (HZ) is a cutaneous disease caused by the reactivation of latent varicella zoster virus from dorsal root or cranial nerve ganglia. The pain associated with HZ can be described as aching, burning, stabbing, or shock-like, with postherpetic neuralgia (PHN), defined as pain persisting after the rash has healed, as a common complication. PHN-associated pain may be severe and can persist for years, thus adequate pain control is important. While opioids are highly effective analgesics, their misuse is common and considered an ongoing epidemic.

Objective: To examine pain management practices among HZ patients in U.S. retrospective claims databases and report incremental healthcare resource use (HCRU) and costs associated with opioid use among HZ patients.

Methods: Three cohorts of adults 18+ years of age were extracted from Marketscan databases from 2012-2018: HZ patients receiving opioid pain medication, HZ patients receiving nonopioid pain medication; and non-HZ patients (results not shown). Among patients with HZ, types of therapies received and time to treatment initiation were evaluated. In the opioid cohort, initial opioid dose, days supplied, and dose escalation were reported. Multivariable logistic regression models identified opioids-associated factors. HCRU and costs were assessed for various durations after an HZ episode.

Results: In total, 26% of Commercial/Medicare patients received opioids following an HZ diagnosis, with 78% of these patients receiving a weak opioid (codeine, dihydrocodeine e.g.). Opioid dose escalation was not common and patients had an average of 1.6 opioid prescriptions. Patients in the opioid cohort had a median of 3 days between their first observed claim with a HZ diagnosis and opioid treatment, with >60% receiving an opioid prescription during the first month. The likelihood of opioid receipt tended to decrease over the observed time period of the database. Multivariable logistic regression observed the strongest risk factor for receipt of an opioid was a diagnosis of PHN. Adjusted healthcare costs were substantially higher among HZ patients receiving opioids than among HZ patients receiving nonopioid therapies. Costs also tended to increase with increasing patient age for both HZ patient cohorts.

Conclusions: In this retrospective study, we observed opioids prescribed to over 25% of HZ patients. The presence of PHN was the strongest risk factor for receipt of an opioid. Healthcare costs were substantially higher in HZ patients receiving opioids.

Sponsorship: GlaxoSmithKline Biologicals SA (study ID HO-18-19084).
METHODS: A decision-tree model was created to determine the cost-effectiveness of cefiderocol vs colistin based regimens, ceftazidime/avibactam, and ceftolozane/tazobactam for the treatment of CR Infections in the U.S. HCUP analyses and reviews of the published literature were used to obtain costs and outcomes inputs, and U.S. susceptibility data was calculated for the three Priority 1 CR pathogens (Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacteriaceae) plus intrinsic CR Stenotrophomonas maltophilia. The evaluation was performed from both a healthcare and a societal perspective on a lifetime time horizon, using the ICER Reference Case discount rate of 3%. A probabilistic sensitivity analysis (PSA) was also conducted to account for uncertainty.

RESULTS: For the base case analysis at a cost-effectiveness threshold of USD$100,000, cefiderocol was shown to be cost effective when compared with colistin based regimens, with an ICER of $33,950 (Incremental Costs $5,402; Incremental QALYs 0.159). Cefiderocol was also cost-effective when compared with ceftazidime/avibactam and ceftolozane/tazobactam, but further research is warranted due to uncertainty in these results.

CONCLUSIONS: Cefiderocol, a new siderophore cephalosporin antibiotic recently approved in U.S., is a cost-effective option for the treatment of confirmed CR infections in the U.S. when compared to colistin, but further research is warranted for comparisons to other antibiotics.

SPONSORSHIP: Shionogi BV.

B8 Assessment and characterization of U.S. government funding decisions for COVID-19 vaccine and treatment development programs and manufacturing

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BACKGROUND: In March 2020, the WHO declared the SARS-CoV-2 virus (COVID-19) a global pandemic and as of June 2020 there was more than 7 million confirmed cases worldwide, resulting in over 400,000 deaths. Researchers around the world are developing over 300 vaccines and treatments against COVID-19 with some setting industry records in development speed. The race for vaccines and a cure is being fueled by government funding of research, clinical trials, and manufacturing. The United States Biomedical Advanced Research and Development Authority (BARDA) has provided significant funding for fighting the COVID-19 virus.

OBJECTIVE: To characterize U.S. government funding decisions for COVID-19 vaccines and treatments and compare characteristics of vaccine development programs and companies awarded acceleration grants.

METHODS: U.S. Department of Health and Human Services documents detailing funding decisions for COVID-19 vaccine and treatment programs were gathered and reviewed. The therapeutic platforms and the assessments of manufacturing capacity of companies the U.S. government partnered with were documented and compared. BARDA funding awards were analyzed and described.

RESULTS: As of June 2020, BARDA had entered into six significant funding agreements with biopharmaceutical research organizations to advance the development of vaccines and nine agreements for therapeutic agents for COVID-19. The BARDA Medical Countermeasure Portfolio consisted of over $2.8 billion in investment and funding for COVID-19 vaccine research and manufacturing. More than $1.7 billion (60.8%) was awarded to programs that adapted previously used vaccine platforms to be used for COVID-19. Nearly $500 million (17%) was awarded for a novel mRNA vaccine platform with the goal of FDA licensure. More than $628 million (22.1%) was awarded to commit manufacturing capacity and pave the way for biotechnology innovators to ensure stable supply. Over $350 million was awarded by BARDA for development and testing of a variety of therapeutic agents which consisted of several new antibodies, two FDA approved drugs, immune globulins, and interleukin inhibitors.

CONCLUSIONS: Key factors leading to U.S. government funding for COVID-19 vaccines and therapeutics included programs utilizing previously approved vaccine platforms, products being rapidly deployable, companies having significant domestic and global manufacturing capacity and scalability, and companies having established U.S. development and manufacturing supply chains. Enhanced development and regulatory pathways will have to be matched with reimbursement and access decisions.

SPONSORSHIP: Apperture Health.

C1 Real-world evidence-based patient profiles and treatment patterns among patients with recurrent or metastatic squamous cell carcinoma of the head and neck (R/M HNSCC) from 2016-2019

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BACKGROUND: Given recent therapeutic advancements for patients with R/M HNSCC, there is a need to better describe the current treatment landscape, particularly to understand the impact of anti-PD1 treatment introduction.

OBJECTIVE: The study objectives were to investigate treatment patterns and clinical outcomes of R/M HNSCC patients in the community oncology setting.

METHODS: This was a retrospective observational study of patients with R/M HNSCC who received care in the U.S. Oncology Network and initiated treatment between 01 January 2016-30 September 2019. Data was extracted from the iKnowMed (iKM) electronic health record (EHR) and Limited Access Death Master File (LADMF). Patients included in this study had a diagnosis of R/M HNSCC, had ≥ 2 visits within the USON, were ≥ 18 years of age, not enrolled in clinical trials, and did not have active non-HNSCC forms of primary cancer. Patient characteristics at baseline were captured from the iKM EHR data. Treatment index dates for R/M HNSCC were established as the dates of initiation of first-line (LOT1), second-line (LOT2) and third-line (LOT3) therapies. Treatment patterns for the study cohort...
were described including the line of therapy, treatment duration, and sequencing. Kaplan-Meier estimates were used to evaluate real world overall survival (RW OS) and time to next treatment (TTNT).

**RESULTS:** 726 patients met the inclusion criteria and were included in this analysis. Mean age was 66 years, 74% were white, and 76% were male. Mean follow-up time from LOT1 was 9.6 months (SD = 9 mo). The median time from locoregional treatment to LOT1 initiation was 5.5 months, and the median TTNT from LOT1 initiation was 5.8 months for the overall population. The most common LOT1 regimens were nivolumab (18.7%), pembrolizumab (16.8%), carboplatin + paclitaxel (12.8%), and cetuximab (10.2%). 41% of patients advanced to LOT2, and the most common regimens were pembrolizumab (29.9%) and nivolumab (28.5%). 23.2% of patients had LOT3 regimens documented in iKM. The unadjusted median RW OS from start of LOT1 was 13.0 months (95% CI: 11.1-15.1 mo).

**CONCLUSIONS:** This study provides information on the evolving therapy landscape in R/M HNSCC. Pembrolizumab-based regimens were approved in the U.S. and Europe for use in the first-line setting in 2019, and there are multiple ongoing clinical trials assessing novel regimens as there remains an unmet need for this indication. Further planned analyses will establish the real world clinical and safety outcomes associated with current treatment regimens and explore the clinical burden for this population.

**SPONSORSHIP:** GSK study 207139.

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**C3**

Hospitalizations and real-world clinical outcomes of liposomal irinotecan in a NAPOLI1-based regimen among patients with metastatic pancreatic ductal adenocarcinoma (mPDAC): a multi-center chart review

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**BACKGROUND:** The NAPOLI1 trial demonstrated that liposomal irinotecan in combination with fluorouracil (5-FU) and leucovorin (LV) prolonged survival with a manageable safety profile in patients with mPDAC previously treated with gemcitabine-based therapy. There is limited real-world (rw) data on economic and clinical outcomes associated with liposomal irinotecan in NAPOLI1-based regimens.

**OBJECTIVE:** This retrospective multi-center chart review study evaluated rate of hospitalizations and related costs along with clinical outcomes in mPDAC patients in the United States who received NAPOLI1-based regimens.

**METHODS:** Eligible patients had mPDAC treated with liposomal irinotecan in a NAPOLI1-based doublet regimen (treatment initiation defined index date) at six academic cancer centers. Hospitalizations were assessed per-patient-per-month (PPPM) during liposomal irinotecan treatment (i.e., within line of therapy during which liposomal irinotecan was received), based on data available at the centers. Hospitalization costs from a payer perspective were imputed by applying unit cost inputs from literature to the frequency of hospitalization encounters. Kaplan-Meier methodology was used to assess median rw overall survival (rwOS). Initial results are presented here.

**RESULTS:** Of the 325 patients included in this analysis, median age was 68 years, 51% were female, ECOG status 0 (9%), 1 (54%) and ≥ 2 (22%). Patients received liposomal irinotecan in first-line (1L; 17%), 2L (43%), and 3L+ (40%), in a NAPOLI1-based regimen with 5-FU, with 75% also receiving LV. Median treatment duration was 3.4, 2.1, and 1.4 months, for 1L, 2L, and 3L+, respectively. Mean ± standard deviation (SD) hospitalizations (corresponding costs) PPPM during line of liposomal irinotecan treatment were 0.2 ± 0.7 ($2,160 ± 4,628), 0.2 ± 0.4 ($2,478 ± 7,014), and 0.2 ± 0.5 ($3,134 ± 11,112), for 1L, 2L, and 3L+, respectively. Median (95% confidence interval [CI]) rwOS in months was 8.6 (4.6, 9.8), 7.4 (5.3, 9.3), and 4.8 (4.0, 6.3), for 1L, 2L, and 3L+, respectively.

**CONCLUSIONS:** Patients treated with NAPOLI1-based liposomal irinotecan doublet regimens in academic centers are older with poorer prognosis based on ECOG scores compared to participants in the trial, though rw effectiveness was comparable. Liposomal irinotecan was also used in 3L+ settings, providing benefit in rw where no treatment has been approved. Hospitalization costs were slightly higher among patients treated with liposomal irinotecan in 3L+ compared to earlier lines.

**SPONSORSHIP:** Ipsen Biopharmaceuticals.

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**C4**

Comorbidities and economic burden of patients diagnosed with hepatocellular carcinoma treated with systemic therapy in the United States

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**BACKGROUND:** Many patients with hepatocellular carcinoma (HCC) have advanced disease either at diagnosis or following progression from earlier stages.

**OBJECTIVE:** The objectives of this study were to examine patient comorbidities and healthcare costs of patients with HCC who initiated first line of systemic therapy (LOT1).

**METHODS:** Adult patients with HCC who initiated systemic therapy (index date) were identified from the MarketScan Commercial and Medicare Supplemental databases (July 1, 2013-May 31, 2018). Patients were required to have ≥ 6 months of continuous insurance coverage with data available at the centers. Hospitalization costs were slightly higher among patients treated with liposomal irinotecan in 3L+ compared to earlier lines.

**RESULTS:** Of the 74+ HCC patients who initiated systemic therapy (median age: 63 years, male: 78%, 92% received sorafenib in LOT1, 5% bevacizumab, and 3% immune checkpoint inhibitors (ICI)). Among the study population, the most prevalent hepatic comorbidities were cirrhosis (62%), chronic HCV infection (40%), and portal hypertension (24%). Prevalent non-hepatic comorbidities included those which were cardiovascular (hypertension: 64% and congestive heart failure: 8%) and diabetes (38%). Additionally, 22% had esophageal varices.

**SPONSORSHIP:** Ipsen Biopharmaceuticals.
(4% with bleeding; 18% without bleeding). Before initiating LOT1 systemic therapy, 27% received TAE/TACE or TARE (59% had 1 procedure, 34% had 2-3 procedures, 7% had >4 procedures). The median durations of LOT1 sorafenib, bevacizumab, and ICI therapy were 56, 43, and 61 days, respectively. Only 10% received a second LOT (of whom 39% got IO therapy). The mean (standard deviation [SD]) total all-cause PPPM healthcare costs were $20,217 ($19,165). About 80% of these costs were HCC-related. Patient OOP costs were $422 (all-cause) and $300 (HCC-related) PPPM.

**CONCLUSIONS:** Patients with HCC in the U.S. had significant comorbidities, especially related to cardiovascular conditions. For every 4 patients receiving systemic therapy, 3 patients had no prior embolization, suggesting that a relatively high proportion of patients were first diagnosed at advanced stages. The direct healthcare economic burden of HCC patients treated with systemic therapy is substantial.

**SPONSORSHIP:** AstraZeneca Pharmaceuticals.

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**C6 An evaluation of the efficacy and safety of second-line (2L) treatments in metastatic colorectal cancer (mCRC)**

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**BACKGROUND:** mCRC is associated with a poor prognosis and overall survival (OS). Treatment options typically include cytotoxic chemotherapy (FOLFOX or FOLFIRI) and targeted therapies (TT), combined and sequenced through several lines of treatment. Among treated patients, up to 60% will receive first line (1L) FOLFOX until disease progression. In patients who received FOLFOX, guidelines recommend 2L treatment with FOLFIRI alone or in combination with TT.

**OBJECTIVE:** A systematic literature review (SLR) was conducted to evaluate efficacy and safety outcomes of FOLFIRI-based 2L regimens in mCRC.

**METHODS:** Using PRISMA guidelines and pre-defined search terms, EMBASE, MEDLINE, and Cochrane were searched to identify studies from 2009 to the search date (01/21/2020) reporting efficacy and safety outcomes in patients receiving any systemic 2L treatment for mCRC. Relevant congresses (2017 to 2019) and clinicaltrials.gov were also searched. Outcome measures of interest included OS, progression-free survival (PFS), objective response rate (ORR), and safety.

**RESULTS:** 36 randomized controlled trials (RCTs) met inclusion criteria. 16 were FOLFIRI-based, 9 FOLFOX-based, 5 FOLFIRI- or FOLFOX-based, and 6 evaluated other therapies. Of the 16 FOLFIRI-based RCTs, five were Phase 3 RCTs with a total 3953 patients (128 to 614 per arm). Among patients in 5 RCTs, 57-63% were male, mean 61-62 years old, 94-100% with ECOG 0-1. 3 RCTs compared FOLFOX alone to FOLFIRI + TT (2 RCTs of VEGF inhibitors, 1 RCT of an EGFR inhibitor), 1 RCT compared FOLFIRI to mXELIRI, and 1 to irinotecan+5-FU. Median OS for FOLFIRI+TT ranged from 11.7 to 17.8 months, with -0.4 to 2 months incremental improvement vs. FOLFIRI alone. Median PFS ranged from 4.5 to 8.4 months, with -3.1 to 5.4 months incremental PFS vs. FOLFIRI alone. Response rates of 13.4% to 36% were reported with FOLFIRI+TT, vs. 9.8% to 18.8% with FOLFIRI alone. Treatment regimens were associated with severe toxicity, with 94% to 84% of patients reporting grade 3+ adverse events. Skin toxicities were commonly reported with EGFR inhibitors; thromboembolic events were common with VEGF inhibitors.

**CONCLUSIONS:** Few of the current FOLFIRI-based regimens in 2L mCRC offer meaningful improvements in PFS and OS, demonstrating only modest incremental gains in survival compared to chemotherapy alone. A significant unmet need exists for treatments that provide a robust and more lasting survival benefit with meaningful response, while offering an acceptable and manageable toxicity profile.

**SPONSORSHIP:** Boston Biomedical.
BACKGROUND: Bevacizumab-awwb (MVASI), a biosimilar to bevacizumab (AVASTIN), was the first FDA approved biosimilar for treatment of metastatic colorectal cancer (mCRC) with intravenous 5-FU-based chemotherapy for 1st- or 2nd-line (L) treatment.

OBJECTIVE: To evaluate initial, real world experience with bevacizumab-awwb (launched 07/19/2019) in community oncology practices.

METHODS: This retrospective analysis identified mCRC patients initiating treatment with bevacizumab-awwb as 1st- or later-L treatment from existing medical records. Eligibility criteria included treatment with bevacizumab-awwb in any line following mCRC diagnosis, patient age ≥ 18 years (y), and known Eastern Cooperative Oncology Group (ECOG) performance status score of 0-2 at mCRC diagnosis. Patients were identified from the Concerto Health AI Definitive Oncology Dataset representing geographically diverse practice locations in the U.S. The source practices are primarily community oncology practices, including rural and urban centers and members of different group purchasing organizations. Patient characteristics were evaluated using descriptive statistics.

RESULTS: Among patients who received bevacizumab-awwb, 69 were eligible for this analysis. Mean age was 65.1 y at mCRC diagnosis and 55.1% (n = 38) of patients were male. Most patients (88.4%, n = 61) were either White (66.7%, n = 46) or African American (21.7%, n = 15). T(66.7%, n = 46) stage IV at diagnosis and 94.2% (n = 65) had adenocarcinoma histology. First use of bevacizumab-awwb in mCRC occurred within 20 days of product launch. Additionally, 75.4% (n = 52) of patients had previously received brand bevacizumab. 82% (n = 14) of pts with no prior bevacizumab history received bevacizumab-awwb in 1st line setting. Comorbidities present in ≥3% of patients were diabetes (31.9%, n = 22) and chronic obstructive pulmonary disease (11.6%, n = 8). Most patients had ECOG score of 0 (34.8%, n = 24) or 1 (30.4%, n = 21) and a slight majority received biomarker testing (NRAS: 55.1%, n = 38; KRAS: 66.7%, n = 46; BRAF: 58.0%, n = 40; MSI: 58.0%, n = 40; MMR: 63.8%, n = 44).

CONCLUSIONS: This is the first study to report real world uptake and utilization of biosimilar bevacizumab. Results depict demographic and clinical characteristics of mCRC patients receiving bevacizumab-awwb in community oncology settings within the first few months of product launch. Uptake and utilization of bevacizumab-awwb will be monitored for longer-term follow-up information.

SPONSORSHIP: Amgen.
OBJECTIVE: To estimate and describe productivity loss incurred by working-age BC and NSCLC patients and caregivers in the U.S.

METHODS: BC and NSCLC patients and unpaid caregivers completed web-based surveys, reporting pre- and post-cancer diagnosis income, hours worked, time to complete tasks, and teamwork. The responses allowed U.S. to estimate absenteeism and presenteeism and to calculate ‘teamwork multipliers,’ which were used to estimate the productivity losses of co-workers. Multivariable analyses explored relationships between patient characteristics, teamwork, and absenteeism.

RESULTS: A total of 404 participants (104 BC, 100 NSCLC patients; 100 BC, 100 NSCLC caregivers) enrolled. 319 participants (82 BC, 76 NSCLC patients; 80 BC, 81 NSCLC caregivers) who worked ≥40 weeks in the year pre-diagnosis were included in the analysis. Over one-third of the NSCLC (33%) and BC (43%) patients left the workforce after diagnosis. For patients, estimated mean annual productivity loss equaled $123,792 (144% of mean income/pre-diagnosis) for NSCLC and $123,502 (209% of mean income/pre-diagnosis) for BC. For caregivers, estimated mean annual productivity loss was $90,421 (108% of mean income/pre-diagnosis) for NSCLC and $143,839 (190% of mean income/pre-diagnosis) for BC. Exploratory analyses found that patient age and stage at diagnosis were positively correlated with greater absenteeism. Workers in scientific/technical services had higher teamwork multipliers compared with workers in other industries.

CONCLUSIONS: Only considering the income loss of patients significantly underestimates the value of productivity loss corresponding to a cancer diagnosis. These results underscore the importance of holistic approaches, such as the multiplier method, that include lost wages, fringe benefits, and teamwork effects to better understand the amplified impact cancer can have on patients, caregivers, co-workers, and employers. Comprehensive measurement of productivity losses is essential for both patient and payer informed decision-making about treatment choice and appropriate valuation of new and existing treatments for cancer.

SPONSORSHIP: AstraZeneca.

C10 Using machine learning to identify patient factors associated with hospitalization and emergency department visits in patients with advanced lung cancer and treated with immune checkpoint inhibitors

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BACKGROUND: Immune checkpoint inhibitors (ICI) have been shown to improve survival in patients with advanced lung cancer (LC). Potential patient factors related to hospitalization (HOSP) or emergency department visits (EDV) while receiving ICI can help physicians design care plans to reduce undesirable events.

OBJECTIVE: To identify patient factors related to HOSP or EDV in 6 months of ICI use in patients with advanced LC.

METHODS: This retrospective cohort study identified patients with ICD-9/10-CM diagnosis codes for primary LC and metastasis in U.S. electronic health records from Jan 2010-Jun 2018. The index date (IDX) was the first ICI record. Baseline covariates included patient demographics, comorbidities, medication (Rx) use, procedures performed, lab results, and HOSP or EDV in 12 months pre-IDX. The outcomes were binary variables for all-cause and cancer-related HOSP and continuous variables for all-cause and cancer-related EDV within 6 months post-IDX. A hypothesis-free, data-driven proprietary machine learning platform was used to build 4 model ensembles for all-cause or cancer-related HOSP and EDV separately. Each ensemble had 128 Bayesian regression models: logistic regression for HOSP and generalized linear regression for EDV. Selection frequency (SF) and distribution of effect size were used to assess effects of covariates on outcomes. Sensitivity analyses included reassigning first administered ICI as IDX, excluding patients with other primary cancers, and regrouping some covariates for clinical granularity.

RESULTS: The study included 6068 patients with mean (SD) of age 67 (10) years, 53% were male. Mean (SD) all-cause HOSP and EDV per patient per month were 1.0 (1.3) and 0.9 (1.5) pre-IDX, and 0.7 (1.0) and 0.5 (1.0) post-IDX. Prior all-cause HOSP (100% SF) was the most selected covariate with higher risk of both all-cause and cancer-related HOSP. All-cause EDV (100% SF) and hydrocodone combinations ( >80% SF) were the top 2 covariates selected with higher risk of both all-cause and cancer-related EDV. In the sensitivity analysis, prior all-cause HOSP and EDV remained the most selected covariates with higher risk of all-cause or cancer-related HOSP and EDV, respectively. Pain control Rx might be related to higher risk of all-cause or cancer-related HOSP and gastritis/GERD Rx might be related to higher risk of all-cause or cancer-related EDV.

CONCLUSIONS: HOSP and EDV are lower in the 6 months of ICI use in patients with advanced LC. Prior HOSP or EDV was the best predictor of future events. Any association between gastritis/GERD Rx and EDV warrants future studies.

SPONSORSHIP: Bristol-Myers Squibb.

C11 Budget impact of capmatinib in adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to MET exon 14 skipping in the United States

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BACKGROUND: Lung cancer is most commonly diagnosed in people 65-74 years of age in the United States (U.S.). Mutations that lead to MET exon 14 (METex14) skipping occur in approximately 3% of non-small cell lung cancer (NSCLC) cases. Capmatinib, an oral and selective kinase inhibitor, is the first FDA-approved MET inhibitor for the treatment of adults with metastatic NSCLC (mNSCLC) whose tumors have a mutation that leads to METex14 skipping.

OBJECTIVE: To estimate the budget impact of adding capmatinib as an option for treatment-naïve and previously treated patients with mNSCLC whose tumors have a mutation that leads to METex14 skipping to a commercial or Medicare health plan in the U.S.

METHODS: A budget impact model was developed. The target population size was estimated using published epidemiology data. Clinical data were obtained from the GEOMETRY mono-1 trial and published
trials. Treatments in the current market mix included crizotinib, pembrolizumab, ramucirumab and chemotherapies, with treatment combinations varying in each population per label and clinical practices. Uptake of capmatinib (400mg twice daily) and testing rates were based on market research. All costs (drug acquisition and administration, progression, terminal care, adverse event, and mutation testing) were estimated based on public sources (in 2020 USD).

RESULTS: In a hypothetical plan with 1 million members, over the first 3 years, an estimated 2 to 3 patients with commercial insurance and 34 to 44 patients with Medicare health plan were eligible to receive capmatinib each year. Total budget impact was estimated to range from $9,695 to $67,725 for commercial, and $141,350 to $985,695 for a Medicare plan. The introduction of capmatinib was estimated to have a marginal increase in per member per month budget impact (commercial: $0.0008 to $0.0056; Medicare: $0.0118 to $0.0821). Capmatinib entry resulted in lower medical costs (commercial: -$0.0003 to -$0.0007; Medicare: -$0.0037 to -$0.0106), offsetting increased drug costs (commercial: $0.0111 to $0.0064; Medicare: $0.0154 to $0.0928). Lower medical costs were mainly driven by a reduction in post-progression and terminal care costs (commercial: -$0.0003 to -$0.0009; Medicare: -$0.0037 to -$0.0125). The results were most sensitive to capmatinib market share and treatment duration.

CONCLUSIONS: The budget impact of capmatinib for the treatment of mNSCLC with a METrxH skipping mutation is expected to be minimal due to the small number of patients with this disease. The increased drug costs are expected to be partially offset by savings in post-progression and terminal care costs.

SPONSORSHIP: Novartis.

C12 Payers’ first-line treatment preferences in metastatic non-small cell lung cancer
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BACKGROUND: Immune checkpoint inhibitors for metastatic non-small cell lung cancer (mNSCLC) have transformed the first-line (1L) treatment setting. With more options, the benefit-risk trade-offs underlying payer (PY) decisions on managing access to new treatments should be considered.

OBJECTIVE: This study quantified PY preferences for attributes of chemotherapy and immunotherapy for mNSCLC.

METHODS: PYs representing Medicare and commercial lives completed an online survey assessing treatment preferences via 2 discrete choice experiments (DCEs) for 2 patient (pt) groups: 1) those with PD-L1 tumor cell (TC) ≥1% and 2) those with PD-L1 TC ≥50% expression. In a series of tasks, PYs chose the profile for which they would impose the fewest reimbursement hurdles from 2 alternatives varying on 6 attributes preidentified in qualitative research: overall survival (OS), progression-free survival (PFS), serious adverse event (SAE) that may require hospitalization, grade (G) 3/4 diarrhea/colitis, G3/4 pneumonitis, and G3/4 neutropenia. Hierarchical Bayes models were used to estimate preference weights for each attribute level.

RESULTS: PYs (N=78, 60% medical directors) representing national (39%), regional (50%), and Blues (12%) plans participated. Across pt groups, PYs prioritized reducing the risk of a SAE that may require hospitalization, followed by OS, G3/4 neutropenia, PFS, G3/4 diarrhea/colitis, and G3/4 pneumonitis. Among PD-L1 ≥1% pts, reducing the risk of a SAE that may require hospitalization from 70% to 18% was almost twice as important as improving OS from 12 to 21 months (relative importance [RI]: 46% vs. 27%); both attributes were similarly valued for PD-L1 ≥50% pts when OS improves from 12 to 30 months (RI: 40% vs. 36%). These two attributes were ≥3 times as important as improving PFS by 4 months (RI: 8%) in both pt groups. PYs would accept increases in the risk of a SAE that may require hospitalization by 29% and 49% in exchange for improvements in OS of 9 and 18 months, respectively. PYs would also accept an increase in G3/4 neutropenia from <1% to 25% in exchange for reducing the risk of a SAE that may require hospitalization by 10% and 11%, respectively, in each pt group.

CONCLUSIONS: Although PYs placed high importance on reducing the risk of SAEs that may require hospitalization, the importance of OS is dependent on the magnitude of improvement. When OS is improved by 18 months, it reaches a similar level of importance as risk of SAEs that may require hospitalization. PYs prioritize these attributes well above PFS.

SPONSORSHIP: AstraZeneca.

C13 Budget impact of alectinib in aplastic lymphoma minase-positive (ALK+) metastatic non-small cell lung cancer (MNSCLC) in the United States
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BACKGROUND: In the United States, 4%-5% of mNSCLC patients are ALK+ While many ALK inhibitors are available for these patients, alectinib has become the standard of care since its approval and is recommended by the NCCN Guidelines as the preferred first-line (1L) treatment.

OBJECTIVE: To estimate the potential budget impact of maintaining alectinib at current market shares in 1L therapy for ALK+ mNSCLC patients in a simulated one million-member plan.

METHODS: A budget impact model, developed from a U.S. private payer perspective using a 3-year time horizon, estimated the number of patients eligible for treatment, cumulative and annual total costs, and the per member per month (PMPM) cost in a hypothetical plan of all ages. The population eligible for treatment was estimated based on mNSCLC incidence rates, projected ALK testing and positivity rates. Comparators in the 1L model included crizotinib, ceritinib, brigatinib and a best supportive care arm comprised of other chemotherapy regimens. Cost inputs included drug wholesale acquisition costs (WAC), drug administration and adverse events. The base case scenario simulated costs according to projected market distribution where alectinib 1L shares decreased with brigatinib entry (70%, 68%, 60% for alectinib, and 8%, 10%, 18% for brigatinib in years 1-3, respectively). An alternative scenario that assumed alectinib maintains current 1L market shares at 75% over 3 years was compared to the base case to estimate the budget impact.
**RESULTS:** In a one million-member plan, the budget impact model estimated 5 ALK inhibitor eligible patients. The monthly drug cost (WAC) is $15,621 for alectinib, $13,364 for ceritinib, $16,198 for brigatinib, and $17,961 for crizotinib. Maintaining alectinib as the current 1L market share (alternative scenario) resulted in a cost saving of $28,931 (-$0.001 PPM) over 3 years.

**CONCLUSIONS:** Maintaining alectinib as a formulary 1L therapy at current market share for ALK+ mNSCLC patients is expected to result in cost savings over a 3-year period ($0.001 PPM) from a U.S. private payer perspective.

**SPONSORSHIP:** Genentech.

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**C14 Economic analysis of introducing liquid biopsy reflex testing to detect epidermal growth factor receptor (EGFR) mutations in metastatic non-small cell lung cancer (MNSCLC) using a patient flow model**

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**BACKGROUND:** NCCN guidelines recommend targeted therapy for all patients with metastatic NSCLC with appropriate oncogenic driver gene mutations. Identification of patients with mutations requires biomarker testing. While tissue biopsy is the gold standard for biomarker testing, multiple challenges such as insufficient tissue, rebiopsy, and turnaround time may lead to suboptimal patient identification. Guidelines recommend using liquid biopsy testing (reflex testing) for patients who fail or in whom tissue biopsy is not feasible to ensure identification of all patients eligible for targeted therapy. In absence of liquid biopsy, some patients in whom tissue biopsy is not performed may start with inappropriate therapy.

**OBJECTIVE:** We present an economic analysis to illustrate the impact of introduction of liquid biopsy to tissue biopsy testing on identification of EGFRm patients and associated costs from a U.S. payer perspective.

**METHODS:** A patient flow model on 1,000 metastatic NSCLC patients was used to assess the difference in the total costs needed to identify treatment eligible patients identified between two testing strategies (tissue biopsy alone [TBA] and tissue reflex to liquid biopsy[TRLB]). Number of patients eligible for TKIs, costs associated with testing, rebiopsy and associated complications, and treatment were captured until identification of right therapy for all 1,000 patients. All model inputs are based on published peer reviewed literature and assumptions based on market research.

**RESULTS:** Out of 1,000 metastatic NSCLC patients, the model estimated the numbers of patients who were eligible for TKI therapy are 65 for the TBA strategy and 141 using tissue TRLB strategy. Adding the liquid biopsy into the tissue biopsy resulted in an additional $1.4 million ($57.0 million TRLB vs $55.6 million TBA) for 1000 patients. Costs to identify TKI therapy eligible patient was $87,273 for TBA and $45,604 for TRLB strategy.

**CONCLUSIONS:** Tissue reflex to liquid biopsy strategy can improve patient identification and resulting in more patients receiving appropriate therapy in metastatic NSCLC at lower costs per patient to identify those eligible for TKI therapy.

**SPONSORSHIP:** AstraZeneca.

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**C22 The impact of chemotherapy-induced peripheral neuropathy in metastatic breast cancer patients treated with paclitaxel or Abraxane**

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**BACKGROUND:** Intravenous paclitaxel and Abraxane (P/A) are commonly used in metastatic breast cancer (mBC). Chemotherapy-induced peripheral neuropathy (CIPN) is a prominent taxane side effect that can lead to therapy changes and detrimentally impact patient outcomes.

**OBJECTIVE:** This study examined the incremental burden of CIPN in patients with mBC treated with P/A.

**METHODS:** Adult women in the MarketScan Commercial and Medicare Supplemental Database with a mBC diagnosis newly initiating P/A from 11/1/2013-9/30/2018 were identified. The first P/A administration served as the index date. Women with continuous enrollment 12 months prior and ≥ 3 months following index were selected and followed until the end of continuously available data. Those with evidence of CIPN in the pre-period were excluded. Eligible patients were stratified into cohorts with and without a CIPN diagnosis over the post-period. Outcomes including treatment characteristics and per-patient-per-month (PPPM) healthcare utilization and costs were compared between propensity score matched CIPN and non-CIPN cohorts over the variable length post-period.

**RESULTS:** A total of 5,870 women qualified for the analysis, 42.7% had a CIPN diagnosis. The matched CIPN and non-CIPN cohorts were composed of 1,950 women each and were followed on average 21 months. The duration of the first line of P/A therapy (1LOT) was similar between cohorts (CIPN 96 days; non-CIPN 99 days). Mean time to CIPN diagnosis was 169 days after P/A initiation; 46.7% of women were diagnosed during the 1LOT. Compared to the non-CIPN cohort, women with CIPN were more likely to experience an inpatient admission (IP) or ER visit over the post-period (P < 0.01). Elevated costs in the CIPN cohort largely stemmed from increased office visits, other outpatient services, and pharmacy fills (P < 0.05). Similar trends were observed for BC related costs, with CIPN patients incurring an additional $725 per month per patient ($7,889 vs. $7,164, P < 0.01). Elevated BC related costs in the CIPN cohort were due to significant increases in office and other outpatient service costs (P < 0.001).

**CONCLUSIONS:** CIPN is a common side effect of treatment with P/A, and its development is associated with increased healthcare utilization and costs. Alternative therapies with reduced toxicity profiles stand to not only improve patient outcomes but also reduce healthcare costs due to lower rates of side effects like CIPN.

**SPONSORSHIP:** Athenex.
BACKGROUND: About 5-6% of women diagnosed with breast cancer (BC) have metastatic disease (mBC). Taxanes like paclitaxel and Abraxane play a large role in the treatment of mBC. While effective, these agents are associated with toxicities and demanding dosing schedules, which may impact therapy duration and clinical benefit.

OBJECTIVE: This study assessed the treatment patterns, toxicities, and cost burdens of IV paclitaxel or Abraxane (P/A) in the management of mBC.

METHODS: Adult women with a BC diagnosis between 1/1/2014 and 9/30/2018 were selected in the MarketScan Commercial and Medicare Supplemental Database. Women were required to have a diagnosis of mBC and newly initiate treatment with P/A. The first P/A administration was the index date. Continuous medical and pharmacy eligibility for 12 months prior and ≥3 months following index were required; women were followed until the end of continuously available data. Outcomes including treatment characteristics, toxicities, and per-patient-per-month (PPPM) healthcare utilization and costs were assessed over the total variable length post-period and the duration of the first line of P/A therapy (1LOT), which was the time from index to a regimen change.

RESULTS: A total of 8,890 women qualified for the study. Mean ± SD age at index was 54.6 ± 10.9 years; average follow-up was 18.9 months. Most women (82.0%) initiated P/A as monotherapy; mean 1LOT duration was 98.6 ± 62 days. Early discontinuation (defined as <6 cycles) was seen in 83.1% of women; 77.2% of women ended 1LOT due to dropping a component of the regimen. During the 1LOT, 78.6% of women had ≥1 side effect; 22.7% had CIPN and 7.0% had an infusion reaction. Over the post-date, hospitalizations and ER visits were common, with 39.7% and 43.0% of patients with ≥1 visit respectively. All-cause PPPM costs averaged $11,991 over the post-period ($17,978 PPPM over 1LOT); other outpatient services, which included chemotherapy administration costs, accounted for 75.6% of monthly per patient costs (83.2% over 1LOT). BC-related costs comprised 68.2% of all-cause costs over the post-period (78.0% over 1LOT).

CONCLUSIONS: Many patients who received P/A for mBC discontinued treatment early, which has the potential to limit the effectiveness of therapy. Further, patients incurred substantial healthcare costs along with high rates of hospitalization and emergency visits. Treatments with increased tolerability and reduced dosing complexity have the potential to improve mBC treatment while reducing costs, especially those associated with chemotherapy administration.

SPONSORSHIP: Athenex.

SPONSORSHIP: None.
Insurance coverage and health care expenditures among adult cancer survivors in the United States

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BACKGROUND: Health care expenditures for cancer care has increased significantly over the past decade and is further projected to rise. Not much is known about health insurance coverage of cancer survivors and their health care expenditures by insurance type.

OBJECTIVE: This study examined the association between health insurance coverage types and total annual health care expenditures and further assessed expenditure by the type of service among cancer survivors living in the United States.

METHODS: A retrospective, cross-sectional study was conducted using the 2017 Medical Expenditure Panel Survey data (MEPS). The study sample comprised of adults aged ≥18 years identified using International Classification of Diseases, Tenth Revision codes specific for cancer. Health insurance coverage was categorized into Private, Medicare, Medicaid, and Uninsured groups. Annual total direct healthcare expenditures comprised the main study outcome. Multivariable ordinary least square (OLS) regression was used to examine the association between logarithmically transformed healthcare expenditures and health insurance, adjusting for cancer type and patient demographics. Costs were retransformed using Duan’s smearing estimators.

RESULTS: 1,140 adult cancer survivors (weighted: 13,878,530) were living in the U.S. during 2017 out of which 62.8% had private insurance, 30.2% had Medicare, 5.8% had Medicaid while 1.2% were uninsured. Unadjusted mean annual health care expenditure by insurance status were as follows: Medicare ($16,179), private insurance ($13,571), Medicaid ($9,738) and uninsured ($3,179). Compared to adjusted mean annual healthcare expenditures for the private group ($14,309), the adjusted mean annual healthcare expenditures for the Medicare group ($20,570) were higher but not statistically significant while for the uninsured group ($2,432), and the Medicaid group were significantly lower ($10,760, P<0.05). Among the Medicare group, prescription medication accounted for highest expenditure ($4,554, standard deviation [SD]: 663) followed by expenditures due to office-based visits ($3,893, SD: 368). On the contrary, privately insured group had highest expenditures for office-based visits ($4,002, SD: 298) followed by prescription medication ($3,752, SD: 487).

CONCLUSIONS: Our findings suggest that cancer survivors with Medicare have higher healthcare expenditures than those with other insurance types. Differences in the use of healthcare services could explain the differences in health care spending. Our findings highlight the need for appropriate health care planning and public policies to reduce costs of cancer care, especially for those with Medicare.

SPONSORSHIP: None.

The budget impact of including fam-trastuzumab deruxtecan-nxki on the formulary for the treatment of HER-2 positive metastatic breast cancer: United States commercial payer perspective

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BACKGROUND: Fam-trastuzumab deruxtecan-nxki (T-DXd) is recently approved by the FDA for the treatment of adult patients with HER2+ unresectable or metastatic breast cancer (mBC) who have received ≥2 prior anti-HER2-based regimens in the metastatic setting. In a phase 2 trial, T-DXd was shown to have an objective response rate of 60.3% and median progression free survival (PFS) of 16.4 months in patients previously treated with T-DM1.

OBJECTIVE: To estimate the potential financial impact of introducing T-DXd to a drug formulary of treatments for HER2+ mBC patients who have ≥2 prior anti-HER2 regimens from a U.S. commercial payer perspective.

METHODS: A model was developed to assess the difference in total healthcare costs before and after adding T-DXd to a drug formulary of a hypothetical 1-million-member health plan. The model evaluated drug acquisition and administration cost, cost for monitoring and treatment of adverse events, and healthcare costs after disease progression over 2 years. Dosing information, monitoring requirements, treatment duration, efficacy and safety of T-DXd and alternative treatments commonly used as 3rd line treatment in HER2+ mBC patients (pertuzumab, trastuzumab, lapatinib, T-DM1, tucatinib, neratinib, chemotherapy and hormonal therapy) were obtained from published sources. Drug costs were based on 2020 wholesale acquisition cost. In base case, market share for T-DXd was assumed to be 10% in year 1 and 15% in year 2. Market shares for other treatments were based on Kanter Health with assumptions.

RESULTS: In the base case, 65 HER2+ mBC patients in a health plan received next line of treatment after receiving ≥2 prior anti-HER2 regimens. Adding T-DXd to formulary increased healthcare budget by $0.0205 per-member-per-month (PMPM). Budget increase due to higher the drug acquisition cost of T-DXd and longer time on T-DXd was partially offset by the reduction in healthcare costs from disease progression to death, due to longer PFS of patients on T-DXd relative to other regimens (PFS range: 1.86-9.00 months). Results were most sensitive to numbers of patients eligible for therapy, T-DXd costs and market share. When T-DXd market share was increased to 15% in year 1 and 22.5% in year 2, the overall PMPM budget increase remained small ($0.0307).

CONCLUSIONS: The inclusion of T-DXd on formulary offers an efficacious treatment option for HER2+ mBC patients who have progressed on ≥2 prior anti-HER2 regimens, in need of a next line treatment with a modest increase in healthcare budget.

SPONSORSHIP: Daiichi-Sankyo and AstraZeneca Pharmaceuticals.
C27 Workplace productivity loss and associated indirect costs among patients with HER2+ metastatic breast cancer in the United States

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BACKGROUND: Treatment advances have allowed many employees with HER2-positive metastatic breast cancer (HER2+ mBC) to remain in the workforce while on anti-cancer treatment. However, data on the indirect economic burden of HER2+ mBC is lacking.

OBJECTIVE: To compare days of work lost and associated costs between HER2+ mBC and employees without cancer diagnosis from a U.S. employers' perspective.

METHODS: A retrospective analysis was performed using the OptumHealth database (Q1 1999-Q1 2017). Patients who received anti-HER2 treatment after the first mBC diagnosis and had earning and disability data were matched 1:1 to cancer-free controls on demographics, health insurance plan, and the start/end date of availability of disability data. The number of days covered by disability claims and days lost from work due to medical conditions resulting in health resource utilization [HRU] were summarized from the first mBC diagnosis to the end of follow-up. Work loss due to HRU was calculated by assuming one day of missed work for inpatient days, days with visit to emergency room, or outpatient infusion service, and half day of missed work for other outpatient visits. The associated indirect cost was comprised of disability claims cost and cost of HRU-related work loss estimated by the product of patient's daily earnings and days of HRU-related work loss.

RESULTS: A total of 265 HER2+ mBC patients were matched with 265 cancer-free controls (99% female, mean age 49-50). In the year pre-index, HER2+ mBC patients had higher comorbidity burden than matched controls (mean Charlson Comorbidity Index: 0.3 vs 0.0, P<0.01) but similar annual earnings ($78,933 vs $68,160, P = 0.25). During the median follow-up of 18 months, HER2+ mBC patients were more likely to have disability claims (30% vs 5%), had more disability days (36 vs 4), HRU-related work loss days (39 vs 4), and total days of work loss (75 vs 8 days; all P<0.01) per person-year than controls. The average annual costs associated with work loss were significantly higher for HER2+ mBC patients than controls ($15,771 vs $1,606), with higher annual cost due to disability ($4,923 vs $662) and HRU-related work loss ($10,847 vs $944; all P < 0.01).

CONCLUSIONS: Despite improvements in prognosis and survival of HER2+ mBC patients, time lost from work is high among HER2+ mBC patients and it is associated with substantial economic burden from a U.S. employers' perspective. The results underscore the unmet need for reducing workplace productivity loss for working HER2+ mBC patients.

SPONSORSHIP: Daiichi-Sankyo and AstraZeneca Pharmaceuticals.

C28 What attributes influence payer preferences for adjuvant endocrine and CDK4/6 treatments in early stage breast cancer?

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BACKGROUND: Selective cyclin-dependent kinase inhibitors (CDK4/6i) are being evaluated in combination with endocrine therapy (ET) for improving invasive disease-free survival (iDFS) in hormone receptor (HR)+/human epidermal growth factor receptor 2 (HER2)-early stage breast cancer.

OBJECTIVE: To investigate how attributes associated with ET mono- therapy and CDK4/6i + ET regimens may influence treatment access decisions among payers in the United States (U.S.).

METHODS: Payers completed an online survey, incorporating three discrete choice experiments (DCEs). The first DCE included a series of tasks asking which of two hypothetical treatment profiles would be preferred for providing favorable access. The profiles varied in seven attributes associated with ET monotherapy and CDK4/6i + ET regimens: iDFS, risks of neutropenia, alopecia, and gastrointestinal symptoms, electrocardiogram (ECG) monitoring, dosing schedule, and annual per patient treatment cost. The latter two DCEs involved selecting between two profiles varying in CDK4/6i + ET attributes versus an ET monotherapy opt-out option (either tamoxifen or aromatase inhibitor). Hierarchical Bayes models estimated attribute-level preference weights, which were used to compute conditional relative importance.

RESULTS: Payers (n = 60) rated annual per patient cost, followed by iDFS, highest in relative importance for treatment access (accounting for 35% and 31% of the variation in preferences, respectively). These attributes were approximately 2 times more important than the next most important attribute (neutropenia risk: 16%). Dosing schedule (5%), alopecia risk (4%), and ECG monitoring (3%) were perceived as least important. An average of 55% of payers were willing to provide favorable access to a CDK4/6i + ET regimen over ET monotherapy.

CONCLUSIONS: While cost was a primary driver of treatment access decision-making among U.S. payers, the majority of respondents were willing to accept higher costs and additional safety considerations in exchange for the potential efficacy benefits associated with CDK4/6i + ET regimens in early stage breast cancer.

SPONSORSHIP: Pfizer.

C31 Budget impact analysis of niraparib for first-line maintenance therapy in advanced ovarian cancer from a U.S. payer perspective

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BACKGROUND: The U.S. Food and Drug Administration recently approved niraparib for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy (PBC).
OBJECTIVE: A budget impact model (BIM) was developed to evaluate the economic impact of this expanded indication. The model considers the impact to U.S. payers of adding niraparib as first-line maintenance therapy over a 3-year time horizon from two perspectives: a commercial health plan and Medicare plan, both with 1 million members.

METHODS: The eligible population was calculated based on the age-specific incidence rate of ovarian cancer (OC) and 70% of incident patients in advanced stage who were eligible for PBC with a response rate of 75%. The model included costs of maintenance treatment, subsequent therapy, diagnostic testing, and management of adverse events grade ≥3 that occurred in ≥5% of patients. Alternative options included olaparib, bevacizumab, and active surveillance. Niraparib market share was assumed to be 5%, 10%, and 15% in years 1, 2, and 3, respectively.

RESULTS: In a hypothetical commercial health plan of 1 million adults, 2 patients were expected to be treated with niraparib in year 1, 7 patients in year 2, and 13 patients in year 3. The base case indicated an annual budget impact of $87,920 in year 1, $93,106 in year 2, and $87,037 in year 3. The model estimated an average per patient with treatment with niraparib per month (PPTPM) cost of $1,017 and an average per member per month (PMPM) cost of $0.007 over the 3 years. In a hypothetical Medicare plan of 1 million adults, 5 patients were expected to be treated with niraparib in year 1, 16 patients in year 2, and 30 patients in year 3. The model estimated an annual budget impact of $206,785 in year 1, $219,017 in year 2, and $204,739 in year 3. The average PPTPM was $1017 and the average PMPM was $0.018 over the 3 years.

CONCLUSIONS: One-way sensitivity analysis for both plans indicated the average budget impact over 3 years was mainly influenced by treatment duration of niraparib, market share of niraparib, overall survival (OS) of niraparib-treated patients, treatment duration of bevacizumab, and OS of olaparib-treated patients. In conclusion, the BIM suggests that introduction of niraparib as first-line maintenance therapy in the U.S. over a 3-year time horizon may result in a PMPM cost of $0.007 to $0.018.

SPONSORSHIP: GlaxoSmithKline.

C32 Cost of HRD biomarker-guided therapy in advanced ovarian cancer
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BACKGROUND: PARP inhibitors (PARPi) have changed treatment paradigms for advanced ovarian cancer (OC) patients. Olaparib is approved as a first line maintenance treatment (1L mtx) as monotherapy for patients with BRCA mutated (BRCAm) OC and in combination with bevacizumab (Bev) for patients with homologous recombination deficient (HRD) OC. Niraparib monotherapy is approved as 1L mtx irrespective of biomarker status.

OBJECTIVE: Given the limited understanding of the cost of HRD biomarker guided (BMG) vs. non-biomarker guided (NBMG) therapy for 1L mtx OC, this analysis aims to understand the cost implications of using HRD BMG compared to NBMG therapy.

METHODS: The model simulates HRD testing and drug costs over 12 months for a cohort of 100 newly diagnosed patients with stage 3/4 OC for BMG and NBMG, independently. Treatment costs include PARPi ($14,673/month), Bev ($10,479/month) and PARPi+Bev ($25,152/month). The BMG group assumes all 100 patients receive HRD test ($4,040 per test), and a HRD test positive (HRD+) rate of 47% (20% BRCAm, 27% non-BRCAm). Germline BRCAm testing is not included. An estimated 65% of patients are eligible for a PARPi (82% receiving and of those 80% responding to platinum chemo). In the BMG PARPi eligible group, all HRD+ patients receive PARPi+Bev and 30% of HRD test negative patients receive Bev (70% receive no mtx). The NBMG PARPi eligible group has no HRD testing costs and all patients receive a PARPi.

RESULTS: Per 100 patient cohort, 65 patients in the NBMG and 41 in the BMG group receive 1L mtx resulting in an additional $523,440 annual cost ($43,620/month) for NBMG therapy. Sensitivity analyses also resulted in higher costs for the NBMG group, including limiting biomarker testing to PARPi eligible patients ($664,032) and assuming a 20% lower cost for Bev biosimilar ($1.5m). If 50% of the BMG HRD+ patients receive PARPi monotherapy and the other 50% receive PARPi+Bev, NBMG is $2.45m more, requiring PARPi use of 25% or lower (remaining receive Bev) for NBMG to be less than BMG therapy. Assuming 50% PARPi monotherapy/50% PARPi+Bev for the BMG HRD+ group and 100% Bev use for the BMG HRD test negative group (all 65 patients receive a therapy in BMG and NBMG groups), BMG therapy is $591,586 ($49,298/month) more costly than NBMG therapy.

CONCLUSIONS: In spite of the additional cost associated with HRD testing, this model projects the monthly cost to be lower for BMG compared to NBMG therapy. Treatment decisions based on HRD test results enable the targeting of PARPi treatment to patients that benefit the most from therapy, while limiting drug costs.

SPONSORSHIP: AstraZeneca Pharmaceuticals.

C36 Major adverse cardiovascular events: number needed to treat analysis for the phase 3 randomized controlled trial (HERO) of relugolix versus current standard of care (leuprolide) in men with advanced prostate cancer
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BACKGROUND: In the U.S., an estimated 3 million men were living with prostate cancer (PC) in 2017. These patients have a high risk of cardiovascular (CV) events and are more likely to die from CV disease than from their cancer. Androgen deprivation therapy (ADT) with luteinizing hormone-releasing hormone (LHRH) agonists is the mainstay of advanced PC (aPC) care, however, it is associated with an increased risk for CV events and death. Relugolix, an oral once daily GnRH antagonist, demonstrated a 54% reduction in the risk of major adverse CV events (MACE) vs LHRH agonist leuprolide in HERO, a phase 3 randomized controlled trial in men (N=934) with advanced PC, comparing relugolix to leuprolide.

OBJECTIVE: To determine the number needed to treat (NNT) as a measure of the potential benefit of relugolix on MACE outcomes.
relative to leuprolide and correlation with onset and cumulative incidence of MACE in the HERO trial.

METHODS: MACE were defined as non-fatal myocardial infarction, non-fatal stroke, and death from any cause. The NNT to prevent 1 MACE with relugolix relative to leuprolide was calculated using the formula NNT = 1/absolute risk reduction (ARR), where ARR = control event rate (CER) minus experimental event rate (EER). The cumulative incidence of MACE in HERO was estimated after 48 weeks of treatment using the Kaplan-Meier (KM) method, with hazard ratio (HR) for relugolix vs leuprolide based on a Cox proportional hazards model.

RESULTS: The CER of MACE (leuprolide arm) was 6.2% (exact 95% confidence interval [CI] 3.8 to 9.5) and EER of MACE (relugolix arm) was 2.9% (exact 95% CI: 1.7 to 4.5). The calculated ARR was 3.3%. The calculated NNT to prevent 1 MACE at 48 weeks with relugolix vs leuprolide was 31. Cumulative incidence of MACE at end of week 48 was 5.6% (95% CI: 3.5% to 8.9%) with leuprolide vs 2.8% (95% CI: 1.8% to 4.5%) with relugolix (HR 0.46 [95% CI: 0.24 to 0.88]). KM curves showed an early separation in cumulative incidence of MACE (within 4 weeks of treatment) favoring relugolix that was maintained through 48 weeks of treatment.

CONCLUSIONS: NNT analysis using HERO trial data indicates that once-daily oral relugolix may prevent 1 MACE for every 31 patients treated vs leuprolide and, based on onset of MACE, may have an early impact. Given the prevalence of PC in the U.S., impact of LHRH agonists on CV events and cost of MACE, the NNT suggests that there may be substantial healthcare saving potential for relugolix in men with aPC.

SPONSORSHIP: Myovant Sciences.

C40 Healthcare resource utilization (HCRU) among first-line (1l) tyrosine kinase inhibitor (TKI) therapy for patients with metastatic renal cell carcinoma (mRCC)

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BACKGROUND: Approximately one-third of pts with RCC are diagnosed with mRCC. While TKIs and immune checkpoint inhibitors have improved outcomes for pts, there is limited real-world evidence as to their impact on HCRU.

OBJECTIVE: To describe the real-world HCRU and associated costs of commonly prescribed TKIs in 1L mRCC across a U.S. commercial and Medicare Advantage population.

METHODS: This retrospective study evaluated 3 treatment groups receiving 1L cabozantinib (C), pazopanib (P), or sunitinib (S) identified from the HealthCore Integrated Research Database between 04/2016 and 10/2019; index date was first outpatient prescription claim of C, P, or S. Adults diagnosed with mRCC with ≥6-month prior (baseline), ≥1-month post-index continuous enrollment, and no mRCC treatments over baseline were included. Claims-imputed ECOG score and metastatic site counts were reported during baseline, treatment-related complications, HCRU, and costs were reported during all available follow-up. All-cause HCRU included emergency room (ER) and hospitalization frequencies, hospital length of stay (LOS), and aggregate medical costs, reported as per-patient-per-month (PPPM) adjusted to 2019 U.S. price levels. No statistical testing between TKIs was performed.
RESULTS: Among 93 C, 233 P, and 139 S pts, mean age was 63, 64, and 62 years; 79%, 72%, and 71% were male; and mean (SD) follow-up was 323 (227), 463 (345), and 402 (312) days, respectively. At baseline, 27%, 29%, and 21% of pts had ECOG ≥2; 58%, 35%, and 36%, had ≥3 metastatic sites; and 44%, 37%, and 39% had bone metastasis, respectively. Mean (SD) treatment duration (max gap of 90 days) for C, P, and S was 192 (167), 206 (124), and 190 (218) days, respectively. Complications at follow-up for C, P, and S occurred in 63%, 58%, and 62% of pts, with related mean (SD) PPPM costs of $2,700 ($1,975), $3,684 ($744), and $4,485 ($11,753). All-cause hospital admissions occurred in 65%, 62%, and 58%; ER visits occurred in 51%, 48%, and 43%. All-cause mean (SD) hospital LOS was 7.3 (6.7) days, 6.5 (4.5) days, and 7.7 (7.5) days. In addition, mean (SD) all-cause medical costs PPPM were $10,558 ($11,196), $11,046 ($15,211), and $13,820 ($23,807) lor C, P, and S, respectively.

CONCLUSIONS: Herein we describe real world patterns of 1L use in mRCC of 3 commonly prescribed TKIs. Despite differences in baseline characteristics, which may reflect preferential use of C in pts with poorer prognosis features, complication rates, HCRU, and medical costs were similar for C, P, and S during follow-up.

SPONSORSHIP: Exelixis.
outpatient costs also declined from T1 to T2 (inpatient: MMCD = -$320, P = 0.007; other outpatient: MMCD = -$560, P = 0.013) and remained stable from T2 to T3 (inpatient: MMCD = $153, P = 0.153; other outpatient: MMCD = -$41, P = 0.126). CLL-specific outcomes were directionally consistent with all-cause outcomes.

**CONCLUSIONS:** For pts with CLL, given the higher frequency of pt monitoring typically conducted early in the course of therapy, significant decreases in HRU and corresponding costs were observed after the initial 6 months of 1L ibrit treatment and were stable thereafter. These findings suggest that HRU burden and related costs reduce/stabilize with persistent use of ibrit for CLL.

**SPONSORSHIP:** Pharmacyclics, an AbbVie Company.

**C47 Treatment patterns, healthcare resource utilization, and cost among relapsed/refractory classical Hodgkin’s lymphoma patients in the U.S.**

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**BACKGROUND:** Understanding current treatment patterns, patient characteristics, and healthcare resource utilization (HRU) and costs in relapsed/refractory (R/R) classical Hodgkin’s lymphoma (cHL) using real-world data may inform the place in therapy of newly approved agents.

**OBJECTIVE:** Evaluate treatment patterns, HRU and cost of R/R cHL patients in the real-world setting.

**METHODS:** Adult R/R cHL patients were identified within the Definitive Oncology Dataset based on community oncology practices in the U.S. between 2000 and 2019. Treatment patterns included all systemic anti-cancer therapies received from R/R cHL diagnosis (i.e., second-line [2L]) through the fourth R/R event (i.e., fifth-line [5L]). R/R HRU included monthly hospitalization rates, emergency department (ED) visits, and infused supportive care drugs. Monthly costs (inflated for 2020$) were based on matched Health Care Utilization Project coded events.

**RESULTS:** A total of 286 R/R cHL patients were included. Most patients were Caucasian (77.3%) with a median age of 35 years (range: 19-86) at the first R/R event. Median length of follow-up was 12 months. More than half of patients (54.9%) received autologous stem-cell transplant (SCT) and 6.6% received allogenic-SCT. Approximately 50.3% had a second R/R event, 33.2% had a third R/R event, and 20.3% had a fourth R/R event. Across the R/R setting, 56 different anti-cancer regimens (monotherapy or in combination) were used in 2L, 47 in third-line (3L), 38 in fourth-line (4L), and 27 in 5L. Patients treated with brentuximab vedotin increased from 2L to 5L (23.5% in 2L, 30.2% in 3L, 38.2% in 4L, 30.0% in 5L). Approximately 23.8% had their first R/R event on/after 2016 (post PD-1 therapy approval). During this time, the use of PD-1 therapy increased from 2L to 4L (0.9% in 2L, 6.9% in 3L, 15.8% in 4L, 12.5% in 5L). In the R/R setting, approximately 62.9% of patients had at least 1 hospitalization, 15.7% reported an ED visit, and 35.7% received infused supportive care treatment. Hospitalization costs were $8,223, ED visit costs were $295, and infused supportive care costs were $459.

**CONCLUSIONS:** There was substantial heterogeneity regarding the management of R/R cHL. Post-approval, the uptake of PD-1 therapy in the R/R setting appears suboptimal in the U.S. R/R cHL patients are susceptible to multiple events, as shown by the high proportion of patients with several disease progressions. These events require additional therapy resulting in higher HRU and cost, which highlights the significant unmet need in this population.

**SPONSORSHIP:** Merck & Co.

**C48 Cost of radiation-induced oral mucositis in head and neck cancer patients: an administrative claims analysis**

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**BACKGROUND:** The standard of care for head and neck cancers (HNC) is radiotherapy (RT). The majority of patients with HNC who are treated with RT develop oral mucositis (OM), which results in debilitating pain, often compromises a patient’s ability to eat or drink, and may require RT interruption and/or hospitalization, potentially compromising patient outcomes. Patients with HNC who develop OM frequently incur an increase in healthcare utilization that has yet to be quantified by nationally representative, real-world data.

**OBJECTIVE:** To evaluate and describe the additional cost associated with the management of OM among a prevalent cohort of patients with HNC from commercial insurance claims data over 6- and 12-month periods following RT initiation.

**METHODS:** A retrospective analysis of commercially insured patients with HNC was performed utilizing the Truven Health Analytics IBM MarketScan database from January 1, 2014, to December 31, 2017. HNC patients who received RT were defined as those who had ≥ 1 administrative healthcare claim that contained both an HNC diagnosis code and an RT healthcare common procedure coding system code. The date of RT initiation defined the index date. Patients who met the selection criteria were stratified into OM and non-OM cohorts for analysis. The total cost associated with OM patients and non-OM patients was evaluated and compared at 6 months and 12 months following the index date.

**RESULTS:** The average total healthcare costs were substantially higher for patients with HNC within the OM cohort compared to the non-OM cohort with a cost difference of $32,480 over 6 months following the index date, and $33,411 over 12 months following the index date.

**CONCLUSIONS:** Overall healthcare costs are substantially higher among patients with HNC who receive RT and develop OM compared to those who do not develop OM at both 6- and 12-month timeframes from initiation of RT. Furthermore, based on the minimal cost difference between the 6- and 12-month periods, and the fact that most cases of OM are developed, treated, and resolved within 6 months of RT initiation, data support that OM in HNC patients drives substantial cost increases for commercial insurance providers predominantly in the first 6 months of treatment.

**SPONSORSHIP:** Galera Therapeutics.
Tisagenlecleucel (tisa-cel) is an effective cell therapy for the treatment of relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL), with a complete response (CR) rate of 38% and an overall response (OR) rate of 52% in the pivotal JULIET trial. The median overall survival (OS) was 11.1 months in tisa-cel treated patients, but was not reached for patients with OR or CR.

**OBJECTIVE:** To conduct a cost-effectiveness analysis (CEA) of tisa-cel vs. salvage chemotherapy (SC) for the treatment of r/r DLBCL and to estimate the cost-effective price range of tisa-cel based on the CEA model using a willingness to pay (WTP) threshold of $150,000 per quality-adjusted life-year (QALY) gained from a U.S. third-party payer perspective.

**METHODS:** A responder-based partitioned survival model with a lifetime horizon and 3% annual discount rate was developed. Health states included progression-free survival (PFS), progressive disease, and death. OS and PFS of tisa-cel were estimated separately for patients with and without OR from JULIET (median follow-up: 33 months). OS of SC was from SCHOLAR-1. Mixture cure models were used to inform the OS of tisa-cel OR or CR responders, supported by the JULIET data indicating no progression or death among responders since month 22 of treatment. For tisa-cel non-responders and SC, survival was predicted using standard parametric models until month 60 and afterwards the survival of DLBCL long-term survivors was used. Costs (2020 USD) and utilities were from literature. QALY gains, total costs, and incremental cost per QALY gained were estimated. In addition, a cost-effective price range was estimated based on all tisa-cel treated patients, OR responders, and CR responders. Deterministic sensitivity analyses (DSAs) were performed.

**RESULTS:** Over a lifetime horizon, tisa-cel was associated with 3.35 QALYs gained vs. SC, and the estimated incremental costs per QALY gained was $79,000 using the WAC price of $373,000. The cost-effective price of tisa-cel in all treated patients was $610,548 at the WTP of $150,000. Tisa-cel OR and CR responders had an increase in QALYs vs. SC, with cost-effective prices estimated at $1,279,734 and $1,550,166, respectively. DSA results supported the WTP of $150,000. Tisa-cel OR and CR responders had an increase in QALY gains vs. SC was $79,000 using the WAC price of $373,000. The estimated incremental costs per QALY gained was $79,000 using the WAC price of $373,000. The estimated cost-effective price range of tisa-cel based on the CEA model using a willingness to pay (WTP) threshold of $150,000 per quality-adjusted life-year (QALY) gained from a U.S. third-party payer perspective.

**CONCLUSIONS:** Tisa-cel is a cost-effective treatment vs. SC for r/r DLBCL. The estimated cost-effective prices ranged from $610,548 for all tisa-cel treated patients to up to 1.5 million USD for patients with CR.

**SPONSORSHIP:** Novartis.
thrombosis for ruxolitinib patients. An updated analysis of FDA’s Adverse Event Reporting System (FAERS) data should be considered to examine the strengths of this potential safety signal.

**OBJECTIVE:** Conduct a comprehensive analysis of the FAERS database to assess post-marketing reporting rates for TEs in patients treated with Jakis.

**METHODS:** FAERS data 1/1/2010-9/30/2019 were searched for reports on all FDA-approved Jakis across all indications, ruxolitinib, tofacitinib, tofacitinib extended-release (XR), upadacitinib, fedratinib, and baricitinib. Consistent with Verden and colleagues, adverse drug reactions (ADRs) of interest included pulmonary thrombosis, pulmonary embolism, portal vein thrombosis, deep vein thrombosis, thrombosis, and venous thrombosis. For each drug-ADR pair, with the drug listed as ‘primary suspect,’ Reporting Odds Ratio (ROR) [two-sided 95% confidence interval] and Empirical Bayesian Geometric Mean (EBGM) [one-sided 95% lower bound] were calculated to detect drug-ADR pairs with higher-than-expected reporting rates within FAERS. Significance was declared when both lower bounds were >1.

**RESULTS:** Increased risk for pulmonary thrombosis was significantly evident with tofacitinib (ROR = 2.36 [1.69-3.31]; EBGM = 2.01 [1.53]) and pulmonary embolism with baricitinib (ROR = 12.23 [8.35-17.89]; EBGM = 7.72 [3.82]). Portal vein thrombosis was significantly elevated with ruxolitinib (ROR = 4.16 [2.70-6.40]; EBGM = 4.52 [3.11]). Deep vein thrombosis reports were increased with baricitinib (ROR = 14.84 [9.64-22.84]; EBGM = 9.49 [5.91]) as was risk for thrombosis with ruxolitinib (ROR = 1.40 [1.20-1.63]; EBGM = 1.72 [1.52]). Relationship between the time of treatment initiation and event occurrence indicated that time to event occurred randomly.

**CONCLUSIONS:** The current study found a significant increased risk for TE events in autoimmune disorder patients treated with Jakis across all indications, providing additional evidence to support the results reported by Verden and colleagues.

**Sponsorship:** Arena Pharmaceuticals.

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**D3 The incremental rate of thromboembolic events in patients with immune-mediated diseases compared to patients without immune-mediated diseases**

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**BACKGROUND:** Immune-mediated diseases (IMDs) have been linked to an increased risk of thromboembolic events (TEs). However, since the introduction of novel agents to treat IMDs, this risk has not been systematically quantified. This study assessed the incremental risk of TEs in patients with any of 8 IMDs (i.e., ankylosing spondylitis, atopic dermatitis, inflammatory bowel disease, multiple sclerosis, psoriasis, psoriatic arthritis, rheumatoid arthritis, and systemic lupus erythematosus) versus patients without IMDs.

**OBJECTIVE:** This study aimed to quantify the incremental risk of TEs (deep vein thrombosis [DVT], pulmonary embolism [PE], myocardial infarction [MI], and ischemic stroke [IS]) in patients with IMDs versus patients without IMDs.

**METHODS:** Adult patients with ≥2 diagnoses of IMD were identified using the IBM MarketScan Commercial and Medicare-Supplemental Claims database (2014-2018). IMD patients were matched 1:1 on age, sex, and index year to a control cohort of patients without IMDs. The index date was the day after a randomly selected IMD medical claim for patients with IMDs, and the day after a randomly selected medical claim for patients without IMDs. The baseline period was the 1-year period prior to index, and the study period was the period following index until end of continuous follow-up (up to 4 years). Unadjusted and adjusted incidence rate ratios (IRR) from generalized estimating equations were used to compare cohorts. The adjusted IRRs controlled for age, sex, comorbidities, medications excluding those for IMD treatment, and baseline TEs of interest.

**RESULTS:** This study included 182,431 matched pairs (mean age 51.3 years, 64.3% female). Rheumatoid arthritis (25.9%), psoriasis (24.9%), and inflammatory bowel disease (19.0%) were the most common IMDs. Unadjusted rates of any TEs were 0.173 and 0.096 per person-year during the study period for patients with and without IMDs, respectively. In multivariable regression, patients with IMDs had 1.49 times the rate of any TE compared to patients without IMDs (P < 0.001). Similar results were observed across individual venous and arterial TEs (adjusted IRRs: 1.78 for DVT, 1.66 for PE, 1.17 for MI, 1.35 for IS; P < 0.05 for all).

**CONCLUSIONS:** Patients with IMDs had statistically significantly increased risks of all types of TEs relative to patients without IMDs. This inherent elevated risk in IMD patients should be carefully considered in the selection of the most appropriate therapies to minimize the incremental TE risk and optimize overall patient outcomes.

**Sponsorship:** Arena Pharmaceuticals.

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**D5 Beyond pain: symptom burden of adolescents and adults with sickle cell disease**

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**BACKGROUND:** Sickle cell disease (SCD) is an inherited hemoglobinopathy that causes hemolytic anemia, painful vaso-occlusive crises (VOCs), organ damage, disability, and accelerated mortality. VOCs have traditionally been used as SCD clinical trial endpoints; however, they are not comprehensive—they miss the burden of daily SCD symptoms that patients find detrimental.

**OBJECTIVE:** To summarize symptoms experienced by adolescent and adult SCD patients for a comprehensive measure of SCD symptom burden.

**METHODS:** In preparation for open-ended interviews with U.S. and UK SCD patients, our literature review identified quantitatively assessed symptoms in SCD. Interviews with SCD experts revealed a range of symptoms, patient descriptions, and coping techniques. These insights were used to develop a patient discussion guide to elicit detailed descriptions of the frequency, intensity, duration, and variability of symptoms. Spontaneously generated symptom concepts were coded and analyzed using Atlas.ti software.
RESULTS: Fifty-six adult and 10 adolescent patients were interviewed in 4 groups. Most patients were female (64%), and the mean age was 33 years. Saturation was reached after interviewing 2 groups. Twenty-five symptom concepts were mentioned. The most common concepts in adults were “tiredness” (73%), non-VOC pain (“sharp” [64%], “throbbing” [59%], “aching” [55%], “stabbing” [39%], “hammering, pounding” [32%]), “can’t focus” (50%), “trouble breathing” (50%), “weakness” (48%), “fatigue” (43%), and “no energy, exhausted” (30%). Adolescents raised similar concepts, except they used “no energy, exhausted” (70%), “restless” (20%), and “feel like a step behind” (30%) to describe fatigue-related symptoms. Other symptoms reported include “depression” (n = 28), “feeling physically weak” (n = 26), “sleeping poorly” (n = 22), “difficulty concentrating” (n = 22), “joint stiffness” (n = 18), “jaundice” (n = 2), “dehydration” (n = 2), “headaches” (n = 2), “losing concentration” (n = 2), “dry throat from coughing” (n = 1), and “feeling irritable” (n = 1), highlighting the complex pathophysiology of SCD. Additional interviews evaluated the content of the items generated and agreed the findings were a valid representation of the patient experience.

CONCLUSIONS: This study identified an extensive range and burden of salient daily SCD symptoms that are not usually counted as VOCs. This burden should be measured so that it can be considered by payers and policy makers.

SPONSORSHIP: Global Blood Therapeutics.

D9 Changes in healthcare resource use and costs after emicizumab initiation for hemophilia A: a secondary claims database analysis

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BACKGROUND: Emicizumab is indicated for prophylaxis in persons with hemophilia A (PwHA) to reduce or prevent bleeds.

OBJECTIVE: This study evaluates changes in healthcare resource use (HCRU) and costs in PwHA after initiating emicizumab prophylaxis.

METHODS: This study used de-duplicated commercial claims data from IBM MarketScan Commercial Research (11/2016-6/2019) and IQVIA PharMetrics Plus (11/2016-9/2019) claims databases. Individuals with evidence of emicizumab use and continuous enrollment for at least 6 months pre- and 1 month post-emicizumab initiation were included in the study and followed until end of study period or continuous enrollment. Patient demographics and clinical characteristics (major bleeds, arthropathy, pain, and comorbidities) were assessed in the pre-index period; major bleeds were defined using an algorithm by Shrestha et al. (2017). Mean annualized HCRU and costs were compared in the pre- and post-period using paired t-tests and Wilcoxon signed-rank tests.

RESULTS: A total of 163 unique individuals who met the inclusion criteria were identified. All patients were male (100%), average age was 23 years (standard deviation [SD] ± 17; range = 1-64), with a mean Charlson Comorbidity Index (CCI) of 0.6 (SD ± 1.5); median follow-up post-index was 5 months (interquartile range = 3-8, range = 1-20). In the pre-index period, 15% (n = 25) had evidence of major bleeds, with an average of 3.2 bleeds (SD ± 1.7, range = 2-8), 28% (n = 46) had evidence of arthropathy or related disorders, and 22% (n = 36) had any pain diagnosis. After emicizumab initiation, there were fewer annualized inpatient stays (0.14 vs. 0.04, P = 0.07) and significantly shorter lengths of inpatient stays (0.98 vs. 0.46 days, P = 0.049) compared to the pre-index period; individuals also experienced significantly fewer outpatient hospital visits (5.49 vs. 3.89, P = 0.005) and physician office visits (9.08 vs. 5.67, P < 0.001), while fewer emergency room visits were observed (0.65 vs. 0.49, P = 0.10). Compared to the pre-index period, the annualized total cost of care was lower in the post-index period, but the difference was not statistically significant ($585,400 ± 1,033,065 vs. $557,815 ± 443,389, P = 0.74).

CONCLUSIONS: Shortly after initiation of emicizumab prophylaxis, individuals experienced reductions in various HCRU categories, without an increase in total costs of care. This is one of the first studies to evaluate HCRU and costs after initiating emicizumab prophylaxis based on early outcomes data. Longer follow-up data will help further examine these real-world outcomes.

SPONSORSHIP: Genentech.

D13 Budget impact analysis of transitioning from reference to biosimilar etanercept from a United States payer perspective

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BACKGROUND: Etanercept biosimilars are FDA-approved for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), ankylosing spondylitis (AS), psoriatic arthritis (PsA), and plaque psoriasis (PsO).

OBJECTIVE: Since biosimilars have the potential to decrease health-care costs, the objective of this study is to describe the potential financial impact of implementing a formulary change from reference to biosimilar etanercept under various utilization scenarios in a U.S. health plan.

METHODS: We evaluated the budget impact of transitioning to biosimilar etanercept for the treatment of RA, JIA, AS, PsA, and PsO from a U.S. payer perspective over a three-year time horizon. The target population was estimated from a hypothetical health plan of 1 million members with variables including population growth, incidence/prevalence rates, and etanercept treatment patterns identified from literature. For the cost of biosimilar etanercept, a base case discount from reference etanercept’s wholesale acquisition cost was estimated from the U.S. biosimilar market experience; Average Sales Price data from the Centers for Medicare and Medicaid Services for other available biosimilars were used as the basis for this assumption. Two biosimilar transitioning scenarios were evaluated. Scenario 1 assumed a 5% baseline and 5% monthly increase in biosimilar uptake, reaching 60% by the end of year 1. Scenario 2 assumed a 5% baseline and 7% monthly increase in biosimilar uptake, reaching 82% by the end of year 1. Total, per switched patient per year, and per switched patient per month cost savings were calculated.

RESULTS: For this hypothetical health plan population of 1 million, 1,786 patients were estimated to be treated with etanercept for all approved indications in year 1, which increased to 1,895 by year 3. For scenario 1, the total cost savings associated with transitioning to
E00-E90 Endocrine, Nutritional, and Metabolic Diseases (e.g., Growth Hormone, Diabetes, Lipids)

Smart insulin pens improve time below range in multiple daily insulin therapy

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BACKGROUND: Less than 30% of persons on insulin therapy in the U.S. achieve A1C glycemic target of <7%. While continuous subcutaneous insulin infusion (CSII) devices provide the guidance supporting insulin management, only 7.7% of those on insulin therapy use CSII due to cost, complexity, and inconvenience. The challenge of current American Diabetes Association (ADA) clinical targets is for patients to increase time in range (TIR) without inducing more than 4% TBR. Smart Insulin Pens (SIP) support patients on multiple daily insulin therapy (MDI) with intelligent algorithms determining optimal bolus insulin doses while accounting for active insulin and blood glucose values to help avoid dangerous hypoglycemia.

OBJECTIVE: To describe the real-world clinical effect of SIP use on key short-term glycemic metrics in individuals with both Type 1 and Type 2 diabetes on MDI therapy.

METHODS: Continuous glucose monitor (CGM) data was used to compare mean TBR among patients in the 60 days pre- and post-initiation of SIP. The sample's population evaluated CGM data for active InPen users with at least 30 days of CGM values in the 60 days pre- and post-established InPen use. CGM data from the first 30 days of SIP use were excluded to account for onboarding. Subset analysis was performed to describe glycemic control outcomes for users with >4% TBR prior to SIP use. Glycemic metrics were compared using paired t-tests with a significance level of 0.05.

RESULTS: An analysis of 482 patients demonstrated a significant reduction in TBR when compared pre- and post-SIP use. The sample parameter estimate of mean TBR falls well below clinical standards while still maintaining an average TIR of >60% pre- and post- SIP use. Further, 18% of patients (n = 88) had an average TBR of >4% prior to SIP use, which was significantly decreased by a mean of 2% in the 60-days post SIP initiation (P < 0.0001). These users experienced a clinically significant decrease in TBR without a significant decrease in TIR (69.6% vs. 69.2%).

CONCLUSIONS: Real-world data from a sample of 482 patients in the U.S. were able to maintain ADA consensus recommendations and demonstrated significant reductions in TBR while using InPen, when compared to their glycemic control using previous insulin delivery methods. Patients at highest risk for severe hypoglycemia may significantly reduce their TBR without compromising their overall glycemic control and without the cost and daily burden of CSII therapy.

SPONSORSHIP: Companion Medical.

E6 Impact of short-acting insulin non-medical switching and utilization among commercially insured members with diabetes

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BACKGROUND: The average price of insulin has increased approximately 200 percent since 2002. This dramatic increase prompted health plans and pharmacy benefit managers to leverage formulary and utilization management strategies to control pharmacy spending. In January 2018, Blue Cross Blue Shield of Michigan (BCBSM) implemented exclusive coverage of short-acting insulins, Novolog and Novolin. Members treated with Humalog/Humulin insulin were required to switch to Novolog/Novolin. Although exclusive coverage of Novolog/Novolin was intended to reduce pharmacy spending by shifting members toward preferred insulins, non-medical switching may have contributed to the discontinuation of short-acting insulin therapy.

OBJECTIVE: To evaluate the impact of exclusive coverage of select insulin products on the utilization of short-acting insulin.

METHODS: This was a retrospective cohort study using pharmacy claims data among 2.4 million commercially insured members with a rejected claim for Humalog/Humulin from September 2017 through December 2019. Members were continuously enrolled in the plan for at least 6 months prior to the index date and divided into three cohorts: 1) received Humalog/Humulin after prior authorization approval for medical necessity; 2) switched to Novolog/Novolin (rejected claim for Humalog/Humulin with a subsequent paid claim within 6 months post index); and 3) abandoned short-acting insulin treatment (rejected claim for Humalog/Humulin with no subsequent paid claim for Novolog/Novolin within 6 months post index). The primary endpoint was to examine the rates of short-acting insulin treatment abandonment and non-medical switching after implementing exclusive coverage of Novolog/Novolin.

RESULTS: Of the 3,034 members who met inclusion criteria, the mean (SD) age was 50 (13.7) years and 1,743 (57.4%) were male. The rate of insulin non-medical switching was 91.3% (2,770 of 3,034). The abandonment rate was 4.8% (146 of 3,034). A total of 3.9% (118 of 3,034) members remained on Humalog/Humulin with approved prior authorization for medical necessity.

CONCLUSIONS: Implementing exclusive coverage of select insulin products resulted in decreased utilization of non-formulary insulin products without a large incidence of short-acting insulin treatment abandonment. Future work will examine the association of these outcomes with total plan paid costs.

SPONSORSHIP: None.
E7 Predictive versus retrospective analytics: identification of patients who are non-adherent to medication

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BACKGROUND: Medication adherence is critical to the control of chronic conditions. Non-adherence can lead to adverse medical outcomes and increased healthcare spend. Predictive analytics can provide insight into patient behavior by trending medication adherence over time, thereby creating opportunity for earlier intervention relative to retrospective identification.

OBJECTIVE: To compare predictive identification to retrospective identification of patients who were non-adherent to their diabetic medication to assess the added value of using predictive methods over retrospective methods.

METHODS: A sample of 1,009 Medicare members, who were 62% female, had a mean age of 64, had a mean of 5.7 chronic conditions, and were non-adherent to their diabetic medication in 2019 were analyzed. The observed cumulative monthly percent of days covered (PDC) was calculated for January 2019 through June 2019, and year non-adherence was calculated. Predicted cumulative monthly PDC for January through June and predicted year-end PDC were estimated. Discrepancies of predicted PDC estimates and first month non-adherent (PDC < 80%) were assessed descriptively. Timing of predictive identification was compared to retrospective identification based on date of clinical outreach using a paired samples t-test.

RESULTS: Mean discrepancies between the observed and predicted PDC ranged from -10.99 to -3.96, with the largest discrepancy observed in January and the smallest discrepancy observed in June. Negative values indicate that the PDC estimates were larger than the observed values, and values closer to 0 indicate smaller discrepancies. Discrepancies between the observed first month non-adherent and the predicted first month non-adherent ranged from -0.31 to 0.63 months. Values closer to 0 indicate smaller discrepancies. Predictive identification identified non-adherent patients 4.4 to 3.4 months early, with the largest value observed in January and the smallest discrepancy observed in June. Retrospective identification identified patients between 4.4 and 1.8 months early. There was no difference between identification methods in January. Predictive identification identified non-adherent patients significantly earlier in February (t [71] = 3.9, P < 0.001), March (t [92] = 3.4, P < 0.001), April (t [122] = 6.9, P < 0.001), May (t [168] = 10.9, P < 0.001), and June (t [199] = 11.5, P < 0.001).

CONCLUSIONS: Predictive analytics can be applied to patients to assess likelihood of medication non-adherence for chronic conditions. Predictive identification provides added value over retrospective identification of at-risk patients through earlier identification.

SPONSORSHIP: Sanofi.

E8 Reduction in healthcare resource utilization and associated costs in insulin-naïve patients with type 2 diabetes initiated on insulin glargine 300 units/mL

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BACKGROUND: The 2nd generation basal insulin analog (BI) insulin glargine 300 units/mL (Gla-300) has shown to improve glycemic control with less hypoglycemia vs 1st generation BIs such as Gla-100.

OBJECTIVE: Based on the previously reported DELIVER NAÏVE study, this study examines healthcare resource use and estimated costs after initiation of these insulins in insulin-naïve adult patients with type 2 diabetes mellitus (T2DM).

METHODS: This retrospective cohort study compared real-world clinical and HCRU data utilizing electronic medical records (EMR) from the IBM Explorys database 6 months before (baseline) and 6 months after (follow-up) the switch date (index date, March 1, 2015 to December 31, 2016) with patients matched 1:2 on a propensity score based on baseline demographics and clinical characteristics. Analyses examined glycemic control, hypoglycemic events, number of all-cause, diabetes-related, and hypoglycemia-related inpatient, emergency department, as well as outpatient (endocrinologist) visits and inpatient lengths of stay. Cost of health care was estimated by applying cost per event (unit cost) to adjusted mean health care events/PPPY using published sources (e.g. Agency for Healthcare Research and Quality [AHRQ] Healthcare Cost and Utilization Project, Medicare Physician Fee Schedule) and adjusted to 2016 U.S. dollars using the medical-care component of the Consumer Price Index.

RESULTS: Gla-300 and Gla-100 matched cohorts comprised 1,004 and 2,008 patients. AIC reduction was significantly better in Gla-300 compared to Gla-100 (1.52% for Gla-300 vs. 1.29% for Gla-100; P = 0.003). Patients initiating Gla-300 experienced lower diabetes-related and hypoglycemia-related events across all event types, with significant reductions in ED-related events and endocrinologist visits. Average estimated costs were $1,689 vs $2,466 (diabetes-related), and $538 vs $1,062 (hypoglycemia-related) per patient per year (PPPY), in favor of Gla-300, representing potential annual savings of $777, or $524. All-cause resource-use generally showed the same trends and result in an estimated average saving of $790.

CONCLUSIONS: In insulin-naïve adults with T2D, initiation of Gla-300 was associated with significantly greater HbA1c reductions, trends for less hypoglycemia and lower resource-use and associated costs compared to Gla-100, similar to findings from the DELIVER 2 study in the non-insulin naïve population.

SPONSORSHIP: Eli Lilly and Company; RTI Health Solutions; Eli Lilly Canada.
from 1/1/2014-9/30/2018. For the first qualifying 24-month enrollment period, months 1-12 designated the baseline period and months 13-24 designated the follow-up period. Patients were required to have evidence of T2DM, an additional CV risk factor (e.g., hypertension), and no evidence of diagnosed cardiovascular disease (CVD) during baseline. The percent of patients with a subsequent CVD diagnosis in the follow-up period and annual all-cause, T2DM-, and CV-related HCRU and costs in the baseline and follow-up periods were reported.

RESULTS: In total 812,144 patients met the inclusion criteria. The most common CV risk factors in the baseline period were prescribed pharmaceuticals (e.g., antihyperlipidemics; 61.7%) and diagnoses of hyperlipidemia (27.6%) or hypertension (21.8%). In the follow-up period, 10.6% of patients had evidence of CVD (i.e., emergent CVD), with peripheral artery disease (34.1%) and coronary artery disease (28.8%) the most common diagnoses. In the baseline period, all patients had mean (SD) all-cause, T2DM-related, and CV-related costs of $13,207 ($27,057), $5,226 ($12,268), and $2,754 ($10,586). In the follow-up period, patients with emergent CVD had mean (SD) all-cause, T2DM-related, and CV-related costs that were substantially higher than costs among patients without CVD (all-cause: $39,365 [$67,731] versus $13,401 [$27,530]; T2DM-related: $18,520 [$37,256] versus $5,732 [$12,540]; CV-related: $18,893 [$43,584] versus $2,650 [$10,501], respectively). In the follow-up period patients with emergent CVD were over 6 times more likely to have an inpatient admission (relative risk [RR]: 6.1) and twice as likely to have an ED visit (RR: 2.0) compared to patients without CVD.

CONCLUSIONS: In a given year, approximately 10% of patients with CV risk are diagnosed with emergent CVD and these patients had 6- and 2-fold higher rates of inpatient and ED visits, respectively, compared to patients without CVD. Correspondingly, patients with emergent CVD had substantially higher all-cause (3-fold higher), T2DM (3-fold higher), and CV-related costs (7-fold higher) compared with patients without CVD.

SPONSORSHIP: Eli Lilly and Company.

E10 Cost-effectiveness analysis of amputation risk and cardiovascular benefits with canagliflozin in patients with type II diabetes
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BACKGROUND: Canagliflozin (Invokana), a sodium-glucose cotransporter-2 inhibitor (SGLT2-I) for type 2 diabetes mellitus (T2DM), has the additional benefit of cardiovascular risk reduction. However, two sister clinical trials in 2017 demonstrated a significant increased risk of amputations with the addition of canagliflozin to background therapy (BT) versus background therapy alone. BT included sulfonylureas, metformin, glucagon-like peptide-1 (GLP-1) agonists, dipeptidyl peptidase-4 (DPP-4) inhibitors, or insulin.

OBJECTIVE: A cost-effectiveness analysis was conducted comparing canagliflozin and BT versus BT alone, weighing its risk of amputation against its net clinical cardiovascular benefits.

METHODS: A six-state Markov model was developed using a payer's perspective and an 84-month time horizon. Transition probabilities were calculated from Kaplan-Meyer progression curves reported in the Canagliflozin Cardiovascular Assessment Study Program (CANVAS). Costs were obtained from published national sources and adjusted to 2020 U.S. dollars using the Consumer Price Index (CPI). Health state and adverse event utilities were weighted based on incidence and duration of events. The incremental cost effectiveness ratio (ICER) was calculated using quality-adjusted life years (QALYs) and a willingness to pay (WTP) of $100,000. Base case and one-way sensitivity analyses were conducted. Probabilistic sensitivity analyses determine an acceptability curve and the minimal level of CV benefit required to offset different amputation risks.

RESULTS: Patients on canagliflozin with BT had a cost of $81,022 and effectiveness of 5.04 QALYs while those on BT alone had a cost of $39,738 and an effectiveness of 5.01 QALYs. Canagliflozin had an incremental gain of 0.03 QALYs and incremental cost of $41,285 when compared to BT. This resulted in a base case ICER of $1,294,370/QALY for canagliflozin over BT. One-way sensitivity analysis showed that the model was not sensitive to the probability of amputation. Use of canagliflozin was not cost-effective compared to BT at canagliflozin’s base case probability of amputation (0.000525) or all other plausible ranges.

CONCLUSIONS: Results suggest canagliflozin with BT is not cost-effective compared to BT alone in high-risk cardiovascular patients with underlying T2DM at a WTP of $100,000. The high cost of canagliflozin and its complications were not found to offset the CV benefits, resulting in an ICER over standard WTP levels. Our model was not sensitive to the trade-offs in probability of amputation and CV risk with use of canagliflozin which was never cost-effective compared to BT.

SPONSORSHIP: None.

E11 Predicting future adherence to statins using previous adherence to antihypertensive drugs
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BACKGROUND: Statins are among the most widely prescribed medications in the United States. Despite well-established benefits, statin adherence rates are suboptimal. Several interventions have been implemented to improve adherence to statins. However, identifying patients who are at risk for developing poor medication adherence at the time of treatment initiation would assist in planning early targeted interventions. Studies have reported that previous adherence to chronic medications is a strong predictor of future adherence to newly initiated medications.

OBJECTIVE: This study aimed to predict patient’s adherence to newly initiated statins by measuring previous adherence to angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs).

METHODS: A retrospective cohort study was conducted using administrative claims data from January 2016 to May 2018. New statin initiators were identified and included in the study if they were continuously enrolled in the health plan and had a prescription of ACEIs/
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ARBS one year prior to statin initiation (baseline period). Patients were excluded from the study if they had any contraindication for ACEIs/ARBs use during the baseline period or for statins during the follow-up period. Baseline adherence to ACEIs/ARBs was calculated one year prior to statin initiation using proportion of days covered (PDC) and defined as PDC ≥ 0.80. Adherence to statins was assessed one-year post statin initiation and was the primary outcome with a PDC ≥ 0.80 considered as adherent. Patient demographics were measured during the baseline period. Multivariable logistic regression was conducted to determine an association between previous adherence to ACEIs/ARBs and future statin adherence controlling for various demographic and clinical characteristics.

RESULTS: A total of 1,223 statin users were identified, among which 41.62% were adherent to statins during the first year of treatment initiation. In the regression model, baseline adherence to ACEIs/ARBs (OR = 1.75; 95% CI: 1.37-2.25; P < 0.0001) and having low income subsidy (OR = 1.280; 95% CI: 1.009-1.624; P = 0.042) were significant predictors of one-year adherence to statins. Patients ≥ 80 years old were less likely to be adherent to statins (OR = 0.62; 95% CI: 0.41-0.92; P = 0.041).

CONCLUSIONS: Prior adherence to ACEIs/ARBs may predict future adherence to newly initiated statins. Identifying patients at a higher risk of statin non-adherence during treatment initiation could enable healthcare providers to intervene earlier and enhance future adherence.

SPONSORSHIP: None.

E17 A retrospective claims analysis of primary hyperoxaluria: clinical and economic outcomes

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BACKGROUND: Primary hyperoxaluria (PH, types 1, 2, and 3) is an ultra-rare, severe genetic disorder characterized by oxalate overproduction, with oxalate accumulation resulting in kidney damage and debilitating complications.

OBJECTIVE: This retrospective analysis of U.S. commercial claims data examined the clinical characteristics, healthcare resource utilization (HCRU), and costs of patients with PH.

METHODS: PH patients were identified from the IQVIA PharMetrics Plus Database (1/2014-12/2019) based on ≥ 1 claim with ICD-10 code E72.53 (PH) after 10/2018 and no evidence of secondary hyperoxaluria (SH). PH patients were matched 1:5 to non-PH, non-SH patients in a random 5% sample of the dataset based on age, sex, and payer. Matched cohorts were compared based on clinical characteristics and economic impact, including the Charlson Comorbidity Index (CCI), kidney stone occurrence, costs, and HCRU over a 12-month period. Costs were adjusted to 2019 dollars.

RESULTS: The matched PH (n = 324) and non-PH (n = 1620) cohorts showed significantly different CCI scores (0.79 vs. 0.35; P < 0.001). Annualized costs across age groups (median; mean [SD]) were significantly higher in the PH cohort ($11,017; $22,549 [$36,716]) compared to the non-PH cohort ($1,662; $8,436 [$31,893]; P < 0.001). Clinical characteristics of the PH cohort included more frequent manifestations of renal impairment relative to the non-PH cohort, including at least 1 kidney stone (80% vs 0%), 2 or more kidney stones (47% vs 0%), and any stage Chronic Kidney Disease (8% vs 2%) in the observation year (P < 0.001). On average, the PH cohort had 13 physician office visits versus 6 visits in the non-PH cohort (P < 0.001), and it was more common for PH patients to see specialists, including nephrologists (19% vs 2%, P < 0.001).

CONCLUSIONS: Diagnosed PH patients are associated with significant morbidity, significant HCRU, and about 7 times the median cost of care versus matched non-PH patients. This analysis demonstrates the high cost burden of this rare disease, but it may underestimate the true patient and cost burden of PH due to limitations of commercial claims analyses. Additional research is required to determine the specific contributions associated with PH types 1, 2, and 3 to overall cost of care and HCRU, to understand the cost burden and HCRU of PH in Medicare populations, and to address unmet clinical needs in the broader PH population that may favorably impact cost of care and HCRU.

SPONSORSHIP: Dicerna Pharmaceuticals.
RESULTS: In the budget impact analysis, for a hypothetical 1,000,000-member health plan, the base case analysis estimated that there would be 10 patients with hATTR receiving treatment. Assuming a 5% market share for inotersen in year 1, 6.7% in year 2, 8.6% in year 3, 10.8% in year 4, and 13.4% in year 5 results in a 5-year cumulative health plan savings of $52,696 or $0.001 PMPM. The wasted or discarded portion of patisiran was estimated to cost approximately $81,505 or 18% of the total drug cost per patient over one year. In the one-way sensitivity analysis, the budget impact is most influenced by the cost of patisiran (including wasted drug), cost of inotersen, and size of the patient population.

CONCLUSIONS: Inotersen may have a modest cost savings due to offsetting costs as the annual costs per patient of inotersen are slightly lower than those of patisiran.

SPONSORSHIP: Akcea Therapeutics.

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

F3 Real-world clinical treatment and patient outcomes in Parkinson’s disease psychosis: interim year 2 findings from the INSYTE observational study

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BACKGROUND: Parkinson’s disease (PD) prevalence in the United States (U.S.) is roughly 1 million persons and more than half will develop psychosis (PDP) over the course of their PD. As the population ages, the economic impact of PDP on society will remain large. Though treatment initiation is essential, PDP symptom recognition can be challenging. Real-world (RW) studies are needed to help inform healthcare decision makers related to diagnosing, treating and managing patients with PDP.

OBJECTIVE: To understand clinical, treatment and humanistic outcomes in patients with PDP from interim RW data.

METHODS: INSYTE is a prospective, non-interventional, observational study designed to collect RW data on PDP patients in the U.S. with first patient enrolled in February 2017. Enrollment has been completed with the last patient enrolled in August 2019; data for enrolled patients are being collected for up to 3 years. Data were extracted on October 9, 2019 to complete a 2nd interim analysis (IA#2) for patients with baseline (BL), follow-up 1 (FU1) and follow-up 2 (FU2) data. Descriptive data were assessed for patients with consistent treatment in four cohorts at BL&FU1 (representing 86.7% of all enrolled patients): No antipsychotics (No AP); Pimavanserin (PIM) only; Quetiapine (QUET) only; and PIM and QUET (PIM+QUET).

RESULTS: 337 patients were evaluated for this IA#2: No AP (n = 207, 61%), PIM (n = 76, 23%), QUET (n = 32, 9%), PIM+QUET (n = 22, 7%). To date, these patients were in the study for 422-435 days. There were ≥57% males, mean age was 73.8 yrs, 93% were of White race, 72% married/partnered, and 75% retired. Patients visited their provider approximately every 3-4 months. Over half of the patients in the IA#2 (with ≥2 FU visits at time of data cut) had no treatment from BL through their FU1 visit; nearly half of these patients remained untreated with an AP from BL through FU2. Patients in the No AP group were oldest (66 yrs) at PD diagnosis, oldest (73 yrs) at PDP diagnosis, had normal/slight cognitive impairment at BL, and were mild/moderate PD status at BL versus all other groups. The EQ-5D-VAS scores showed a modest improvement in overall health status for the PIM group (BL = 62.3, FU2 = 65.0) and PIM+QUET group (BL = 60.0, FU2 = 63.9) versus other groups (for which no change was documented).

CONCLUSIONS: The INSYTE study is the largest observational study to date to explore PDP treatments and patient outcomes in a RW setting. The data generated from this work will inform the scientific community to better recognize and manage PDP patients.

SPONSORSHIP: Acadia Pharmaceuticals.

F4 Healthcare resource utilization and associated costs for dementia patients with psychosis: a Medicare database study

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BACKGROUND: Patients with dementia commonly exhibit neuropsychiatric symptoms (NPS), including psychosis. Dementia NPS have been associated with increased healthcare resource utilization (HCRU) and costs compared with dementia alone. Psychosis in patients with dementia can be distressing to both patients and caregivers, but data on its impact on HCRU and costs are lacking.

OBJECTIVE: Examine changes in all-cause HCRU and associated costs in dementia patients newly diagnosed with psychosis.

METHODS: This was a retrospective cohort study using a 20% Medicare random claims dataset from 2008-2016. Dementia was defined by 1 dementia diagnosis code and anti-dementia prescription or ≥2 dementia diagnosis codes ≥30 days apart. Patients were defined as incident psychosis patients with 1 psychosis diagnosis code plus an antipsychotic (AP) prescription or 2 psychosis diagnosis codes ≥30 days apart. The date of first psychosis diagnosis or AP prescription was the index date. All-cause HCRU and associated costs were evaluated in the year prior to and the year following psychosis diagnosis. Costs are reported as 2015 U.S. dollars.

RESULTS: Data from 49,509 dementia patients with psychosis were included. The number of doctor visits per patient per year increased from a mean of 26.7 (standard deviation [SD] 20.0) prior to psychosis to 38.4 (SD 41.9) post psychosis diagnosis. When looking at HCRU specifically related to psychosis, doctor visits per patient per year increased from a mean of 0.77 (SD 0.95) prior to psychosis to 2.17 (SD 9.19) post psychosis diagnosis. The number of inpatient hospitalization claims overall increased from 1.0 (SD 1.4) in the year prior to psychosis to 1.7 (SD 5.8) in the year post psychosis diagnosis. In the same time periods, mean cost per patient per year for inpatient hospitalization was $9989 (SD $18,367) and increased to a mean of $25,982 (SD $98,608). Mean total cost prior to psychosis was $48,753 (SD $46,068) and increased to a mean of $89,384 (SD $125,116) post psychosis diagnosis.
CONCLUSIONS: In the year following psychosis diagnosis in patients with dementia, both HCRU and costs increased substantially from the year prior. These results indicate the importance of supporting dementia patients newly diagnosed with psychosis and highlight the need for timely diagnosis and for management strategies and treatments that can reduce HCRU and costs.

SPONSORSHIP: Acadia Pharmaceuticals.

F8 Variations in DEA-waivered provider utilization of medications for opioid use disorder before and after the launch of long-acting injectable buprenorphine (BUP-XR)
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BACKGROUND: Opioid use disorder (OUD) continues to be a public health emergency and yet access to effective treatments remains a barrier. The passage of the Comprehensive Addiction and Recovery Act (CARA) of 2016 was intended to improve access to Office Based Opioid Treatment (OBOT). While the number of waivered providers may have increased, those who are utilizing their waiver to prescribe buprenorphine (BUP) requires further evaluation. In addition, the medications to treat OUD (MOUD) expanded during the same time period including the introduction of BUP-XR (Sublocade).

OBJECTIVE: The purpose of this analysis is to evaluate the change in distribution of waivered versus active prescribers after the implementation of CARA and assess the variation in utilization of BUP products for the treatment of OUD before and after the launch of BUP-XR.

METHODS: Using Symphony Data and Veeva CRM database, waivered providers were identified by X-DEA number. Waivered providers were separated into those who had and those who had not prescribed BUP by state and county. Two time periods (3/2017 to 2/2018 and 3/2019 to 2/2020) were evaluated to identify geographic variation in waiver patient limit (PL) maximization, provider type, provider specialty, and patterns of BUP utilization.

RESULTS: The overall number of waivered providers has increased from 43,249 to 74,332 between 3/2017 and 2020. Out of the 74,332 waivered providers, 49.7% did not prescribe BUP. Among the states with the highest occurrence of OUD, the lowest prevalence of active waivered prescribers was found in PA, TN, and KY. The waivered prescriber mix has changed from 37,752 MDs (87.3%), 4,336 NPs (10.0%) and 1,161 PAs (2.7%) in 2017-18 to 56,121 MDs (75.5%), 14,446 NPs (19.4%) and 3,764 PAs (5.1%) in 2019-20. In addition, the percentage of active prescribers maximizing their PLs was 26.5% for PL-30, 46.8% for PL-100, 25% for PL-275. The utilization of BUP-XR increased over the time periods and was most prevalent in PA, CA and NY. BUP-XR accounted for 0.6% of overall BUP utilization from 3/2019 to 2/2020.

CONCLUSIONS: Although MOUD access and treatment options continue to expand, the maximization of PLs is low with a high percentage of waivered providers not prescribing. In addition, a 270% growth in BUP-XR utilization and 91% growth in unique prescribers represents early adoption of BUP-XR by waivered providers. Potential limitations of data sources include timeliness of waiver verification and under-representation of waivered prescriptions.

SPONSORSHIP: Indivior.

F9 Cost-effectiveness analysis of a prescription digital therapeutic for the treatment of opioid use disorder
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BACKGROUND: Opioid use disorder (OUD) is responsible for approximately 41 of every 10,000 emergency department visits (~585,000 visits/year) with a 30-day readmission rate of 24%. The first and only prescription digital therapeutic for the treatment of OUD, reSET-O, was FDA-authorized based on randomized-controlled trials (RCTs) of its web-based precursor, the Therapeutic Education System (TES). The reSET-O therapeutic delivers treatment based on the community reinforcement approach or CRA, an intensive form of cognitive behavioral therapy indicated as part of the gold standard treatment. The economic value of reSET-O using health state utilities has not been established.

OBJECTIVE: To evaluate the cost-effectiveness of reSET-O based on the pivotal RCT for TES.

METHODS: A decision analytic model was constructed: Twelve weeks of treatment with reSET-O, as an adjunct to treatment-as-usual (TAU)-oral buprenorphine, face-to-face counseling, contingency management (immediate rewards for negative drug tests logged) vs. TAU only. Abstinence was determined by urine drug screening and defined, according to guidelines, as 100% of tests between weeks 9 and 12 being negative for opioids or cocaine (reSET-O + TAU: 75.9% abstinent, vs. TAU: 60.6%). The addiction severity index score and patient characteristics were mapped to week 12/change from baseline SF-6D utility scores for reSET-O + TAU (abstinent: 0.784/0.035; non-abstinent: 0.739/0.0323) and TAU (abstinent: 0.769/0.0182; non-abstinent: 0.743/-0.0217). Twelve-week abstinence-related costs estimates were obtained from a recent claims data analysis of buprenorphine-treated patients (non-adherent: $11,219; adherent: $3,887). A sensitivity analysis used utility change scores added to study population’s average baseline score (0.745).

RESULTS: Over 12 weeks, incremental costs and quality adjusted life year (QALY) gain with reSET-O + TAU vs. TAU were $78.20, and 0.003, corresponding to an incremental cost-effectiveness ratio (ICER) of $23,535/QALY gained over one year. Using utility change scores resulted in a greater utility gain (0.007), and an ICER of $10,578/QALY.

CONCLUSIONS: reSET-O was shown to be cost effective as compared to a treatment that included some face-to-face counseling and contingency management, which may be challenging for many practices to implement due to limitations in available time, resources, and personnel.

SPONSORSHIP: Pear Therapeutics.

F11 Trends in off-label antipsychotic use among Texas Medicaid adults
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CONCLUSIONS: reSET-O was shown to be cost effective as compared to a treatment that included some face-to-face counseling and contingency management, which may be challenging for many practices to implement due to limitations in available time, resources, and personnel.

SPONSORSHIP: Peer Therapeutics.
BACKGROUND: Antipsychotic (AP) off-label use is prevalent and its prevalence differs substantially depending on characteristics of the patient population, as well as wide variations in off-label definitions utilized. However, little is known regarding off-label AP use in Texas Medicaid.

OBJECTIVE: To describe AP off-label use and examine factors associated with off-label use among Texas Medicaid adults.

METHODS: Texas Medicaid prescription and medical claims (01/01/13-08/31/16) were used to identify adults aged 18-63 years who filled ≥1 AP prescription. The index date was first AP prescription date and patients who were continuously enrolled for 1 year were included. AP combination therapy users were excluded. AP users were categorized as: 1) "on-label" if there was an FDA-approved indication; 2) "off-label" if a mental health disorder diagnosis was present, but not associated with an FDA-approved indication; and 3) "no diagnosis" if there was no mental health disorder diagnosis (ICD-9 290-319 or ICD-10 F01-F09). Chi-square tests were performed (2015 data) to assess whether there were differences between diagnostic status (on-label vs. off-label/no diagnosis [combined]) and age group (18-19, 20-34, 35-59, and 60-63 years), gender, and antipsychotic type (first generation [FGA] vs. second generation [SGA] antipsychotics).

RESULTS: From 2013 to 2016, the samples included 51,257, 54,523, 49,843, and 39,151 (Jan-Aug) AP users, respectively. The proportions of AP users with no mental health disorder diagnosis were: 7.5%, 8.1%, 7.3% and 9.4% respectively, and the proportions of off-label AP use were 16.1%, 16.2%, 13.2%, 10.3%, respectively. The most common off-label diagnosis was anxiety (19.5%). In 2015, a higher proportion of AP users were female compared to male (56.1% vs 43.9%) and ~90% were SGA users. Chi-square analyses (2015 data) showed that the proportion of off-label/no diagnosis AP users combined were significantly different across age groups (P<0.001), with those 18-19 years having the highest (29.7%) followed by 60-63 years (22.5%), 20-34 years (22.4%) and 35-59 years (18.3%). Additionally, off-label/no diagnosis combined AP use was significantly higher among males vs. females (21.9% vs 19.4%, P<0.001); and among FGA vs. SGA users (30.8% vs 19.5%, P<0.001).

CONCLUSIONS: Over 75% of Texas Medicaid adult AP users were on-label and <9.5% had no mental health disorder diagnosis. The proportion of off-label/no diagnosis AP use declined from 23.6% (2013) to 19.7% (2016). Younger adults, males and FGA users had significantly higher off-label/no diagnosis AP use.

SPONSORSHIP: None.

F12 Assessment of the prevalence and mental health service utilization among adults with co-occurring major depressive disorder and substance use disorders using the National Survey on Drug Use and Health

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BACKGROUND: About 16 million adults experienced major depressive disorder (MDD), and about 20 million adults battled substance use disorders (SUD) in the United States. Since patients with MDD often present concurrently with the SUD, it is important to examine the prevalence and barriers to accessing mental health (MH) service utilization among those with MDD and SUD.

OBJECTIVE: To examine the 12-month prevalence and mental health service utilization among adults with MDD and SUD using the 2018 National Survey on Drug Use and Health (NSDUH) data.

F16 Economic burden of dementia-related psychosis among Medicare beneficiaries: a state-transition Markov analysis of total annual direct costs

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BACKGROUND: Dementia related psychosis (DRP), characterized by debilitating symptoms such as hallucinations and delusions, is estimated to affect 2.4M people with dementia in the U.S. Patients with DRP may have twice the rate of dementia progression compared to patients with no DRP. Given that dementia disproportionally impacts the elderly, a comprehensive cost-of-illness analysis may add to the current understanding of the economic burden of DRP.

OBJECTIVE: To estimate the cost of DRP from a Centers for Medicare and Medicaid Services (CMS) perspective.

METHODS: A five state-transition Markov analysis, adapted from Green et al, was conducted to assess the annual direct DRP cost burden to CMS. Patients entering the model were allowed to transition between three at-home health-states (mild dementia plus psychosis, moderate dementia plus psychosis, severe dementia plus psychosis), one long-term care/nursing home (LTC/NH) stay, or death (absorbing health state) at any given time. Since the model accommodates tunnel health-states based on dementia, psychosis and functioning severity levels, patients stayed in the same health-state or transitioned to a more severe health-state or progressed to death (i.e., absorbing health-state) between each 30-day cycle. Prevalence, disease-severity, and state-transition probability estimates were derived from literature while direct costs of DRP were derived from a Medicare claims analysis. Costs were discounted at 3%. Model robustness was tested to check if results were sensitive to changes in inputs and assumptions.

RESULTS: Of the estimated 61.5M Medicare beneficiaries, about 6.87M may suffer from dementia. In the base-case scenario, an estimated total of 2.2M DRP patients enter the model based on dementia severity into one of the 4 non-absorbent health-states: three at-home (10% mild, 60% moderate, and 10% severe) and one LTC-NH (10%). Total Medicare annual direct DRP costs are estimated to be approximately $119.98B ($113.96B-$125.96B) and about $54K PPPY (Per-Patient-Per-Year) costs (2019 USD). NH costs and patient volume at higher severity levels are significant cost drivers. Sensitivity analysis results show that the model is sensitive to disease severity and disease progression.

CONCLUSIONS: These results suggest that DRP imposes a significant direct cost burden despite its low prevalence. Especially given the aging population in the U.S., DRP could become an increasing public health concern. There is a significant need for education and awareness about DRP cost burden.

SPONSORSHIP: Acadia Pharmaceuticals.
METHODS: Data were from 50,939 eligible civilian, noninstitutionalized adults who participated in the 2018 NSDUH. MDD cohort was defined as if participants reported major depressive episodes; the SUD cohort was defined as if participants reported dependence on or abuse of alcohol or an illicit drug; the MDD + SUD cohort was defined as if participants reported both; and the reference cohort was defined as if participants reported neither MDD nor SUD. The prevalence and mental health service utilization were examined during the past 12 months and weighted to reflect the U.S. adult population.

RESULTS: Among 248.9M adults, the weighted results suggested that 7.0% (17.5M) reported with MDD, 7.8% (19.3M) reported with SUD, 1.6% (3.9M) reported with MDD + SUD during the past 12 months. MH service utilization was higher for MDD + SUD cohort vs. MDD cohort vs. SUD cohort vs. reference cohort: hospitalization; 7.2% vs. 4.6% vs. 3.3% vs. 0.6%, outpatient visit, 43.3% vs. 37.3% vs. 17.4% vs. 5.2%, prescription, 51.8% vs. 47.9% vs. 23.6% vs. 8.9%.

CONCLUSIONS: This study evaluates the prevalence and MH service utilization of MDE concurrent SUD patients. The information suggested that the likelihood of experiencing barriers to accessing MH services was higher among MDD concurrent SUD patients which might require policies and interventions to address these barriers.

SPONSORSHIP: None.

F17 Comorbid medical conditions, outpatient healthcare resource use, and charges associated with diagnosis of chronic insomnia in the U.S.

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BACKGROUND: Insomnia is defined as trouble initiating or maintaining sleep with daytime symptoms of impaired decision making, work performance, and quality of life; it is considered chronic when persisting ≥3 times per week for ≥3 consecutive months. Prevalence of chronic insomnia is estimated as ~5-10% and increases with age and comorbidity.

OBJECTIVE: To describe the clinical and financial burden among patients following diagnosis of chronic insomnia, and to assess treatment patterns for the recommended first-line treatment, cognitive behavioral therapy for insomnia (CBTi), using psychotherapy and health behavior codes as proxies.

METHODS: An adult insomnia cohort was selected from a 2015-2018 Veradigm dataset of Allscripts outpatient medical claims and electronic medical records. Continuous eligibility for 12-month pre- and post-index was required. Index date was first insomnia diagnosis if accompanied by a second insomnia claim within 6-months, or sleep medication prescription between 3 months pre- to 6 months-post first insomnia claim. Proportion of patients with comorbidity, outpatient visits (OPV), charges, and CBTi codes were measured in 12-month pre- and post-diagnosis periods. Pre- and post-period OPV and charges (2019-adjusted) were compared using McNemar’s tests and Wilcoxon signed-rank tests. A mixed model compared charges in patients with and without comorbidity.

RESULTS: Study sample consisted of 9,505 patients, (73.2% female, median age 51 years). Majority of insomnia diagnoses were in primary care (46%) vs specialist (6%) setting. Most common pre-index comorbidities showed relative increases in prevalence post-index: anxiety (63%), back (21%) and chronic (39%) pain, GERD (37%), osteoarthritis (19%), migraines (43%). Number of OPV (office, hospital, and other) increased following insomnia diagnosis (by 44%, 16%, and 28%, respectively) each p < 0.001. Median charges increased by $472 (p < 0.001) for OPV office but not OPV hospital/other. Median charges were higher for all OPV among patients with Charlson Comorbidity Index (CCI) ≥1 ($2,435) vs CCI = 0 ($1,384; p < 0.001); both groups experienced a similar post-index increase in median charges (37.2% vs 34.6%). CBTi codes were used in 5.5% of patients post-index; CCI scores (0.7 vs 0.53) and total charges ($4,381 vs $2,085) were higher compared to non-CBTi patients.

CONCLUSIONS: Chronic insomnia patients experienced increased comorbidity, OPV and charges following diagnosis, charges increased regardless of comorbidity. Proxy measures indicate CBT of any kind is infrequently used and is more likely delivered to patients with greater comorbidity, suggesting significant unmet need.

SPONSORSHIP: Pear Therapeutics.

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

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BACKGROUND: Research shows that healthcare plans (HP) impose restrictions in roughly 40% of coverage policies for rare disease drugs. However, it is unclear how consistently they impose coverage criteria.

OBJECTIVE: To examine HP coverage criteria for recently approved therapies for rare (prevalence < 20,000) neuromuscular diseases (NMD).

METHODS: Coverage policies issued by 17 large commercial HPs (representing >130 million people in the United States) from the Tufts Medical Center Specialty Drug Evidence and Coverage Database were examined. Policies included Spinraza (nusinersen) and Zolgensma (onasemnogene abeparvovec-xioi) for spinal muscular atrophy, Radicava (edaravone) for amyotrophic lateral sclerosis (ALS), and Exondys 51 (eteplirsen) for Duchenne muscular dystrophy. Level of additional coverage criteria beyond the FDA-approved indication label was determined.

RESULTS: Of 64 coverage policies, four did not impose additional coverage criteria. HPs imposed additional criteria in 53 policies and did not cover the therapy in seven policies (all excluded eteplirsen only). HPs imposed additional criteria in 88% (15/17) of nusinersen policies, 93% (14/15) of onasemnogene abeparvovec policies, 100% (16/16) of edaravone policies and 89% (8/9) of eteplirsen policies in which the HPs covered the therapy. Plans often imposed different coverage criteria for the same therapies. For nusinersen, six HPs required that...
patients were not fully ventilator dependent, and two required that patients maintained voluntary motor function. For onasemnogene abeparvovec, 14 HPs required a certain number of survival of motor neuron 2 (SMN2) gene copies (in general, more copies results in a milder phenotype): 10 HPs required ≥3 copies, two HPs ≤2 copies, one HP two copies, and one HP two or three copies. For edaravone, nine HPs imposed four additional criteria: (1) ≥2 points on the ALS Functional Rating Scale; (2) normal respiratory function; (3) diagnosis using El Escorial criteria, and; (4) disease duration ≤2 years. Six HPs required three of these three criteria, and one HP required two criteria. For etepirsen, six HPs imposed motor function related coverage criteria, but requirements varied (e.g. ability to walk vs. ability to walk with assistance vs. ability to manipulate objects using upper extremities).

CONCLUSIONS: Most HP coverage policies for the included rare NMD therapies were more restrictive than FDA-approved indication labels. Plans imposed inconsistent coverage criteria which has important implications for patients’ access to care.

SPONSORSHIP: Genentech.

G11 CVT-301 treatment provides consistent and clinically significant improvements in Unified Parkinson’s Disease Rating Scale part III scores over 12 weeks
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BACKGROUND: CVT-301 is an inhaled levodopa (LD) for OFF period treatment in people with Parkinson’s disease (PD) on an oral dopa-decarboxylase-inhibitor/LD regimen. In the SPAN-PD study, CVT-301 84 mg improved motor function in patients with OFF periods at week 12, as measured by lower Unified Parkinson’s Disease Rating Scale Part III (UPDRS-III) scores, 30 min postdose (P = 0.009 vs placebo); 58% of subjects achieved and maintained an ON state within 60 min postdose vs 36% on placebo (P = 0.003).

OBJECTIVE: A post hoc analysis of UPDRS-III sequential changes over the 12-week treatment period of a phase 3 study.

METHODS: PD subjects (n = 351) experiencing OFF periods and on a stable oral carbidopa/LD regimen were randomized to placebo or CVT-301 60 mg or 84 mg for treatment of OFF period symptoms up to 5 times/day. UPDRS-III was assessed during screening and at predose, 10, 20, 30, and 60 min postdose at weeks 4, 8, and 12 treatment visits.

RESULTS: CVT-301 84 mg was associated with consistent improvement in mean UPDRS-III scores at all timepoints postdose, and at all visits (every 4 weeks) when administered in an OFF period. Mean placebo scores improved in the first 20 min postdose at all visits, but at >20 min remained largely unchanged, whereas CVT-301 scores continued to improve through 60 min. Mean UPDRS-III score % improvement from predose showed that CVT-301 84 mg improved within 60 min postdose at each visit, whereas placebo % improved until 20 min and then largely declined. When in an OFF period, subjects achieved a clinically relevant improvement of 30% by 20 min at 4 weeks and by 30 min at all other visits for CVT-301, whereas the placebo group did not achieve this threshold at any visit. Mean UPDRS-III score for fully ON CVT-301 subjects at screening (after subject’s usual oral carbidopa/LD dose) was 14.9. At 30 min postdose mean UPDRS-III score for CVT-301 subjects at each visit returned to an ON range of 18.3-19.3.

CONCLUSIONS: CVT-301 84 mg was associated with consistent improvements in UPDRS-III scores at weeks 4 through 12 when administered in an OFF period and improvements were consistently
A total of 56 patients were included in the analysis; median age was 58 years (mean: 56.4 ± 18.3) and 62.5% were male. IV edaravone infusion was initiated at home among 34 (60.7%) patients, in an outpatient facility among 20 (35.7%) patients, and at an unspecified site for 2 (3.6%) patients. Almost all IV edaravone patients (98.2%) had at least 1 claim for IV edaravone (between August 2017 and September 2019) and at least 6 months of pre- and post-index continuous enrollment in the CDM database. The start date of IV edaravone was the index date. Demographics, costs, and HRU were assessed descriptively. Costs were reported as total all-cause costs adjusted by the Consumer Price Index to 2019 U.S. dollars.

RESULTS: A total of 56 patients were included in the analysis; median age was 58 years (mean: 56.4 ± 18.3) and 62.5% were male. IV edaravone infusion was initiated at home among 34 (60.7%) patients, in an outpatient facility among 20 (35.7%) patients, and at an unspecified site for 2 (3.6%) patients. Almost all IV edaravone patients (98.2%) had at least 1 claim for a professional outpatient office visit with an average of 4.0 visits per patient; 94.6% of the patients had at least 1 claim for an outpatient facility visit with an average of 10.0 visits per patient; 80.4% of the patients had at least 1 claim for a durable medical equipment; and 80.4% of the patients had at least 1 claim for home healthcare visit. Average total all-cause costs were $155,847 ± $105,681 (median: $133,742; interquartile range: $69,077) in the 6 months following initiation of IV edaravone.

CONCLUSIONS: This is the first analysis to provide a description of HRU and direct costs in commercially insured ALS patients treated with IV edaravone in a real-world setting. Future studies are needed to quantify the financial impact of IV edaravone stratified by real-world outcomes (eg, time to use of non-invasive/invasive ventilation).

SPONSORSHIP: Mitsubishi Tanabe Pharma America.
BACKGROUND: Published evidence comparing patient characteristics of commercially-insured versus Medicare enrollees with multiple sclerosis (MS) is lacking. Such knowledge may be important in optimizing disease management and outcomes.

OBJECTIVE: To conduct a retrospective database analysis of patients with MS with commercial insurance or Medicare in a large health plan to better understand patient characteristics and comorbidities.

METHODS: This observational cohort study used administrative claims data from January 1, 2012 through December 31, 2016 and indexed on the claim date (index). The cross-sectional analysis included all patients prescribed siponimod within a one-year period (1st claim= index date), a large health plan with commercial fully-insured and Medicare Advantage members with medical and pharmacy benefits ≥12 months before and after index; and age ≥18. Patients with inflammatory bowel disease receiving natalizumab, enrolled in a compassionate care program, or hospice care were excluded.

RESULTS: A total of 5000 patients met eligibility criteria. Mean (SD) age was 52.6 (12.9) years, 75.2% were female, 53.3% had commercial insurance, and 46.7% had Medicare (59.2% of whom were <65 years old [i.e., Social Security Disability Insurance (SSDI)]). Patients with Medicare were older (Medicare SSDI 53.3 [8.0] years, ≥65 Medicare 70.8 [5.2] years vs. commercial 45.7 [10.2] years), lived in more rural locations (Medicare SSDI 43.5%, ≥65 Medicare 47.7% vs. commercial 35.1%), and had greater overall comorbidity burden (Charlson Comorbidity Index; Medicare SSDI 1.17 [1.64], ≥65 Medicare 1.65 [1.95] vs. commercial 0.53 [1.02], all P<0.0001). MS-specific symptoms (i.e., malaise, fatigue, depression/anxiety, spasms, fibromyalgia, convulsions) were more common among Medicare SSDI beneficiaries (all P<0.0001), whereas age-related and other comorbidities (i.e., hypertension, hyperlipidemia, dyspepsia, osteoarthritis, osteoporosis, glaucoma, thyroid disorders, diabetes, cerebrovascular disease, and cancer) were more common among ≥65 Medicare beneficiaries (all P<0.0001). Many patients with MS had multiple comorbidities (overall median 4), particularly those with Medicare SSDI (median 6) and ≥65 Medicare (median 7).

CONCLUSIONS: Patient characteristics and comorbidities differed between patients with MS with commercial insurance and patients with Medicare. Multiple comorbidities are highly prevalent among patients with MS and should be considered in the context of clinical decision making to ensure comprehensive MS management.

SPONSORSHIP: Novartis Pharmaceuticals.

G19 The economic burden of progression to wheelchair in patients with severe disability

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BACKGROUND: Multiple Sclerosis (MS) is a chronic neurodegenerative condition characterized by insidious worsening of walking disability, which often results in dependence on a wheelchair for ambulation; wheelchair dependence correlates to Kurtzke Expanded Disability Status Score (EDSS) ≥7. While it has been recognized that the utilization of healthcare services increases with increased disability, the incremental cost of progression to a wheelchair is not well described.

OBJECTIVE: To understand the economic burden of wheelchair dependence among MS patients with severe disability in the United States (U.S.).

METHODS: This was a retrospective cohort study of adult MS patients ≥18 years in the U.S. with severe disability (EDSS >6), utilizing adjudicated health plan claims data. Eligible patients were identified between January 1, 2012-December 31, 2016 and indexed on the

SPONSORSHIP: Novartis Pharmaceuticals.

G18 The first 12 months of siponimod utilization following approval in the United States

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BACKGROUND: Siponimod was approved by the U.S. Food and Drug Administration in March 2019 for relapsing forms of Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive MS (SPMS). The approved indication does not fully align with the typical SPMS patients studied in the pivotal phase 3 EXPAND trial. This discordance creates uncertainty around how siponimod is utilized in the real-world.

OBJECTIVE: To characterize the real-world demographics and clinical characteristics of MS patients prescribed siponimod in the 12 months following approval in the U.S.

METHODS: The cross-sectional analysis included all patients prescribed siponimod in the U.S. Patient demographic and clinical characteristics were collected from a patient support program provided by the manufacturer, which allows for coordination of necessary testing and benefits investigation prior to starting siponimod. The U.S. prescribing information requires all patients to titrate to the respective maintenance dose based on their metabolic genotype profile. For patients with specific cardiac criteria, it is recommended to receive first-dose monitoring. Data on all patients ≥18 years of age prescribed siponimod (first-time prescriptions and re-initiations) from April 2019-April 2020 were included in the analysis.

RESULTS: Among the 5,219 patients prescribed siponimod, 16.1% were 18-40 years while most patients (54.8%) were 41-60 and 29.1% were ≥61 years. Patients were predominantly female (74.8%) and all geographic regions of the U.S. were represented, while 49.0% had government insurance (Medicare/Medicaid) and 46.6% had commercial insurance. Of patients with a recorded MS phenotype, 58.4% had SPMS (n=2,249) and 41.6% had RRMS (n=1,596). At the time of the analysis, 3,738 patients had completed the onboarding process and received siponimod (97.9% new starts and 2.1% re-initiations); 87.9% were on the 2mg maintenance dose, and 12.1% were on the 1mg maintenance dose. Of all siponimod prescriptions, 8.8% of patients were recommended to receive FDO by their prescribing physician.

CONCLUSIONS: This study characterizes all patients prescribed siponimod in the first 12 months following approval in the U.S. The demographic and clinical phenotypic profile of real-world patients signifies that siponimod is being prescribed in older patients with progressed disease. This suggests clinicians are prescribing based on the population studied in the EXPAND trial.

SPONSORSHIP: Novartis Pharmaceuticals.
first MS diagnosis date. Baseline severity was approximated using a proxy-aligned measure of disability, which identified components of the functional systems that comprise the EDSS over a 1-year baseline period to assign a score. Patients with severe disability were identified and evidence of wheelchair dependence was assessed during the baseline period including the index date to define the patient cohorts (i.e., wheelchair vs. non-wheelchair). Generalize linear model-adjusted all-cause healthcare, medical, and pharmacy costs (2018 U.S$) were estimated by wheelchair dependence in the 1-year post-index period.

RESULTS: In total, 5,799 eligible MS patients with severe disability were identified, of which 545 (9.9%) had evidence of a wheelchair at baseline. The wheelchair cohort compared to the non-wheelchair cohort were older (56 vs. 50 years, respectively) and had more comorbidities (mean CCI, 1.6 vs. 1.1, respectively). Adjusted total healthcare costs in the wheelchair cohort was 8% higher than those patients without wheelchair dependence ($64,668 vs. $60,142, respectively). While pharmacy costs were 23% lower in the wheelchair cohort than patients with no wheelchair ($27,557 vs. $35,592, respectively), inpatient costs were 88% higher ($18,463 vs. $9,798, wheelchair vs. non-wheelchair).

CONCLUSIONS: This study shows that MS patients who have progressed in their disease to a point of wheelchair dependence have a greater cost burden than patients with substantial severity (using a walking aid) but without wheelchair dependence, which significantly exceed the cost of the wheelchair itself. As such, delaying the time to disability progression can have substantial impact to the healthcare system.

SPONSORSHIP: Novartis.

G34 Budget impact of a novel treatment for insomnia from U.S. commercial and Medicare payer perspectives

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BACKGROUND: Lemborexant, a recently approved orexin receptor antagonist, is indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Affecting 10% of adults in the U.S., insomnia is known to increase risk of falls and some common insomnia medications may further increase the risk of these costly events.

OBJECTIVE: Estimate the budget impact of adding lemborexant for the treatment of insomnia to a health plan formulary from U.S. commercial and Medicare payer perspectives.

METHODS: A budget impact model was developed in Microsoft Excel 2010 to compare total costs in the current environment (“market without lemborexant”) with those of the new environment (“market with lemborexant”) over a 1-year time horizon. Market share for common therapies currently used to treat insomnia (trazodone, zolpidem immediate-release and extended-release, benzodiazepines) were estimated using IBM MarketScan and Medicare claims data and adjusted to account for the suvorexant and lemborexant. The base case scenario assumed 1-million commercial or Medicare covered lives. Total healthcare costs were inclusive of pharmacy benefit costs of the insomnia drugs of interest, other pharmacy benefit costs and medical benefit costs. The model considered insomnia treatment-specific fall rates (obtained from claims analyses or clinical trial data adjusted to account for likelihood of receiving medical care) and healthcare costs varied depending on the likelihood of whether or not patients suffered falls. Other inputs were based on the published literature or expert opinion. No discounting was applied to drug costs and results were reported in 2020 U.S. dollars.

RESULTS: In a hypothetical commercial plan, an estimated 41,000 patients received treatment for insomnia. The total costs in the market without lemborexant and in the market with lemborexant were $807,332,409 and $807,325,559, respectively, yielding a budget savings of $6,810 following the adoption of lemborexant. In a hypothetical Medicare plan, an estimated 60,000 patients received treatment for insomnia. The total costs in the market without lemborexant and in the market with lemborexant were $685,107,622 and $684,984,750, respectively, yielding a budget savings of $122,872 following the adoption of lemborexant.

CONCLUSIONS: Over a 1-year period, lower fall rates for lemborexant compared to other insomnia drugs appear to result in healthcare cost offsets to lemborexant medication costs that translate into cost neutrality for commercial and Medicare plans.

SPONSORSHIP: Eisai.

G35 Higher health care resource use and costs associated with falls among elderly Medicare beneficiaries on commonly used insomnia medications in the United States

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BACKGROUND: Insomnia affects approximately 10 percent of U.S. adult population. It is associated with increased likelihood of serious accidents such as falls. Fall injuries are among the 20 most expensive medical conditions, and fall-related costs increase with age. Falls annually affect more than one-third of those aged 65 years and older.

OBJECTIVE: To evaluate healthcare resource use (HCRU) and costs between older adult patients treated with common insomnia medications and older adults with no sleep disorders, and to estimate incremental HCRU and costs associated with falls.

METHODS: In this retrospective cohort study, the Medicare Claims Research Identifiable Files (Jan 2011-Dec 2017) were used to identify patients: (1) aged >65 years; (2) who received one of these commonly used prescription insomnia therapies: zolpidem immediate release (IR), zolpidem extended release (ER), trazodone, or benzodiazepines; (3) with ≥ 12 months continuous coverage prior and post-treatment initiation; and (4) with no evidence of insomnia treatment during the 12-month baseline period. A 1:1 age and sex-matched control cohort was identified and evidence of wheelchair dependence was assessed during the baseline period including the index date to define the patient cohorts (i.e., wheelchair vs. non-wheelchair). Generalize linear model-adjusted all-cause healthcare, medical, and pharmacy costs (2018 U.S$) were estimated by wheelchair dependence in the 1-year post-index period.

RESULTS: In a hypothetical commercial plan, an estimated 41,000 patients received treatment for insomnia. The total costs in the market without lemborexant and in the market with lemborexant were $807,332,409 and $807,325,559, respectively, yielding a budget savings of $6,810 following the adoption of lemborexant. In a hypothetical Medicare plan, an estimated 60,000 patients received treatment for insomnia. The total costs in the market without lemborexant and in the market with lemborexant were $685,107,622 and $684,984,750, respectively, yielding a budget savings of $122,872 following the adoption of lemborexant.

CONCLUSIONS: Over a 1-year period, lower fall rates for lemborexant compared to other insomnia drugs appear to result in healthcare cost offsets to lemborexant medication costs that translate into cost neutrality for commercial and Medicare plans.

SPONSORSHIP: Eisai.
CONCLUSIONS: Among this national sample of Medicare beneficiaries, insomnia treatment was associated with markedly increased HCRU and costs. Additionally, elderly insomnia patients who experienced a fall incurred twice the healthcare costs of elderly insomnia patients who did not.

SPONSORSHIP: Eisai.

G36 Risk of falls among elderly Medicare beneficiaries on commonly used insomnia medications in the United States

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BACKGROUND: One-third of U.S. adults have insomnia symptoms, and insomnia disorder affects 10% of the population. Side-effects associated with insomnia include comorbid conditions, as well as reduced quality of life. Insomnia is known to increase risk of falls, particularly among the elderly. Some common insomnia medications may further increase the risk of these events.

OBJECTIVE: To evaluate the fall risk associated with common insomnia medications.

METHODS: In this retrospective cohort study, the Medicare Claims Research Identifiable Files (Jan 2011-Dec 2017) were used to identify patients (1) aged >65 years; (2) who received a commonly used prescription insomnia treatment: zolpidem immediate release (IR), zolpidem extended release (ER), trazodone, or benzodiazepines; (3) with ≥12 months continuous coverage prior and post-treatment initiation; and (4) with no evidence of insomnia treatment during the 12 month baseline period. A 1:1 age and sex-matched control cohort with no evidence of sleep-related diagnoses or treatment was identified. Falls were operationalized as ≥1 diagnosis for fall, hip fracture, and/or traumatic brain injury. After adjustment for covariates (age, sex, geographic region, comorbidity burden), odds ratios (ORs, using logistic regression models) and hazard ratios (HRs, using Cox proportional hazard models) were estimated for the overall insomnia treated cohort as well as each specific treatment cohort, and compared to matched controls.

RESULTS: 1,699,913 Medicare beneficiaries (mean age 75 years, 60% female) receiving zolpidem IR (36.2%, n = 615,945), zolpidem ER (0.5%, n = 8,196), trazodone (n = 34.2%, 581,117) and benzodiazepines (29.1%, n = 494,655) were identified. Comorbidity burden differed between groups—mean baseline Charlson Comorbidity Index (CCI) score was 1.7 for the insomnia treated cohort and 0.7 among matched controls. Relative to controls, more treated patients experienced a fall within 12 months following treatment initiation (9.4% vs. 3.1%, P<0.01). The overall risk of falls varied by insomnia medication, ranging from 6.0% for zolpidem ER to 11.3% for benzodiazepines. Relative to matched controls (ref = 1.0), the adjusted OR for falls was 2.34 (95% CI: 2.31-2.36) times as high and the adjusted HR was 2.25 (95% CI: 2.23-2.27) as fast for the insomnia treated cohort. ORs and HRs varied by medication.

CONCLUSIONS: Relative to older adults without sleep disorders, individuals treated with common insomnia medications demonstrated elevated rates of falls. These results suggest an unmet need.

SPONSORSHIP: Eisai.

G37 Risk of falls among adult patients on commonly used insomnia medications in the United States

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BACKGROUND: One-third of U.S. adults have insomnia symptoms, with insomnia disorder affecting 6-10% of the population. Insomnia is associated with numerous comorbid conditions and reduced quality of life. It is known to increase risk of falls, and some common insomnia medications may further increase the risk of these events.

OBJECTIVE: To evaluate the fall risk associated with common insomnia medications.

METHODS: In this retrospective cohort study, the IBM MarketScan Commercial and Medicare Supplemental databases (Jan 2011-Sep 2018) were used to identify patients (1) aged >18 years; (2) who received a commonly used prescription insomnia treatment: zolpidem immediate release (IR), zolpidem extended release (ER), trazodone, or benzodiazepines; (3) with ≥12 months continuous coverage prior and post-treatment initiation; and (4) with no evidence of insomnia treatment during the 12 month baseline period. A 1:1 age and sex-matched control cohort with no evidence of sleep-related disorders was identified. Falls were operationalized as ≥1 diagnoses for falls, hip fractures, and traumatic brain injuries. After adjustment for covariates (age, sex, geographic region, comorbidity burden), odds ratios (ORs, using adjusted logistic regression models) and hazard ratios (HRs, using adjusted Cox proportional hazard models for time to first fall) were estimated for the overall insomnia treated cohort as well as each specific treatment cohort, and compared to the matched control.

RESULTS: 313,086 enrollees (mean age 52 years, 59% female) receiving zolpidem IR (48.1%, n = 150,503), zolpidem ER (2.8%, n = 8,573), trazodone (32.3%, n = 101,194) and benzodiazepines (16.9%, n = 52,816) were identified. The mean baseline Charlson Comorbidity Index (CCI) score was 0.87 for the insomnia treated cohort and 0.45 for matched controls. Relative to controls, a larger proportion of patients with treated insomnia experienced a fall (3.3% versus 1.3%, P<0.01). The overall risk of falls varied by insomnia medication and ranged from 1.9% for zolpidem ER to 4.6% for trazodone. Relative to the matched control cohort (ref = 1.0), the adjusted OR for falls was 2.36 (95% CI: 2.27-2.44) times as high and the adjusted HR was 2.31 (95% CI: 2.23-2.40) as fast for the insomnia treated cohort. ORs and HRs varied by insomnia medication (lowest for zolpidem IR and highest for trazodone).
CONCLUSIONS: Adults receiving insomnia medications were more likely to experience falls and experience them sooner than adults without sleep disorders, with risk varying by insomnia medication.

SPONSORSHIP: Eisai.

G38 Treatment patterns for insomnia pharmacotherapy among Medicare patients and patients in the commercially insured population in the United States

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BACKGROUND: One-third of U.S. adults report insomnia symptoms, and 10% of the population meets diagnostic criteria for insomnia disorder. While multiple medications are often prescribed to treat insomnia, treatment patterns associated with these medications have not been well elucidated.

OBJECTIVE: To evaluate treatment patterns associated with commonly prescribed insomnia medications.

METHODS: This retrospective cohort study was conducted in two datasets: Medicare Claims Research Identifiable Files for elderly patients (age ≥65 years during Jan 2011-Dec 2017) and IBM MarketScan Commercial and Medicare Supplemental database for commercially insured patients (age ≥18 years during Jan 2011-Sep 2018). These datasets were used to identify patients who received any of the following prescription insomnia treatment: zolpidem immediate release (IR), zolpidem extended release (ER), trazodone, or benzodiazepines. Descriptive analyses of treatment patterns overall and for individual medications were conducted.

RESULTS: Within the Medicare sample, 3,505,697 beneficiaries (mean age 75, 67% female) initiated zolpidem IR (39.1%, n = 1,369,068), zolpidem ER (1.5%, n = 54,100), trazodone (21.0%, n = 735,055) and benzodiazepines (38.4%, n = 1,347,474). Within the IBM MarketScan sample, 2,191,637 enrollees (mean age 49, 64% female) initiated zolpidem IR (38.7%, n = 847,560), zolpidem ER (4.0%, n = 87,911), trazodone (16.6%, n = 364,869) and benzodiazepines (40.7%, n = 891,297). During the 12 months following initiation of index therapy, mean duration of use among Medicare beneficiaries was 180 days (ranging from 174 days for zolpidem ER to 181 days for zolpidem IR and benzodiazepines). Mean duration of use among IBM Marketscan enrollees was shorter–156 days (ranging from 137 days for trazodone to 192 days for zolpidem ER). During the 12 months following initiation of index therapy, average monthly number of pills among Medicare beneficiaries was 18.8 pills (ranging from 14.7 pills for zolpidem IR to 24.1 pills for benzodiazepines). Among IBM MarketScan enrollees, the average monthly number of pills was 17.5 (ranging from 13.6 for zolpidem IR to 22.1 for benzodiazepines).

CONCLUSIONS: Relative to commercially insured enrollees in IBM Marketscan, older Medicare beneficiaries remained on their initial prescription insomnia medication for a longer period of time and also had a higher average monthly number of pills. Results varied by specific insomnia medication, with patients on benzodiazepines showing higher monthly pill count.

SPONSORSHIP: Eisai.

G39 Direct cost and healthcare resource utilization of patients who initiate calcitonin gene-related peptide monoclonal antibodies by the number of prior preventive migraine medication classes

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Eli Lilly and Company

BACKGROUND: Current American Headache Society clinical guidelines recommend initiating the novel class of calcitonin gene-related peptide monoclonal antibodies (CGRP mAbs) after failure with at least two conventional preventive migraine medications (PMM). The economic implications of this placement in line of therapy is unknown.

OBJECTIVE: To describe the cost and healthcare resource utilization (HCRU) among patients in four migraine preventive therapy groups based on the number of prior PMM classes used before initiating CGRP mAbs.

METHODS: A retrospective analysis of claims from IBM Marketscan database was conducted for adult patients (≥18 years of age) with ICD10 migraine diagnosis code who initiated CGRP mAbs during index period (May 1, 2018-Dec 31, 2019). Patients were divided into four therapy groups based on the number of prior non-CGRP PMM classes used during 24 months pre-index period before initiating CGRP mAbs (P0 = none, P1 = one, P2 = two, P3 = three or more). The inclusion criteria also required at least 24 months of continuous enrollment during the pre-index period. Categorical variables were summarized using frequencies with proportions and continuous variables were summarized using mean with standard deviations (SDs).

RESULTS: A total of 23,288 patients who initiated CGRP mAbs were included in the analysis. The study population was mainly female (86%) with a mean ± SD age of 45 ± 12 years, mean Charlson Comorbidity Index of 0.69 ± 1.17 and majority had chronic migraine (60%). The average unadjusted total healthcare cost over a period of 24 months was highest in P3 ($100,548 ± 153,258 per patient) and lowest in P0 group ($50,576 ± 82,854 per patient). The highest cost was attributed to pharmacy ($23,266 ± 59,526) and procedure/imaging related expenses ($40,211 ± 72,802). Similarly, HCRU during the 24 months pre-index period was seen to numerically increase with the number of prior PMM classes used (average outpatient visits for P0 = 34, P1 = 40, P2 = 46, P3 = 54). The most common class of PMM used was anti-epileptics (49%) and the most common class of acute medication used was triptans (75%) followed by prescription non-steroidal anti-inflammatory drugs (71%) across all four groups during the study period.

CONCLUSIONS: The total direct healthcare cost and HCRU was found to numerically increase with the number of prior PMM classes patients used before initiating CGRP mAbs. The results might provide evidence about potential for CGPR mAbs placement earlier in the line of therapy as a measure to reduce cost burden on healthcare system. Additional studies are needed to evaluate changes in healthcare costs and HCRU in post-initiation period.

SPONSORSHIP: Eli Lilly and Company.
Comparative efficacy of insomnia treatments: a network meta-analysis

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BACKGROUND: Insomnia is a common disorder involving sleep disturbances such as difficulty in falling asleep or premature waking. Lemborexant (LEM) is a new dual orexin receptor agonist approved for the treatment of insomnia.

OBJECTIVE: Compare efficacy and safety of a novel treatment for insomnia, lemborexant, with other insomnia treatments.

METHODS: Searches of Medline and EMBase were conducted in Oct 2017 and updated in Feb 2019. English, randomized controlled trials (excluding crossover trials) in adult or elderly patients with primary insomnia with at least two interventions of interest or placebo following at least one week of treatment were included. Interventions of interest were LEM, suvorexant (SUV), benzodiazepines (BZDs), non-BZDs (zolpidem, eszopiclone, zaleplon, zopiclone), trazodone and ramelteon. Efficacy outcomes included wakefulness after sleep onset (WASO), sleep efficiency (SE), latency to persistent sleep (LPS)/sleep onset latency (SOL), total sleep time (TST) and Insomnia Severity Index (ISI). Bayesian network meta-analyses were performed at 4 weeks, 3 months and 6 months. Safety outcomes included serious adverse events (AEs) and withdrawals due to AEs.

RESULTS: A total of 45 studies covering 14 treatments were included in the NMA. LEM had the highest probability of being the best treatment for three of the four outcomes measured objectively by polysomnography (PSG): TST, LPS and SE, and was ranked second to SUV on WASO at 4 weeks. Eszopiclone was highly ranked for subjectively measures at 4 weeks, 3 months and 6 months. LEM was rated more highly than SUV in subjective measures of WASO, TST or SOL at 4 weeks, although differences were not statistically significant. No statistically significant interactions were found between treatment effect and the elderly, indicating that the treatment effect was similar in elderly and non-elderly. LEM safety profile was broadly similar to other treatments for SAE and withdrawals. Limitations include, earlier lower quality scoring studies conducted when there were fewer treatment options. Second, all recommended doses were combined for treatments. Most subjects in long-term eszopiclone trials took a 3mg dose which has a warning for use in the elderly and has been associated with increased risk of next-day impairment. Data was only available for 20/15 mg SUV dose. In contrast, LEM trials included equal numbers of subjects in 5 mg and 10 mg groups.

CONCLUSIONS: Lemborexant was ranked highest of the treatments studied on three out of four objectively measured insomnia efficacy outcomes, with a safety profile similar to other insomnia treatments.

SPONSORSHIP: Eisai.

Adherence to and discontinuation rates of eslicarbazepine acetate or brivaracetam among patients with focal seizures after historical use of oxcarbazepine

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BACKGROUND: Eslicarbazepine acetate (ESL) and brivaracetam (BRV) are third-generation antiepileptic drugs (AEDs). Typically, these newer branded agents are used later in the treatment cycle after prior second-generation AEDs, mostly generic, such as oxcarbazepine (OXC). Comparative adherence data for newer third-generation agents among patients who have switched from prior generation AEDs are lacking.

OBJECTIVE: To assess adherence rates, days on treatment, and discontinuation rates of ESL and BRV after historical use of OXC in patients with focal seizures (FS).

METHODS: This retrospective, longitudinal cohort analysis used Symphony Health’s Integrated Dataverse claims data. Key inclusion criteria were age ≥ 4 years; FS diagnosis; historical use of OXC; and a new prescription for ESL or BRV during 4/1/2015-6/30/2018. Index date was the earliest dispensed pharmacy claim for ESL or BRV. Outcomes were assessed up to 6 months following the index date. Adherence to index drug was measured with Proportion of Days Covered (PDC). Patients with PDC ≥ 80% were defined as highly adherent. Days on treatment was calculated as the time from index drug initiation to the last day of possession or end of follow-up. Discontinuation was defined as a gap in possession of the index drug exceeding the indicated permissible gap length with adjustment for overlapping prescription fills. Continuous variables and proportions were compared with t-tests or Chi-square tests, respectively.

RESULTS: 476 patients initiated ESL (mean age 39.1 years; 61.1% female; mean prior AEDs 4.4) after prior OXC. Most patients initiating ESL or BRV were commercially insured. ESL (61.6%) and BRV (70.7%) were mostly used as adjunctive therapy. At 6 months, patients who initiated ESL had higher mean PDC (71 ± 31% vs. 62 ± 33%; P = 0.0015) and PDC ≥ 80% (55% vs. 46%; P = 0.0222). Patients who initiated ESL spent significantly more days on treatment with a 30-day (129 ± 64 vs. 113 ± 69; P = 0.0023), 45-day (133 ± 62 vs. 117 ± 68; P = 0.0018), and 60-day (137 ± 61 vs. 120 ± 67; P = 0.0009) permissible gap. Discontinuation rates with a 30-day (41% vs. 51%; P = 0.0017), 45-day (37% vs. 47%; P = 0.0106), and 60-day (32% vs. 44%; P = 0.0008) permissible gap were significantly lower in patients who initiated ESL.

CONCLUSIONS: This real-world study showed ESL initiation was associated with significantly higher adherence and lower discontinuation rates compared to BRV after historical use of OXC in patients with FS.

SPONSORSHIP: Sunovion Pharmaceuticals.
The Activity Impairment in Migraine-Diary (AIM-D) instrument was developed in accordance with FDA PRO guidance including input from people with migraine, clinical experts, and PRO instrument developers. Content validity was established through concept elicitation and cognitive interviews with episodic (EM) and chronic migraine (CM) patients.

OBJECTIVE: Evaluate psychometric properties and interpretation of AIM-D scores in EM and CM patients.

METHODS: In a 13-week prospective, observational, non-interventional study, participants completed a daily eDiary including AIM-D, a headache diary used in clinical trials with questions on activity level and limitation, and periodically completed PRO instruments on tablets. Item performance (item descriptive characteristics and correlations), exploratory factor analysis (EFA), confirmatory factor analysis (CFA), and item response theory analyses were used to determine factor structure and scoring algorithm. Psychometric properties were evaluated using internal consistency, test-retest reliability, convergent and known-groups validity, and ability to detect change.

RESULTS: Of 369 participants enrolled, 316 (EM: n = 186; CM: n = 130) were eligible for analysis; mean ± SD age was 45 ± 13 years, 86% were female. EFA and CFA supported 2-domain factor structure measuring performance of daily activities (7 items) and physical impairment (4 items). Each domain score demonstrated good internal consistency (range: 0.67–0.82) and test-retest reliability (intraclass correlation coefficient: 0.32–0.53), activity limitation (0.53–0.87), migraine days (0.48–0.77), and Functional Impact of Migraine Questionnaire scores. Known-groups validity showed the 2 AIM-D domain scores differentiated between groups based on migraine days (all p < 0.01), activity limitation (all p < 0.001), and Headache Impact Test-6 (all p < 0.05). Each AIM-D domain score differed significantly across absolute change in headache days (all p < 0.01) and activity limitation (all p < 0.0001) from baseline to Week 12.

CONCLUSIONS: The AIM-D demonstrated robust psychometric properties with high internal consistency, good reproducibility, and construct validity. The AIM-D is a fit-for-purpose PRO instrument suitable for clinical trial endpoint measurement of the impact of migraine on performance of daily activities and physical impairment.

SPONSORSHIP: Allergan.

Psychometric evaluation of a novel patient-reported outcome instrument assessing the impact of migraine in episodic and chronic migraine: the Activity Impairment in Migraine-Diary (AIM-D)

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Real-world impact of a CBT-I digital therapeutic: treatment outcomes and prescription sleep medication use among 5,877 adults

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BACKGROUND: Cognitive behavioral therapy for insomnia (CBT-I) is the American Academy of Sleep Medicine guideline-recommended first-line treatment for chronic insomnia, but it is not widely available. Therapeutics that can deliver CBT-I digitally can improve treatment accessibility. One such digital therapeutic, SHUTi (Sleep Healthy Using the Internet) has demonstrated effectiveness in randomized controlled trials. Real-world data (RWD) describing the impact of SHUTi on insomnia treatment response, remission, and prescription sleep medication use is described herein.

OBJECTIVE: Examining RWD may have implications for how prescription digital therapeutics (PDTs) may fare in the real world as Somryst, the mobile version of SHUTi, was recently cleared by FDA as the first PDT for the treatment of chronic insomnia (CI).

METHODS: Data were evaluated from 5,877 adults with CI: (Insomnia Severity Index [ISI] score > 8) who used the digital therapeutic within a 9-week treatment period between 12/15/2015 and 2/23/2019. The digital therapeutic delivers six treatment sessions (Cores), targeting underlying cognitive and behavioral factors that perpetuate CI. ISI assessments were completed at the beginning of each Core. Daily sleep diaries that included a question on nightly sleep medications were completed throughout treatment. Standard ISI cut-off scores were used to define treatment response (7-point reduction in score) and remission (<8 total score). Kruskal-Wallis H-test was used to test the distribution of proportion of medicated nights.

RESULTS: Median age range for this real-world sample was between 45 and 54. Median duration of sleep problems was 60 months. During the first Core of treatment, patients reported insomnia in the moderate severity range, and 61% reported using prescription sleep medications. Between the completion of the ISI at Core 1 and Core 6, a robust reduction in ISI score was observed (Cohen’s d = 1.87, 95% CI: 1.81-1.94). Of users completing at least one Core, 42% demonstrated a clinically significant treatment response, and, by the start of Core 6, 25% achieved insomnia remittance. On average, frequency of medicated nights also decreased; sleep diaries showed a decrease in the proportion of prescription medicated nights from 39.3% in Core 1 to 26.2% in Core 6 (P < 0.001).

CONCLUSIONS: Findings demonstrate the clinical benefit of a CBT-I digital therapeutic for treatment-seeking people with chronic insomnia in the real-world. Data showed clinically meaningful improvements in both insomnia severity and reduction in medication use outside of a clinical trial.

SPONSORSHIP: Pear Therapeutics.
G46 Patient characteristics and utilization associated with galcanezumab initiation in patients with migraine

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BACKGROUND: Galcanezumab (Emgality; Lilly, Indianapolis, IN) was approved for preventive treatment of migraine in adults in 2018. It is a monoclonal antibody specifically designed to bind to and inhibit the activity of calcitonin gene-related peptide (CGRP) ligand.

OBJECTIVE: The purpose of this study is to describe demographic and clinical characteristics of patients who initiated galcanezumab, as well as, adherence and persistence.

METHODS: Adult patients with at least 1 pharmacy claim for galcanezumab during the index period (01/01/2019-09/30/2019) and ≥ 1 claim for migraine (ICD-10 code G43.XX) at index or in the 12 months prior to index were identified within the IBM MarketScan Early View Database. This database includes longitudinal administrative claims data for more than 136 million enrollees in commercial and Medicare Advantage insurance plans. Patients were required to be continuously enrolled for 12-months prior to the index date (date of first fill of galcanezumab during the index period) and at least 6 months post-index. Descriptive analyses of pre-index demographic, clinical characteristics and 6 months adherence and persistence were conducted. Adherence was defined by medication possession ratio (MPR) and proportion of days covered (PDC) during 6 months post-index. Persistence (length of therapy [LOT]) was defined as the time from the index date until first discontinuation with a gap greater than 60 days or to 6 months post-index.

RESULTS: A total of 4,277 patients with migraine who initiated galcanezumab were identified (mean (SD) age: 44 (12) years; female 87%) with 56% diagnosed with chronic migraine at index or in the 12 months pre-index. Neurology (51%), Family Practice (16%), and Nurse Practitioner (7%) were the most common prescriber specialties. Approximately 79% of patients who initiated galcanezumab were on a preventive therapy in the pre-index period and the majority (93%) were on an acute medication. Average 6-month post-index MPR and PDC were 0.86 (0.14) and 0.71 (0.27), respectively and average LOT was 128 days.

CONCLUSIONS: The majority of patients who initiated galcanezumab had a prior preventive treatment for migraine and used acute medications. Additionally, over half were diagnosed with chronic migraine. At 6 months, both mean adherence (MPR, PDC) and persistence (LOT) were high with galcanezumab. Understanding characteristics of patients who initiate galcanezumab as well as adherence and persistence will provide valuable insights to clinicians and other health care decision makers.

SPONSORSHIP: Eli Lilly and Company.

G59 Real-world adherence, persistence, switching, and reinitiation in patients prescribed Ajovy in U.S. physician practices

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BACKGROUND: Ajovy (fremanezumab), a fully-humanized monoclonal antibody (IgG2Δa) that selectively targets calcitonin gene-related peptide (CGRP), has been approved for preventive treatment of migraine in adults.

OBJECTIVE: To evaluate real-world adherence, persistence, switching, and reinitiation among patients prescribed Ajovy in the U.S.

METHODS: Data for this study were obtained from the Veradigm Health Insights Database (AllScripts and Practice Fusion Electronic Health Records [EHR] Databases). The study period was from January 1, 2014 to June 30, 2019. Patients were included if they had: ≥1 migraine diagnosis during the study period (first migraine diagnosis date was the initial diagnosis date); a medication record for Ajovy on or after the initial diagnosis date during the identification period (September 1, 2018 to December 31, 2018; Ajovy initiation date was the index date); and age ≥ 18 years on the index date. Patients were excluded from the study if they had missing/unknown age or sex information, prescription record for any CGRP pathway-targeted therapy at any time prior to the index date, or evidence of pregnancy or childbirth at any time during the study period. Adherence and persistence were evaluated for all patients with dosing data, and switching and reinitiation for the first treatment change were evaluated for patients with dosing data who discontinued treatment (i.e., gap of ≥ 45 days followed by activity in EHR).

RESULTS: 987 patients prescribed Ajovy were included; 594 (60.2%) had episodic migraine and 393 (39.8%) had chronic migraine. Most patients were female (842 [85.3%]) and 41-64 years of age (595 [60.3%]). Anxiety (152 [15.4%]) and depression (143 [14.5%]) were the most common comorbidities during the baseline period. Based on proportion of days covered of ≥ 80% and medication possession ratio of ≥ 80%, 738 (74.8%) and 780 (79.0%) patients, respectively, were adherent. 746 (75.6%) patients were persistent for ≥ 6 months. Of 216 (21.9%) patients who discontinued Ajovy, 7 (3.2%) switched to other CGRP pathway-targeted treatments (Emgality or Aimovig), 89 (41.2%) switched to a different acute or non-specific preventive treatment class, 21 (9.7%) reinitiated Ajovy treatment, and 103 (47.7%) permanently discontinued any acute or preventive migraine therapy.

CONCLUSIONS: Real-world treatment adherence and persistence were high with Ajovy; the majority of patients who discontinued treatment switched to a different preventive treatment class or discontinued any treatment, and several patients restarted Ajovy.

SPONSORSHIP: Teva Pharmaceuticals.

G60 Implementation of a clinical pharmacy specialist anti-epileptic drug management program in pregnant women with epilepsy

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BACKGROUND: The management of pregnant women with epilepsy (WWE) on anti-seizure drugs (ASD) is complicated by a lack of randomized controlled clinical studies, outdated guidelines, pregnancy-derived serious pharmacokinetic changes, and non-adherence. Worsened seizure control is associated with risk of physical injury to mother and fetus and increased health care costs. We describe a pharmacist-led program in a managed care organization that comprises comprehensive medication education, individualized therapeutic drug monitoring (TDM), and medication adherence review and education with the intention of improving and/or maintaining seizure control during pregnancy and immediately post-partum in this high-risk population.

OBJECTIVE: To improve the management of pregnant WWE on ASDs by implementing a standardized, clinical pharmacist driven, management program during pregnancy and postpartum.

METHODS: Pregnant WWE on ASDs are referred to CPSN and prior to outreaching the patient, CPSN reviews and assesses contraception and folic acid use, seizure history, pharmacokinetic concerns, prior ASD levels, and any prior pregnancies while on ASDs. A pre-pregnancy ASD level, or the earliest obtained during pregnancy, is used as a baseline for comparison of TDM results throughout pregnancy, which are checked on an average of every 4 weeks. When ASD levels are baseline for comparison of TDM results throughout pregnancy, which are checked on an average of every 4 weeks. When ASD levels are obtained, CPSN will recommend ASD dose adjustments, if needed. CPSN will also assess for ASD adherence, continued folic acid use, and the presence of breakthrough seizures. A post-delivery plan including instructions on how the patient should decrease their ASD dose is created. During postpartum, CPSN ensures ASD dose(s) have been adjusted and contraception/future preconception planning are discussed. The methodology performed by CPSN is reviewed by the prescribing neurologist and communicated to all health care providers.

RESULTS: A total of 40 patients have been referred. Thirty-two patients were on ASD monotherapy and eight patients were on polytherapy. No delivery complications occurred in 24 patients who have delivered. Levetiracetam and lamotrigine doses were increased an average of 83% and 90% during pregnancy, respectively. Of the 21 patients referred during the first or second trimester, a total of 10 patients remained seizure free during pregnancy regardless of pre-pregnancy seizure control. Provoking factors were identified for some breakthrough seizures occurring during pregnancy.

CONCLUSIONS: This program demonstrates that a personalized, consistent approach to delivering high-quality of care for pregnant WWE can result when management is led by CPSN.

SPONSORSHIP: None.

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

H2 Assessing long-term response to teprotumumab in thyroid eye disease

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BACKGROUND: Thyroid eye disease (TED) is an autoimmune disease that presents with inflammation that often results in difficult to treat exophthalmos (proptosis) and diplopia, significantly altering patients’ vision and appearance. Teprotumumab, the first therapy approved to treat TED, was shown in 2 placebo-controlled trials to improve rigorous primary endpoints such as proptosis (decrease of ≥ 2 mm) alone and in combination with clinical activity score (CAS) improvement, in a high percentage of pts at 24 weeks, although limited data exist on clinically meaningful changes in proptosis and other important TED symptoms over the long term after drug discontinuation.

OBJECTIVE: Here we assess long-term impact of treatment on inflammation and difficult to treat proptosis and diplopia individually and collectively over study follow-up.

METHODS: Pts with moderate/severe TED from the phase 2 trial were followed for 51 wks (study wk-72) after the last infusion of teprotumumab. To mirror clinical practice, we performed an assessment of % of observed pts with any improvement in the CAS, proptosis (mm) and grade of diplopia (Gorman Score) and % with disease inactivation (CAS of 0/1) at wk-72. Pts were also assessed for any improvement in one or more of: CAS, proptosis, or diplopia collectively. This was an analysis of pts randomized to teprotumumab.

RESULTS: 42 pts received teprotumumab, 37 completed the 24 wk study with 37 reporting one or more of the outcomes under evaluation at wk-72: 97% (36/37) improved CAS (decrease of ≥1), 86% (31/36) had any decrease in proptosis, 70% with baseline diplopia (23/33) improved ≥1 grade of diplopia, 70% (26/37) had disease inactivation (CAS 0/1) and 100% (37/37) had improvement in ≥1 of the outcomes: all from baseline. Four individual pts included in one or more of the outcomes above received non-teprotumumab therapy during follow-up.

CONCLUSIONS: These ‘real world’ follow-up analyses indicate that high percentages of pts who received teprotumumab during a placebo-controlled study demonstrate some improvement from baseline in a variety of important TED outcomes 51 weeks after the last dose. Noteworthy were improvements in the longer term and progressive outcomes of proptosis and diplopia. Active inflammation becomes quiescent overtime but fibrosis can remain creating long term morbidity. The long-term extension of the phase 3 study is investigating whether those few patients who may not show an immediate benefit might respond to a second course of therapy.

SPONSORSHIP: Horizon Therapeutics.

H7 Economic impact of a payer management strategy to improve the utilization of lower cost anti-VEGF therapies for the management of diabetic macular edema (DME) or diabetic retinopathy (DR)

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BACKGROUND: Diabetic retinopathy (DR) and diabetic macular edema (DME) are leading causes of vision loss in working-age adults. Intravitreal therapy (IVT) with anti-vascular endothelial growth factor (anti-VEGF) agents is commonly used for the management of DR/DME. Lucentis (ranibizumab) and Eylea ( aflibercept) are FDA-approved for treatment of DR/DME while bevacizumab is commonly used off-label. Due to significant cost differences between agents
indicated for DR/DME (Eylea 2.0 mg wholesale acquisition cost or WAC $1,850, Lucentis 0.3 mg WAC $1,170), select health plans have implemented “step therapy” policies that require patients try less costly agents (Lucentis or off-label bevacizumab) prior to Eylea.

**OBJECTIVE:** To assess the utilization and economic impact of implementing step therapy of FDA-approved anti-VEGF IVT for the treatment of DR/DME.

**METHODS:** A retrospective cohort study evaluated utilization and cost data from paid medical claims managed by Magellan from two large health plan partners. Patients who received IVT for a diagnosis of DR/DME were included, and comparisons were made between FDA-indicated agents Lucentis and Eylea. We evaluated how step therapy policy impacted 1) new patient starts by IVT agent, and 2) compared utilization and costs in the period prior vs. post-policy implementation. Health plans from which data were combined instituted the same policy change on a different date ranging from 3/1/2018 to 8/1/2018.

**RESULTS:** A total of 1,457 patients initiating therapy on either Lucentis or Eylea in DR/DME (912 patients pre-, and 545 post-policy implementation) were evaluated. While overall new starts decreased 37% following policy implementation (largely due to a decrease in plan size), new starts for Lucentis increased 2% (324 vs 338 patients) accounting for 62% of new starts, whereas new starts with Eylea decreased 65% (588 vs. 207 patients) accounting for 38% of new starts. The average 12-month drug cost for a patient starting on Lucentis was $4,352 and $7,183 for Eylea. This would result in total 12-month costs would be $4.9 million resulting in savings of ~$0.7 million among patients initiating therapy.

**CONCLUSIONS:** Enacting an IVT step therapy policy for patients with DR/DME resulted in a significant reduction of new starts with Eylea and an estimated 12% reduction in drug costs among FDA-indicated agents over a 12-month period.

**SPONSORSHIP:** Biogen.

**H9**

**Cost-effectiveness of hydruis plus cataract surgery compared to cataract surgery alone in the United States**

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**BACKGROUND:** Primary open angle glaucoma (POAG) is treated with intraocular pressure (IOP) lowering medications, laser and surgical procedures to diminish rates of vision loss. The HORIZON trial showed that Schlemm’s canal implantation of Hydrus + cataract surgery (CS) was associated with fewer medical and postoperative surgical interventions at 60 months vs CS alone.

**OBJECTIVE:** This analysis evaluates cost-effectiveness of Hydrus + CS vs CS alone for treating patients with POAG in the United States.

**METHODS:** A societal-perspective semi-Markov model simulated the natural history of POAG to assess patients’ costs, health outcomes, and quality-adjusted life years (QALYs) over 15 years (age 65; 66% males, 66%; commercial health insurance, 66%). Overall, the CHM group had higher mean baseline CCI (0.47 vs. 0.26; P<0.001). In the follow-up period after adjusting for CCI, the CHM group had more hospital admissions (0.09 vs. 0.06; P=0.03), outpatient visits (22 vs. 11; P<0.001), and emergency department visits (0.41 vs. 0.26; P<0.001) per patient per year. The CHM group had higher overall annual costs ($15,372 vs. $9,285, P=0.005), this difference was primarily driven by higher outpatient costs for the CHM group ($836 vs. $4,720, P=0.02). The CHM group consistently had higher costs than the matched control group, particularly in the age range between 20 and 44 years ($14,544 vs. $9,953, P=0.01).

**CONCLUSIONS:** The CHM group had higher health resource utilization and costs compared with the matched control group. These findings are comparable with published estimates of mean annual costs per person for individuals with severe visual impairment. These results provide some economic context around the excess health care utilization associated with CHM and can inform U.S. payers about the impact of CHM.

**SPONSORSHIP:** Biogen.
of life inputs and costs associated with blindness. Public databases such as Medicare Fee Schedules and MediSpan PriceRx were used to identify procedure costs and wholesale acquisition costs (WAC) for medications. Scenario analyses were used to explore the impact of key inputs and assumptions, including market distribution of medications to inform class-level costs.

RESULTS: Patients with CS alone experienced 54% more surgeries than patients with Hydrus + CS. Based upon the semi-Markov model, Hydrus + CS was associated with lower cost (savings of $3,586 to $1,382) and greater glaucoma related QALYs (0.108, 1.3 months) over a 15-year horizon. Hydrus + CS was projected to become cost-neutral, based on reduced need for glaucoma medications, fewer postoperative glaucoma procedures and lower risk of progression to blindness, in approximately 5 years using average WAC per drug class, and in approximately 9 years when assuming generic dominated drug costs based on estimated prescribing patterns.

CONCLUSIONS: Hydrus implantation + CS is a cost-saving intervention for long term management of mild-to-moderate POAG due to reduced need for glaucoma medications and postoperative surgical interventions relative to CS alone.

SPONSORSHIP: Ivantis.

Impact of motivational interviewing intervention in Texas Medicare Advantage patients with hypertension

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BACKGROUND: Effective management of hypertension in patients with concomitant dyslipidemia presents enormous challenges due to patient nonadherence. Prior studies have shown pharmacist-led telephonic motivational interviewing (MI) interventions can enhance medication adherence. An MI intervention, conducted by pharmacy students and tailored by past adherence trajectories among non-adherent statin users, showed improvement in statin adherence 6 months post-MI intervention.

OBJECTIVE: The aim of this study was to explore if prior MI intervention, conducted by pharmacy students, also improved adherence to antihypertensive medications in a Medicare Advantage (MA) population.

METHODS: A cohort of patients with a history of nonadherence to statins was randomly allocated to receive intervention between January-September 2017. The study population comprised of 152 patients who received the intervention compared to 304 controls. Patients with prescriptions filled for both statin and antihypertensive medications 6 months before and after the intervention were identified from pharmacy claims data. The primary outcome was adherence to antihypertensive medications, defined as proportion of days covered (PDC) during the 6 months following the intervention. The baseline difference in post-intervention adherence was compared between the intervention and control groups using Chi-square tests and T-tests. Logistic regression analysis was used to evaluate the effect of the intervention on adherence to antihypertensive medications during the 6 months post-intervention, adjusting for patient demographics and baseline adherence.

RESULTS: A total of 80 (52.6%) patients from the intervention group and 159 (52.3%) patients from the control group filled prescriptions for antihypertensive medications. No significant difference in antihypertensive medication adherence during 6 months post-intervention was observed with the statin targeted intervention. Significant predictors of adherence included pre-PDC ≥ 0.80 (OR=4.19, 95% CI: 2.1-8.75) and patients above the age of 70 years (OR=2.14, 95% CI: 1.09-4.2).

CONCLUSIONS: Enhancing medication adherence to chronic medications will likely require interventions customized to the specific medication group(s). Tailoring the intervention to assist in identifying and addressing the associated patient behavioral and socioeconomic barriers to adherence is advisable.

SPONSORSHIP: None.

Major adverse cardiovascular events and associated costs following acute myocardial infarction: a 90-day perspective

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BACKGROUND: Centers for Medicare and Medicaid Services (CMS) has implemented a voluntary bundled payment program centered on a 90-day period for acute myocardial infarction (AMI) to increase quality of care and reduce costs. While clinical practice guidelines recommend effective Standard of Care (SoC) pharmacotherapy for secondary prevention following AMI, most current treatments are slow to become efficacious, leaving patients at risk for recurrent events in the immediate post-AMI period. The clinical and economic burden of recurrent AMI events among guideline treated patients, specifically in the 90 day period post AMI, has been relatively unexplored.

OBJECTIVE: To quantify the clinical and economic burden of recurrent AMI events in the 90- and 365-day periods post AMI, among guideline treated patients.

METHODS: A retrospective analysis was conducted using the IBM Health MarketScan Commercial Claims and Encounters database (July 1, 2013-June 1, 2016). We evaluated recurrent AMI events within 90- and 365-days post-AMI and their associated costs among commercially insured individuals with a primary diagnosis of AMI who received SoC pharmacotherapy.

RESULTS: Of the 21,977 patients included in the analysis, few received all SoC pharmacotherapy classes (17%). Among those who did, the risk of recurrent AMI events at 90 days (OR=1.03 [95% CI: 0.73-1.46]) and 365 days (OR=0.80 [95% CI: 0.60-1.07]) did not differ significantly compared to patients not receiving SoC pharmacotherapy. When projected to a 1 million member population, total avoidable costs of recurrent AMI were $14,752,820 (90 days) and $32,825,686 (365 days).

CONCLUSIONS: Recurrent AMI events were observed at both 90 and 365 days, despite guideline directed SOC following discharge in a commercially insured population. Opportunities to reduce the economic burden of recurrent AMI events warrant further investigation.

SPONSORSHIP: CSL Behring.
**Understanding the role of value-based contracts in improving patient access**

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**BACKGROUND:** As the U.S. healthcare system shifts from a “volume to value”, there has been increased implementation of Value Based Contracts (VBCs) between manufacturers and payors. However, some payors remain sceptical of VBCs due to lack of direct cost-savings.

**OBJECTIVE:** To understand the role of VBCs in improving patient (pt.) access to specialty drugs, by evaluating the effect of VBCs on (1) change in no. of patients (pts.) per month and, (2) average (avg.) per pt. drug cost to a payor.

**METHODS:** Claims data obtained from DRG (Decision Research Group) repository was evaluated for Entresto, Praluent, Enbrel and Forteo. Time-periods studied were based on the tenure of the contract. SAS 9.4 program was used to extract the data using ICD9/10 code, NDC code, date of claim submitted, drug cost per pharmacy claim. The analysis involved: a. Time trends (for effect of VBCs within single payors) and, b. Difference-in-difference (DID) (to compare effect amongst multiple payors). Before-after analysis, regression analysis and DID model was run in STATA/SE 15.0. DID equation: Avg. no. of pts. per month = a + bD + bT + bE + error; Avg. per pt. per month drug cost = a + bD + bT + bE + error; D:Treatment group; T: time period; E: effect of intervention, VBC.

**RESULTS:** Entresto: For Payor 1 (Cigna), Payor 2 (Aetna) and Payor 3 (Harvard Pilgrim) VBC is associated with +45 (<0.005), +60 (<0.005), +6.44 (P<0.005) increase in pts per month; and +$92.35 (P<0.005), +$80.45 (P<0.005) and +$72.64 (P=0.434) increase in per pt. per month avg. cost. The DID analysis shows +$440 (P<0.001) pts. due to VBC and -$23.16 (P<0.001) avg. per pt. per month cost. Praluent: No effect observed at single payor level. However, when compared between payor with and without VBCs, the DID analysis shows +$140 (P<0.005) pts. increase and nominal +$11.45 (P>0.05) avg. per pt. per month increase. Enbrel: No effect observed at single payor level. DID analysis using payors with and without VBCs, showed +$11.37 (P<0.001) number of Enbrel pts. and +$135.56 (P<0.001) avg. per pt. per month increase. Forteo: Similar to Enbrel and Praluent no single payor impact was documented, however the DID analysis using payors with and without VBCs, showed +$69.96 (P>0.5) avg. per pt. per month increase.

**CONCLUSIONS:** The data shows that VBCs increased number of pts. able to access specialty products. They serve as managed entry tool for launch products (Praluent, Entresto) or, helped maintain formulary listing for mature products (Enbrel, Forteo). VBCs did not have any significant cost savings to payors.

**SPONSORSHIP:** Amgen.

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**Sacubitril-valsartan real-world assessment of total cost of care and resource utilization pre/post initiation among commercially insured members with reduced ejection fraction heart failure**

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**Prime Therapeutics**

**BACKGROUND:** Sacubitril-valsartan (sac-val) is FDA approved to treat heart failure with reduced ejection fraction (HFrEF) in NYHA class II-IV and been proven to reduce mortality and hospitalizations. Little is known of sac-val real-world impact on total cost of care (TCC) or medical events.

**OBJECTIVE:** To assess the extent to which CER findings are integrated into CMS formulary coverage of DOACs.

**METHODS:** Two separate analyses were designed. First, a systematic literature review was conducted from 2011-2017 using MEDLINE and Google Scholar to identify CER evidence (meta-analyses, systematic reviews, randomized controlled trials, observational studies) comparing DOACs. Secondly, change point analysis was conducted using Part D files to assess the changes over time (2011-2017) in tier level, quantity limit, prior authorization, cost type and amount for each DOAC using changepoint package in R version 3.5.3. Associations were evaluated between the CER evidence and formulary changes.

**RESULTS:** CER evidence on DOACs’ efficacy evolved from 2011-2017. Until 2013, dabigatran and rivaroxaban showed comparable efficacy. In 2014, studies showed apixaban was superior to dabigatran and rivaroxaban in stroke prevention. In 2015, studies showed that edoxaban’s efficacy was similar to rivaroxaban, but inferior to apixaban and dabigatran. In 2016, some studies showed no difference between DOACs, while some supported apixaban’s superiority. In 2017, studies suggested that dabigatran and apixaban had similar efficacy that was superior to edoxaban. Throughout 2011-2017, studies showed that apixaban was the safest drug with lowest bleeding risk, followed by dabigatran and rivaroxaban. Evidence on edoxaban’s safety was unclear. Formulary data analysis showed that 50-75% of plans covered dabigatran, rivaroxaban and apixaban under Tier 3 until 2015, after which the majority of plans covered dabigatran and edoxaban under Tier 4. About 50% of plans offered cost sharing (copayment or coinsurance) for all DOACs through 2016. Of those, 25% eliminated cost sharing after 2016. Mean copayments decreased significantly for rivaroxaban after 2013 and apixaban after 2014, but increased significantly for dabigatran and edoxaban after 2015. From 2011-2017, less than 30% of plans required prior authorizations, and about 50% imposed quantity limits for the drugs.

**CONCLUSIONS:** The majority of CMS plans covered apixaban more favorably, but covered dabigatran and edoxaban less favorably, which appears consistent with the CER evidence for DOACs.

**SPONSORSHIP:** Internal grant.
OBJECTIVE: To determine the pre- and post-period change in TCC and events: hospitalizations (hosp) and emergency department (ED) visits in members newly initiating sac-val to treat HFrEF using real world data.

METHODS: Among 15 million commercially insured members with integrated medical and pharmacy claims data, those 18 to 65 years, newly initiating sac-val from Oct 2018 to Sep 2019, with HFrEF, continuously enrolled 12 months pre/post sac-val initiation, and sac-val adherent proportion days covered ≥80% during post period had their pre to post TCC and events compared. There was a 2-month wash-out period pre and post the sac-val initiation date where medical costs and events were excluded because sac-val is generally initiated as a result of HF hosp. Pre/Post TCC and events comparison consisted of the 10 months (12 to 0) pre and 10 months (3 to 12) post sac-val initiation. TCC included all pharmacy and medical claims member share and plan allowed amounts with all sac-val discounts applied; post costs were adjusted for inflation. Statistical change was assessed using the student’s paired T-test for costs and McNemar test for percentage change of members with an event.

RESULTS: 658 members met study criteria with a TCC pre-period mean $46,242 (standard deviation [SD] $89,058) and median $18,973 compared to post-period mean $36,383 (SD $64,251) and median $16,953, P < 0.01, for a mean decrease $9,889 (21.3%) with a 95% confidence interval decrease of $2,675 to $17,042 in TCC associated with sac-val initiation. Pharmacy costs increased 144%, P < 0.01 and medical costs decreased 39.5%, P < 0.01. The percent of members with a hosp was pre 34.8% to post 12.8%, P <0.01 and ED visit percentage pre 45.0% to post 25.2% post, P < 0.01.

CONCLUSIONS: 658 commercially insured members newly initiating and adherent to sacubitril-valsartan for a year were found to have a cumulative $6.5 million lower total cost of care post sac-val initiation compared to prior to initiation. These significant real-world findings along with a pharmaceutical manufacturer value-based contract, clinical trial data, and clinical guidelines resulted in the removal of sac-val prior authorization. Integrated medical and pharmacy benefits provide ability to execute VBCs, feasibility to assess medication value, and inform insurers management decisions.

SPONSORSHIP: Prime Therapeutics.

110 Economic burden of patients with complicated pericarditis: a longitudinal analysis based on a U.S.-based employer claims database

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BACKGROUND: Acute pericarditis (AP) is a debilitating inflammatory heart condition where recurrence may occur in up to 30% of patients (pts) within 18 months of their initial AP episode. Complicated pericarditis (ComP) affects a subset of recurrent patients with multiple recurrences, leading to worse outcomes, and potentially higher healthcare resource utilization (HCRU).

OBJECTIVE: To evaluate the incremental direct healthcare and indirect work-loss costs associated with ComP.

METHODS: Study sample includes adults with a first diagnosis of idiopathic AP identified in the OptumHealth Reporting and Insights dataset (2007-2017) and with ≥12 months of baseline prior to the initial AP diagnosis and ≥18-month follow-up period. Recurrence was defined as ≥2 pericarditis episodes separated by >4 weeks. ComP pts, defined as having ≥2 recurrences, were propensity score matched 1:1 to AP pts without recurrence. HCRU, including direct healthcare costs (hospitalizations, outpatient visits, and prescription drugs) and indirect work-loss costs (disability and medically-related absenteeism), were compared between the ComP and AP cohorts on a per pt per month (PPPM) basis to account for varying follow-up periods by patient.

RESULTS: Each matched cohort had 375 pts. Mean disease duration was 12.7 months for the ComP cohort and mean follow-up was 27.9 months for the AP cohort. The ComP cohort had higher rates of PPPM hospitalizations (0.05 vs 0.02; rate ratio [95% confidence interval] = 2.22 [1.35, 3.65]), outpatient visits (1.91 vs 1.30; 1.46 [1.25, 1.75]), and emergency department visits (0.07 vs 0.04; 1.79 [1.23, 2.61]; all P <0.01) than the AP cohort. Mean total healthcare costs PPPM were significantly higher in the ComP vs AP cohort ($2,728 vs $1,568; cost ratio [95% CI] = 1.74 [1.29, 2.32], P <0.01), which were mainly driven by significantly higher hospitalization costs ($1,180 vs $420; 2.61 [1.80, 4.66], P <0.01) than the AP cohort. Mean indirect costs PPPM were significantly higher in the ComP vs AP cohort ($696 vs $169; cost ratio [95% CI] = 4.12 [1.64, 9.61], P <0.01).

CONCLUSIONS: Pts with ComP have substantially greater direct and indirect costs, including a nearly two-fold increase in direct healthcare costs and four-fold increase in work-loss costs compared to pts with AP alone. Safe, effective, and accessible treatments are needed to prevent recurrences, reduce disease morbidity, and avoid significant economic burden to healthcare systems and employers.

SPONSORSHIP: Kiniksa Pharmaceuticals.

111 Real-world analysis of healthcare utilization among heart failure patients treated with Entresto (sacubitril/valsartan)

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BACKGROUND: Sacubitril/valsartan (SAC/VAL) was approved in the U.S. for treatment of HF with reduced ejection fraction (HFrEF) in July, 2015. Early real-world data showed that patients experienced a lower rate of hospitalization and reduced medical spending following initiation of SAC/VAL. As uptake of SAC/VAL gradually increased since its approval, more recent data are needed to understand whether use of SAC/VAL continues to deliver medical savings in a broader population of HFrEF patients.

OBJECTIVE: To describe changes in all-cause, HF with reduced ejection fraction (HFrEF)-related and HFrEF-specific healthcare costs in the 12-month period before and after SAC/VAL initiation by treatment adherence level.

METHODS: This retrospective cohort study analyzed patients enrolled in a Commercial plan or Medicare Advantage (MA) plan in the Optum claims database between July 1, 2014, and March 31, 2019. Patients with HFrEF diagnosis on ≥1 inpatient or outpatient claim, newly
initiated Entresto between July 1, 2015, and March 31, 2018 (index date) and insured 12 months prior and post index date were included in the analysis. The all-cause, HFrEF-related and HFrEF-specific annual medical costs were examined 12 months before and after initiation of SAC/VAL. Patients were assigned to non-mutually exclusive cohorts based on adherence level to SAC/VAL measured using proportion of days covered (PDC). Three adherence levels were examined, including PDC≥40%, PDC≥60%, and PDC≥80%. All medical costs were adjusted for inflation to 2018.

RESULTS: A total of 1,545 commercially insured and 5,682 MA patients met the study criteria and included in the analysis. Compared to the 12 months prior to SAC/VAL initiation, the commercially insured patients incurred lower all-cause annual medical costs ($12,266 for PDC≥40%, $15,010 for PDC≥60%, and $17,499 PDC≥80%), HFrEF-related annual medical costs ($5,789, $8,073, and $10,930, respectively), and HFrEF-specific annual medical costs ($1,839, $3,004, and $3,341, respectively) in the 12 months following SAC/VAL initiation. Similarly, the MA patients had a decrease in mean all-cause annual medical costs ($3,497, $5,634, and $7,694, respectively), HFrEF-related annual medical costs ($1,111, $2,320, and $3,960, respectively), and HFrEF-specific annual medical costs ($1,858, $2,131, and $2,138, respectively) in the 12 months following initiation of SAC/VAL.

CONCLUSIONS: The commercial and MA insured patients incurred lower all-cause annual, HFrEF-related and HFrEF-specific medical costs within 12 months of SAC/VAL initiation.

SPONSORSHIP: Novartis Pharmaceuticals.

Effect of the initial maintenance dose of droxidopa on treatment persistence in patients with neurogenic orthostatic hypotension

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BACKGROUND: Patients with autonomic dysfunction can experience neurogenic orthostatic hypotension (nOH), a sustained drop in blood pressure on standing, which can lead to falls, impaired function, and poor quality of life. Treatment with droxidopa (approved to treat nOH symptoms) requires titration to an individualized effective dose (100-600 mg 3 times daily [tid]). Per the product label, droxidopa should be titrated every 24-48 hours in 100-mg tid increments to the optimum maintenance dose, based on symptomatic response, up to a maximum total daily dose of 1,800 mg (600 mg tid). In clinical trials, patients were titrated to mean daily droxidopa doses of 1,167-1,404 mg; 82% of patients treated with droxidopa were titrated differently from the product labeling recommendation) and had an average daily titration dose of 567 mg; 47% were titrated according to the product label schedule (48-hours, 37%; 24-hours, 10%) and had daily titration doses of 1,500-1,650 mg. The average daily maintenance doses in patients who received 2, 3-6, 7-24, and >25 dispenses were 938 mg, 969 mg, 1,069 mg, and 1,167 mg, respectively (P<0.0001).

RESULTS: In this analysis of real-world practice, more than half of patients treated with droxidopa were titrated differently from the schedule recommended in the product label (i.e., not 24-48 hours) and received lower daily doses of droxidopa than those treated using recommended titration schedules. A lower daily maintenance dose of droxidopa was associated with shorter treatment persistence (i.e., less dispenses), while patients who were titrated to higher dosage received more follow-up dispensing. Reasons for discontinuation could not be examined in this study, but further investigation of these persistency data is warranted.

J00-J99 Diseases of the Respiratory System (e.g., Asthma, COPD, Rhinitis, RSV)

J2 The role of social determinants of health in adult influenza vaccination: a nationwide claims analysis

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BACKGROUND: The health and economic benefits of the annual influenza vaccine are well defined, yet vaccination rates in the United States are below the Healthy People 2020 goal and multiple factors are likely contributors. By identifying underlying reasons for low annual influenza vaccination, social elements that need targeting may be identified and could guide future interventions or policy development, to achieve vaccination goals and improve overall public health.

OBJECTIVE: To determine the influence of certain social determinants of health on adherence to annual influenza vaccination in American adults.

METHODS: This was a retrospective cohort analysis of American adults (18 years and older) who were continuously enrolled in employer-sponsored, Medicare Advantage, or traditional fee-for-service Medicare coverage between 2013-2016. Receipt of the influenza vaccine was counted over three consecutive influenza seasons and select social determinants were extracted from publicly-available sources. Patient characteristics, health resource utilization, and social determinants of health were included in bivariate and logistic regression analyses to determine their association with annual influenza vaccination.

RESULTS: A total of 7,816,421 adults across employer-sponsored and Medicare coverage groups were analyzed, of which 9.2% received an

P < 0.0001.
influenza vaccine in all three seasons. Higher proportions of vaccine adherence (i.e., all 3 seasons) were observed among females (9.6%), the immunocompromised (10.8%), rural residents (9.9%) (all P<0.0001), and those enrolled in a high-deductible health plan (10.3%). Multivariable models indicated the odds of vaccinating in all 3 years were somewhat more likely in areas of higher health literacy (AOR: 1.035; 95% CI: 1.033-1.036), in individuals with more prescription fills (AOR: 1.006; 95% CI: 1.006-1.006), in communities with lower rates of Internet access (AOR: 1.011; 95% CI: 1.010-1.013), and among those who did not relocate during the observation period (AOR: 1.05; 95% CI: 1.035-1.060). Slightly lower odds were observed in more liberal voting areas (AOR: 0.998; 95% CI: 0.997-0.999).

**CONCLUSIONS:** Key social determinants of health are important factors of vaccine adherence and can guide policy and intervention efforts toward addressing potential hesitancy. A deeper assessment of other contributing social factors is needed in seasonal influenza and other vaccines to better interpret the vaccine-seeking behaviors of adults.

**SPONSORSHIP:** None.

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**J6** Assessment of healthcare resource use by comorbidity burden among COPD patients diagnosed across multiple payer settings

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**BACKGROUND:** The multimorbidity of COPD presents a substantial burden to the healthcare system. However, there is limited real-world evidence describing healthcare resource use (HRU) by comorbidity burden in COPD across payer types.

**OBJECTIVE:** To describe comorbidity burden and HRU prior to and after diagnosis of COPD among patients who are Medicare Fee-for-Service (FFS), Commercial (Com), Managed Medicaid (MM), and Medicare Advantage (MA) health insurance enrollees.

**METHODS:** This retrospective study utilized CMS sourced 100% sample of Medicare FFS claims and the Inovalon MORE2 Registry (Com, MM, and MA). The first diagnosis of chronic bronchitis, emphysema, or COPD in any position from an emergency department (ED) visit, hospitalization, or two outpatient medical visits (>30 days apart) between 1/1/2015-9/30/2018 (MORE2) or 1/1/2015-12/31/2017 for Medicare Advantage (MA) health insurance enrollees. Patients with asthma, interstitial fibrosis, sarcoidosis, pulmonary hypertension, pulmonary embolism, and cancer (excluding lung and skin) were excluded. The number of comorbidities were categorized (0, 1-2, and 3+) and included: smoking, upper respiratory tract infection, pneumonia, hypertension, hyperlipidemia, diabetes mellitus, heart failure, sleep apnea, anxiety and/or depression, and lung cancer. HRU is defined by hospitalization, readmissions, ED visits, physician office visits, and skilled nursing facility use.

**RESULTS:** A total of 1,406,727 patients met study criteria (FFS: 84.1%, Com: 4.5%, MM: 7.5%, MA: 3.9%). Average age for the overall cohort was 70±11.6 and 59.2% were female. In the baseline period, 3.4% of patients had 0 comorbidities, 29.5% had 1-2, and 67.1% had 3+. Overall, the proportion of patients with ≥1 all-cause hospitalization increased with comorbidity burden during the 1-year follow up period (0: 6.8%, 1-2: 14.3%, 3+: 37.6%). The overall proportion of patients with ≥1 COPD-related hospitalization was 0: 1.1%, 1-2: 2.1%, and 3+: 5.1%. Across payer type, rates of inpatient visits for those with 3+ comorbidities were 4 to around 9 times greater than those with 0 comorbidities.

**CONCLUSIONS:** Compared to those with 0 comorbidities, COPD patients who have comorbidities consistently have higher rates of HRU and HRU increases as comorbidity burden increases; this pattern is consistent across payer types. This highlights the need for earlier intervention after COPD diagnosis in these patients and holistic management of their multimorbidity.

**SPONSORSHIP:** AstraZeneca.

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**J7** Evaluating total all-cause and COPD-related costs by comorbidity burden in patients with Medicare fee-for-service

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**BACKGROUND:** COPD patients often have substantial comorbid disease burden, which can lead to increased costs. There is limited real-world evidence describing the cost of care by comorbidity burden in Medicare patients with COPD.

**OBJECTIVE:** To describe all-cause and COPD-related baseline and post-index healthcare costs in COPD patients with Medicare Fee-for-Service (FFS), by comorbidity burden.

**METHODS:** This descriptive retrospective study used Medicare FFS claims data (100% sample, Parts A/B/D) between 1/1/15 and 12/31/17 to identify patients >40 years, with at least one hospitalization, emergency department visit, or two outpatient medical encounters (>30 days apart), and a diagnosis of chronic bronchitis, emphysema, or COPD. Continuous enrollment required a year pre- and post-index. Patients with evidence of COPD diagnosis, COPD related treatment, or with any evidence of asthma, interstitial fibrosis, sarcoidosis, pulmonary hypertension, pulmonary embolism, or cancer during the baseline period were excluded. All reported costs were based on the Medicare payment amount, patient out of pocket spend, and any secondary payments made. Costs were reported in Consumer Price Index (CPI)-adjusted 2018 USD during both baseline and post-index. COPD-related costs were reported post-index. Patients were stratified by post-index comorbidity burden (categorized as 0, 1-2, or 3+ comorbidities).

**RESULTS:** 1,182,786 beneficiaries met inclusion criteria; mean age was 71.5±11.6 years, 59.7% were female, 83.3% were white, and mean baseline Charlson Comorbidity Index (CCI) score was 1.9±2.2. Compared to patients with 0 comorbidities, patients with 3+ had 16% ($27,740 vs. $23,736) and 54% ($33,727 vs. $21,882) greater total all-cause costs during baseline and post-index periods, respectively. Average total all-cause costs increased 22% over baseline for those with 3+ comorbidities and increased 8% for those with 0 comorbidities. In patients with 3+ comorbidities, COPD-related costs were 6-times greater than those with 0 comorbidities ($25,220 vs. $4,118) accounting for 75% of total all-cause costs (vs. 19%).
CONCLUSIONS: The level of multimorbidity among these COPD patients has substantial effects on total costs of care. This highlights the complexity of managing COPD patients and the need for earlier interventions and comprehensive patient-centered treatment strategies.

SPONSORSHIP: AstraZeneca.

J8 Characteristics of patients with non-IPF fibrosing interstitial lung disease as observed in a large real-world electronic health record database

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BACKGROUND: Patients with fibrosing ILD have a combination of lung function abnormalities and can develop a progressive phenotype characterized by worsening lung function, worsening symptoms, and/or increased extent of fibrosis, potentially leading to significant clinical and economic burden. Idiopathic pulmonary fibrosis (IPF) is a chronic fibrosing ILD that always displays a progressive phenotype. While the IPF population and their clinical burden is well characterized, little real-world evidence is available on the characteristics of patients with non-IPF fibrosing ILD, despite their risk of developing progressive disease.

OBJECTIVE: Describe clinical and demographic characteristics of patients with non-IPF fibrosing ILD.

METHODS: This was a retrospective cohort study using the Optum Clinical Database, a large, geographically diverse database including detailed clinical data derived from electronic health records. The study included patients aged ≥18 years with fibrosing ILD, defined as an ICD-10 diagnosis code for a relevant ILD on ≥2 encounters from 4/1/2016-1/31/2019. Patients were required to have ≥1 FVC value within ±30 days of the first qualifying diagnosis code (index date) and ≥1 FVC value 168-212 days later, and clinical activity for 6 months before and >9 months after index date. Patients were excluded if they were diagnosed with IPF, if they were prescribed nintedanib or pirfenidone, or if they had missing demographic information. Patient demographics and comorbidities were measured during the 6 months before index date. Demographic and clinical characteristics, including index FVC percent predicted (FVC%), were reported using descriptive statistics.

RESULTS: 1,494 patients were identified with non-IPF fibrosing ILD and >2 FVC measures, and 833 (56%) met all study eligibility criteria. Mean (standard deviation [SD]) age was 65 (14) years and 56% were female. The most common insurance types were Medicare (40%) and commercial (30%). 16% of patients had both Medicare and commercial. The mean (SD) Charlson Comorbidity Index score was 1.8 (1.8). The most common non-respiratory comorbidities were diseases of the heart (52%), hypertension (46%), and disorders of lipid metabolism (39%). Mean (SD) index FVC% was 81 (26) and 46% of patients, 16% of patients and 37% of patients had FVC% <80, 70-80, <70, respectively.

CONCLUSIONS: Many fibrosing ILD patients have reduced lung function as well as non-respiratory comorbidities. It will be important in future research to understand how lung function changes over time in these patients and how this impacts health and economic outcomes.

SPONSORSHIP: Boehringer Ingelheim.

J9 Clinical and demographic characteristics of patients with idiopathic pulmonary fibrosis who have preserved lung function

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BACKGROUND: In 2014, two medications were approved for treatment of idiopathic pulmonary fibrosis (IPF), a chronic, incurable lung disease characterized by a progressive decline in lung function. Nintedanib, one of these treatments, slows lung function decline in patients with and without preserved lung function. Despite this, many patients with preserved lung function do not receive treatment. Understanding characteristics of patients with preserved lung function may help determine if comorbid conditions or demographics contribute to suboptimal treatment in this population.

OBJECTIVE: This study aimed to examine demographic and clinical characteristics of IPF patients with preserved lung function.

METHODS: Patients with ≥1 FVC result from 01/01/2015-07/31/2019 were identified from the Optum Research Clinical Database, and the earliest observed FVC value was set as index date. Patients were required to have ≥2 encounters with an IPF diagnosis, have either high-resolution computed tomography or lung biopsy during the study period, be ≥40 years of age, and have clinical activity for 26 months prior to index, and ≥3 months after index. Patients were excluded if they had baseline antibiotic treatment; lung transplant; baseline use of supplemental oxygen; baseline or follow-up diagnoses for connective tissue disease; missing demographics; or a FVC% predicted (FVC%) <80. Comorbidities were documented at baseline, as was the diffusing capacity for carbon monoxide percent predicted (DLCO%) during baseline and/or follow-up.

RESULTS: 4,471 patients with IPF and FVC values, 631 patients with IPF and preserved lung function met study eligibility criteria. Mean (standard deviation [SD]) age was 70.9 (9.5) years, 35% were female, 90% were Caucasian, 44% were enrolled in a Medicare plan, 23% in a commercial plan, and 22% in both commercial and Medicare. The mean (SD) Charlson Comorbidity Index was 1.3(1.7), 32% had COPD, and 13% had pulmonary hypertension. The most common non-respiratory AHRQ comorbidities were diseases of the heart (49%), hypertension (35%), and disorders of lipid metabolism (33%). The median (interquartile range) for FVC% at index was 102 (90-120). DLCO% was available in 365 (58%) patients with a mean (SD) of 55 (21; baseline; n = 80) and 53 (20; index/follow-up; n = 348).

CONCLUSIONS: In a real-world population of IPF patients with preserved lung function, respiratory and non-respiratory comorbidities were prevalent and may complicate management of IPF. Future studies may evaluate the impact of preserving lung function in these patients, and its effect on patient outcomes.

SPONSORSHIP: Boehringer Ingelheim.
K4 Novel use of 4 formulary access scenarios in the development of a budget impact model

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BACKGROUND: Typical dual-scenario budget impact models (BIMs) are not well suited for the complex U.S. payer market and inflammatory bowel disease treatment landscape.

OBJECTIVE: To develop a multi-scenario BIM reflective of the real-world environment to estimate the budget impact when including a subcutaneous (SC) formulation of vedolizumab for treatment of moderate-to-severe ulcerative colitis

METHODS: In preparation for the commercial availability of vedolizumab SC in the United States, we consulted payer-facing colleagues at Takeda to identify potential formulary access scenarios. The field medical payer team conducted interviews with clinical decision makers among national and regional payers to evaluate the applicability of these scenarios to their organizations. Comparators were intravenous and SC vedolizumab, infliximab (branded and biosimilar), adalimumab (branded and biosimilar), golimumab, and tocilizumab. Inputs (drug cost and efficacy) and estimated market shares for each scenario were incorporated into a BIM for a 1 million-member health plan to estimate annual drug and medical costs for the first year of each scenario and for cumulative annual drug and medical costs up to 5 years.

RESULTS: The 4 validated scenarios included full access, access with 1 or 2 step-throughs, and no access (“a world without vedolizumab SC”). Scenario 1: Vedolizumab SC is first-line biologic treatment. Comparators’ market share is associated with second-line treatment values. Scenario 2: Adalimumab therapy required before vedolizumab SC. Other comparators do not have this step-through requirement. Scenario 3: Treatment is required with either adalimumab or infliximab (inputs are a weighted average between first- and second-line treatment values) before vedolizumab SC. Scenario 4: No access for vedolizumab SC. Comparative efficacy was estimated using Bayesian network meta-analysis, which included all pivotal randomized controlled clinical trials and one head-to-head trial of vedolizumab vs adalimumab. The model incorporated 52-week probabilities of response and remission and risk of surgery.

CONCLUSIONS: Unlike typical BIM dual scenarios (a world with or without a new drug entrant), this initiative sought to better reflect a spectrum of real-world access scenarios in the complex U.S. payer market. This method provides insights into the budget impact of both the commercial availability of vedolizumab SC and its formulary placement

SPONSORSHIP: Takeda Pharmaceuticals U.S.A.

K5 Cost per responder and cost per remitter analysis of ustekinumab versus adalimumab among patients with moderate to severe ulcerative colitis that have failed conventional therapy in the United States

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BACKGROUND: Ustekinumab (UST) was recently approved for patients with moderate-to-severe ulcerative colitis (UC). Adalimumab (ADA) is an approved biologic that is commonly used in UC. Lacking head-to-head trial data, clinical inputs from a previously conducted network meta-analysis (NMA) for UC were used for both UST and ADA, and a cost per responder and remitter (CPR) model was developed to indirectly compare the cost-effectiveness of the two biologics in patients who have failed conventional therapy.

OBJECTIVE: To compare annual cost per responder and cost per remitter for UST and ADA in moderate-to-severe UC among patients who have failed conventional therapy (non-biologic failure population).

METHODS: A CPR model was constructed using results from the NMA including delayed responders to induction for the non-biologic failure population. Percentage of patients achieving clinical response or clinical remission at the end of one year was the main efficacy outcome and was obtained from the NMA study. Differences between treatment and placebo groups (delta) in percentages of patients achieving clinical response for UST and ADA were 43% and 13%, and for achieving clinical remission were 28% and 10%, respectively. To account for market relevant rebates and discounts, Big Four prices from May 2020 were used to calculate the cost for the comparators ($1,153.92 per UST 130 mg vial, $12,384.50 per ADA 40 mg syringe, and $1,872.16 per ADA 40 mg syringe). Number of doses were derived based on the U.S. package inserts for UC. On average, one induction dose (130 mg vial X3) and 5.5 maintenance doses of 90 mg UST (Q8 weeks) and 6 induction (40 mg x 6) and 24 maintenance doses of 40 mg ADA (Q2 weeks) were used to reflect therapeutic coverage in the first year, respectively (assuming 100% adherence).

RESULTS: The annual cost per responder was $166,457 for UST and $445,752 for ADA and the annual cost per remitter was $254,721 for UST and $855,050 for ADA in the non-biologic failure population of patients with moderate-to-severe UC.

CONCLUSIONS: Using Big Four pricing assumptions, UST shows lower annual cost per responder and remitter than ADA at one year for adults with moderate-to-severe UC who have failed conventional therapy in the United States.

SPONSORSHIP: Janssen Scientific Affairs.

K7 Economic impact of vedolizumab IV versus adalimumab SC for moderately to severely active ulcerative colitis

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BACKGROUND: VARSITY (ClinicalTrials.gov ID: NCT02497469) is the first head-to-head trial comparing 2 biologic therapies, intravenous vedolizumab (VDZ IV) and subcutaneous adalimumab (ADA), in adults with moderately to severely active ulcerative colitis (UC).

OBJECTIVE: We evaluated the cost-effectiveness of VDZ IV vs ADA from a U.S. payor perspective.

METHODS: We used a cohort decision-tree model applied over 1 year. Simulated cohorts included patients with (79%) or without (21%) prior biologic therapy who underwent treatment induction with VDZ IV (300 mg in weeks 0, 2, and 6) or ADA (day 1: 160 mg, day 15: 80 mg)
for a 6-week induction period. Those with an adequate response to induction (as assessed by partial Mayo score) proceeded to maintenance treatment with VDZ IV (300 mg every 8 weeks) or ADA (40 mg every 2 weeks). Maintenance phase remitters continued treatment for the remainder of the model. Values from VARSITY were used to estimate discontinuations. Patients with inadequate response to induction or a serious adverse drug reaction (ADR) switched to treatment with biologics (tacitizumab, infliximab, or golimumab). Patients who could not tolerate subsequent biologic treatment received corticosteroids with or without curative surgery. The effectiveness of VDZ IV vs ADA with respect to induction response, maintenance response, and ADs were extracted from the VARSITY clinical trial. Model outcomes included total direct medical costs associated with drug acquisition, administration, routine monitoring, toxicity management, ADRs, and cost per remission (assessed by Mayo score) achieved. Costs are expressed in 2019 US$.

**RESULTS:** At 1-year follow-up, initiating treatment with VDZ IV was associated with a greater likelihood of remission vs ADA (53% vs 47%); a proportion of remissions were achieved with downstream biologics. Total direct medical costs per year were $70,327 for VDZ IV and $76,722 for ADA in the base case that assumed a mixture of patient treatment experience based on data from VARSITY.

**CONCLUSIONS:** Relying on clinical data selected from the first head-to-head clinical trial of biologic treatments in moderately to severely active UC, these modeled outcomes indicate that initiating treatment with VDZ IV is a preferred strategy with better clinical outcomes and lower direct medical costs.

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

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**K11 Differences in clinical characteristics and patient-reported outcomes of recently hospitalized versus non-hospitalized Crohn’s disease patients: real-world data from the Corrona Inflammatory Bowel Disease Registry**

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**BACKGROUND:** Crohn’s disease (CD) is a chronic inflammation of the gut with extensive disease burden, including hospitalization, representing a sizable burden to payers.

**OBJECTIVE:** To characterize differences in patient-reported outcomes (PROs) between recently hospitalized and non-hospitalized CD patients.

**METHODS:** We included patients aged ≥18 years with a physician diagnosis of CD in the Corrona Inflammatory Bowel Disease Registry between 2017-2020, excluding those with missing data (n = 42), indeterminate colitis (n = 30) or changed diagnosis after enrollment (n = 21). Patients were stratified by CD-related hospitalization in the 12 months prior to enrollment; descriptive statistics and standardized differences (sdiff; effect sizes) were calculated for characteristics at enrollment, with ≥0.10 indicating potentially meaningful differences.

**RESULTS:** Of 943 patients diagnosed with CD, 218 (23.1%) were hospitalized in the 12 months prior to enrollment. Work status differed between the two groups (sdiff = 0.359) with higher proportions of patients identifying as unemployed and disabled in the hospitalized group. Of patients reporting their work status as “Disabled” (n = 75), 64.3% in the hospitalized and 57.4% in the non-hospitalized group reported their disability due to inflammatory bowel disease (IBD; sdiff = 0.140). Hospitalized patients were more likely to be corticosteroid-experienced (64.8% vs 53.3%; sdiff = 0.237) with shorter duration of current therapy (0.9 vs 2.9 years; sdiff = 0.607). More hospitalized patients reported a history of any IBD-related surgeries (41.7% vs 34.8%; sdiff = 0.144), including bowel resections (37.2% vs 28.8%; sdiff = 0.178) and ostomies (11.0% vs 6.3%; sdiff = 0.166). Mean PROMIS PRO scores (last 7 days) for fatigue, sleep disturbance, pain...
interference, depression, and anxiety were higher in the hospitalized versus non-hospitalized group (sdiff ≥ 0.20). Hospitalized patients had lower employment (55.0% vs 66.9%; sdiff = 0.245) and worse Worker Productivity and Activity Impairment (WPAI [last 7 days]) scores: absenteeism (11.7% vs 4.9%; sdiff = 0.316); presenteeism (28.2% vs 16.7%; sdiff = 0.326), work productivity loss (30.0% vs 18.9%; sdiff = 0.380), and activity impairment (35.2% vs 21.3%; sdiff = 0.478).

CONCLUSIONS: Among CD patients in the Corrona IBD Registry, those with CD-related hospitalization in the past 12 months (vs without) had worse PROMIS and WPAI scores and higher biologic and corticosteroid use, with shorter duration of current therapy.

SPONSORSHIP: F. Hoffmann-La Roche.

K13 Characterizing prior healthcare resource utilization by disease severity in Crohn’s disease: real-world data from the Crohn’s disease: real-world data from the Crohn’s disease: real-world data from the Corrona Inflammatory Bowel Disease Registry

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BACKGROUND: Crohn’s disease (CD) is a chronic, lifelong inflammation of the gut that poses a sizable burden for more than 1 million patients in the United States.

OBJECTIVE: To characterize whether healthcare resource utilization (HCRU) is greater with increasing disease severity in CD.

METHODS: Between 2017 and 2020, data were collected at enrollment of adults ≥18 years of age with physician-diagnosed CD in the Corrona Inflammatory Bowel Disease Registry. Exclusion criteria included indeterminate colitis (n = 30), missing data (n = 42), and diagnosis change after enrollment (n = 21). Patients were stratified by disease severity using the Harvey Bradshaw Index (remission, 0–4; mild, 5–7; moderate/severe, >7), and associations between disease severity and history of HCRU outcomes were evaluated. The Cochran-Armitage test for trend was used for binary variables, and the Jonckheere-Terpstra test was used for continuous and ordinal variables.

RESULTS: After inclusion and exclusion criteria were applied, 943 patients with CD were captured (mean age, 46.6 years; female, 58.0%). Significant associations and increasing trends were observed between greater disease severity and history of CD-related hospitalizations in the past 12 months (18.4%, 28.8%, 38.3%; remission vs mild vs moderate/severe, respectively; P < 0.001) and number of CD-related hospitalizations in the past 12 months (0.3, 0.5, 0.8; P < 0.001). Significant trends were observed between greater disease severity and history of ED visits in the past 12 months (0.4, 0.7, 1.0; P < 0.001). Significant associations were observed between disease severity and history of intestinal resections (26.8%, 38.0%, 39.8%; P < 0.001), ostomies (5.5%, 8.7%, 14.8%; P < 0.001), and other surgeries (6.2%, 12.5%, 14.8%; P < 0.001). Fewer patients with greater disease severity were treated with biologics (66.1%, 63.0%, 54.7%; P = 0.017), and more patients with mild than moderate/severe disease were treated with corticosteroids (11.6%, 23.4%, 18.0%; P = 0.002).

CONCLUSIONS: Our study demonstrates a significantly higher trend of HCRU history with increasing disease severity in CD. Patients with greater disease severity used corticosteroids more often than biologics; however, the duration and effect of treatment are unclear. Additional longitudinal analyses are needed to determine whether diminished disease severity will result in reduced HCRU and lower costs in the future.

SPONSORSHIP: F. Hoffmann-La Roche.
BACKGROUND: Irritable Bowel Syndrome (IBS) is defined as recurring abdominal pain or discomfort associated with altered bowel patterns. Treatment effectiveness for a symptom-based condition like IBS relies heavily on patient-reported outcomes (PROs) to detect clinically meaningful improvements.

OBJECTIVE: To review PROs used in randomized controlled trials of IBS with constipation (IBS-C) medications.

METHODS: A literature review conducted using the EMBASE and Cochrane Library databases identified articles of placebo-controlled trials published from 1/2005-4/2020, which met the criteria: evaluated antidepressants, antispasmodics, linaclotide, plecanatide, lubiprostone, tenapanor, or tegaserod (or with another medication if applicable) for IBS treatment, used PROs, and written in English. Excluded studies were systematic reviews and meta-analyses or those whose subjects specifically had comorbid conditions (e.g., depression, diabetes), tested herbal therapies or medications whose development was stopped, or did not include IBS-C patients. PROs used for exclusion or only measured at baseline were not considered.

RESULTS: Thirty articles met selection criteria (8 antidepressant, 6 antispasmodic, 8 linaclotide, 1 plecanatide, 2 lubiprostone, 2 tenapanor, 3 tegaserod). Condition-specific metrics included the IBS-Quality of Life (12), Bristol Stool Form Scale (13), Spontaneous Bowel Movement Frequency (11), Work Productivity and Activity Impairment for IBS-C (3), and IBS-Symptom Severity Scale (1). Other metrics included the Hospital Anxiety and Depression Scale (3), 36-item Short Form Survey (2), global assessments (23), and other symptom severity scales, such as abdominal pain and bloating (25). Similar metrics varied by aspect of the condition investigated and endpoints, (e.g., numeric scales of effectiveness ranking, timing of evaluations), Differences were also noted in responder definitions, such as timespan for combined (≥ 9/12 weeks) vs. sustained responders (≥ 6/12 weeks and ≥ 2 out of final 4 weeks) and global treatment effectiveness (4-point scale with distinct thresholds vs. 3-point scale statistically comparing scores to define efficacy).

CONCLUSIONS: As PROs addressed various aspects of IBS-C, the ability to make direct comparisons of treatment efficacy is limited. In the future, a more standardized set of PROs could provide the opportunity to make better informed formulary decisions and guide clinical decision making for the treatment of IBS-C patients.

SPONSORSHIP: Ironwood Pharmaceuticals.

K21 Epidemiology of nonalcoholic fatty liver disease and steatohepatitis in pediatric population

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BACKGROUND: The epidemiology of Nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) in pediatric population, is not well characterized in the literature.

OBJECTIVE: To describe the incidence and prevalence of NAFLD/NASH in children in the United States

METHODS: Administrative claims data for children (<18 years old) enrolled in the IBM MarketScan database between November 2016 and November 2019 were analyzed to calculate period prevalence
rate (in percentages) and cumulative incidence rate (per 100 person-years) of NAFLD/NASH among children. The rates were stratified by age, sex, pre-existing type 2 diabetes mellitus (T2DM), and comorbid obesity. The ICD-9/10 diagnosis codes were used to define NAFLD/NASH (ICD-9 codes: 571.5 “cirrhosis of liver without alcohol” and 571.8 “other chronic nonalcoholic liver disease”; ICD-10 code: K75.81 “nonalcoholic steatohepatitis”), including all serious and nonserious cases of NAFLD/NASH regardless of whether hospitalization was required. Obesity and T2DM were defined by respective ICD-9/10 diagnosis codes.

RESULTS: During the analysis period, about 18 million pediatric patients were included in the analysis (mean age 8 years, 51% males) with NAFLD/NASH prevalence and incidence rates of 0.1% and 0.005 per 100 person-years, respectively (compared to 1.5% and 0.07 per 100 person-years corresponding rates in adults ≥18 years old). The incidence of NAFLD/NASH is increasing with age; however, the condition is very rare in all age groups (<0.01 per 100 person-years). The absolute number of prevalent NAFLD/NASH cases among pediatric patients is increasing with age; nonetheless, the prevalence rate is higher among children <7 years old compared to older children (0.2% versus 0.1%). The prevalence of NAFLD/NASH is similar between males and females (0.1%), but males showed higher incidence rate than females (0.006 versus 0.004 per 100 person-years). Children with T2DM or obesity have significantly higher prevalence and incidence rates of NAFLD/NASH compared to children without these conditions (Prevalence: 1.3% with T2DM versus 0.1% without T2DM; 0.4% with obesity versus 0.03% without obesity. Incidence [per 100 person-years]: 3.02 with T2DM versus 0.004 without T2DM; 9.18 with obesity versus 0.001 without obesity).

CONCLUSIONS: NAFLD/NASH is very rare in children; however, it becomes common in those with metabolic conditions like T2DM and obesity.

SPONSORSHIP: None.

L00-L99 Diseases of the Skin and Subcutaneous Tissue (e.g., Psoriasis, Pressure Ulcers)

L2 The role of social determinants in timely herpes zoster vaccination among older U.S. adults

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BACKGROUND: The latest CDC recommendation suggests that U.S. adults ≥50 years receive the herpes zoster (HZ) vaccine. However, rates of HZ vaccination, particularly at the recommended age, remain conspicuously low. Very little is known about how social determinants influence timely vaccination against HZ.

OBJECTIVE: To assess the impact of social determinants on timely HZ vaccination among U.S. adults ≥50 years.

METHODS: This retrospective observational study used the IBM MarketScan commercial claims and Medicare supplemental databases to identify U.S. adults aged ≥50 years who had received the HZ vaccine anytime between 2014 and 2016. The study cohort was classified into three groups based on their age of vaccination: early (50-59 years), timely (60-64 years), and late (65+ years) vaccination. Select social determinants from multiple publicly-available sources were linked with the MarketScan data. Multinomial logistic regression assessed the impact of social determinants and other predictors on early and late vaccination.

RESULTS: The study included 549,544 individuals of whom about half were vaccinated at the age of 60-64. Odds of late HZ vaccination increased with higher poverty rates (OR: 1.028, 95% CI: 1.024-1.032) and greater proportion of democratic voters in the community (OR: 1.011, 95% CI: 1.010-1.012) but decreased with higher estimates of health literacy (OR: 0.971, 95% CI: 0.970-0.973). Conversely, higher health literacy and lower poverty rate were associated with higher odds of early vaccination. Lack of Internet access was found to be associated with higher likelihood of late vaccination (OR: 1.028, 95% CI: 1.024-1.032). Males (OR: 1.141, 95% CI: 1.125-1.157), those immunocompromised (OR: 1.537, 95% CI: 1.510-1.565), adults not receiving a seasonal influenza vaccine (OR: 3.090, 95% CI: 3.042-3.138), and higher healthcare utilization were significant predictors of late vaccination. On the other hand, patients who were on an EPO/PPO vs. HMO health plan (OR: 1.029, 95% CI: 1.008-1.051), or resided in North Central, South, or West vs. Northeast region were more likely to receive the HZ vaccine early.

CONCLUSIONS: Results suggest that some social determinants influence deviations from receiving the HZ vaccination at the recommended age. Further research is needed to fully understand the impact of social determinants on HZ and other vaccination.

SPONSORSHIP: None.

L11 Medication use during hospitalizations for generalized pustular psoriasis

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BACKGROUND: Generalized pustular psoriasis (GPP) is a rare and severe, potentially life-threatening auto-inflammatory skin disease. GPP is characterized by recurrent flares that can result in hospitalization due to systemic complications. Evidence is lacking about how GPP patients are treated in the inpatient setting.

OBJECTIVE: This study characterizes medication use during GPP-related hospitalizations.

METHODS: A descriptive, retrospective cross-sectional analysis was conducted in Cerner Health Facts, a U.S. electronic medical record database. GPP-related hospitalizations between October 1, 2015 and July 1, 2017 were identified and included with a GPP diagnosis (ICD-10-CM code: L40.1) in the first or second position at admission or discharge, and a discharge date within the study time period. Hospitalizations were the unit of analysis. Demographics, comorbidities, and medication use were characterized with descriptive statistics.
RESULTS: Out of 2,461,749 hospitalizations with discharge dates during the study time period, 71 GPP-related hospitalizations were included in the study. Hospitalizations were predominately among Caucasian (68%), female (52%) patients with a mean (standard deviation [SD]) age of 51 (22.6) years. The mean (SD) length of stay was 9 (14.0) days. Inflammatory skin conditions/subcutaneous tissue infections (54%/34%), fluid and electrolyte disorders (46%), hypertension (30%), sepsis (24%), and acute renal failure (18%) were frequent comorbidities during hospitalizations.

Medication use during GPP-related hospitalizations included topicals (triamcinolone [42%]; clobetasol [17%]), systemic corticosteroids (prednisone [20%]; methylprednisolone [11%]), and non-biologic and biologic immunosuppressants (cyclosporine [6%]; methotrexate [4%]; etanercept [1%]). Intravenous (IV) fluids (79%), analgesics (acetaminophen 67%; morphine 24%), and antibiotics (vancomycin 21%) were also common.

CONCLUSIONS: Hospitalizations for GPP commonly involved treatment with topicals and systemic corticosteroids, while in some cases immunosuppressants were administered. Frequent use of IV fluids may reflect efforts to treat and stabilize GPP flare complications such as dehydration, sepsis, or acute renal failure. Use of analgesics, including opioids during many GPP admissions suggest a need for significant pain management. Future research should examine treatment patterns preceding hospitalizations to explore unmet needs in GPP flare management.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals.

L12 Health care costs and utilization among patients with hyperhidrosis and concomitant depression and anxiety in a real-world database representing U.S. commercial health plan members

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BACKGROUND: Hyperhidrosis is characterized by excessive sweating beyond that needed to maintain thermal homeostasis and is associated with comorbid social and emotional stress due to health-related quality of life limitations.

OBJECTIVE: This study examined health care resource utilization (HCRU) and costs associated with concomitant depression and/or anxiety in patients with hyperhidrosis.

METHODS: Commercial health plan members with ≥2 hyperhidrosis diagnosis codes and/or antiperspirant prescription claims were identified from January 2010 through November 2017. The index date was the first observed claim indicating hyperhidrosis. Patients had continuous enrollment with medical and pharmacy coverage for 12 months before and 12 months after the index date, and no claims for related medical procedures or pharmacy claims for oral systemic therapies within 7 days of the index date. Depression and anxiety were identified by ≥1 relevant diagnosis code or pharmacy claim. CPI-adjusted all-cause health care costs and HCRU were compared over 12 months between patients with depression and/or anxiety and those without.

RESULTS: A total of 44,484 patients with hyperhidrosis were identified; 58.5% were female and mean (± standard deviation [SD]) age was 36.5 ± 16.5 years (83.5% ≥ 18 years). Post-index medical procedures and surgical options were uncommon. A total of 41.1% of patients with hyperhidrosis had depression and/or (1) anxiety reported during the 12-month follow-up, including 18.2% in whom depression/anxiety was newly reported after the index date. Patients with concurrent hyperhidrosis and depression/anxiety compared with those who did not have depression/anxiety had higher mean [median] all-cause health care costs ($1,905 [$636] vs. $673 [$197], higher mean all-cause medical costs ($1,598 [$412] vs. $544 [$127]), a higher percentage with an inpatient visit (12.9% vs. 4.8%), and a higher percentage with an ER visit (43.3% vs. 26.0%) in the 12-month follow-up period (all P values for differences in means and percentages < 0.001).

CONCLUSIONS: In this real-world analysis, depression and/or anxiety was reported in a substantial percentage of patients in a hyperhidrosis cohort. All-cause health care costs and HCRU were higher in patients with hyperhidrosis who experienced depression/anxiety than those without depression/anxiety. These data demonstrate higher overall health care burden for patients with hyperhidrosis who also experience depression/anxiety.

SPONSORSHIP: Dermira, a wholly-owned subsidiary of Eli Lilly and Company.

L13 The economic and healthcare resource utilization (HRU) burden of central nervous system metastases in patients with metastatic melanoma

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BACKGROUND: Pts with advanced melanoma have a high risk of developing central nervous system (CNS) metastases. Treatment may include systemic and/or local therapies, including radiation and surgery. CNS involvement adversely impacts pt quality of life and is associated with increased costs and higher levels of HRU.

OBJECTIVE: To estimate costs and HRU in pts with metastatic melanoma by comparing those with and without CNS metastases.

METHODS: This was a retrospective cohort study (Jan 2011-Jun 2019) using the IQVIA PharMetrics Plus claims database. The cohort included pts with 2 claims of a diagnosis code for melanoma and 2 claims of a metastasis code; it excluded those with regional lymph node metastases only. Index date was first date of any metastasis; follow-up was ≤ 36 mo. We compared baseline characteristics, HRU, total cost of care, and cost of hospitalizations, outpatient care, and melanoma treatments in metastatic melanoma pts with and without CNS metastases using chi-square tests, two sample t-tests, and Wilcoxon rank sum tests. Mean per patient per month (PPPM) costs are reported in 2019 U.S. dollars. Analyses were conducted overall and by time cohort (2011-14 and 2015-19) to assess impact of changes in therapeutic options over time.
RESULTS: The study cohort included 4,641 pts; 27% (n = 1,256) had CNS metastases, and of these 42% (n = 527) were diagnosed at index. Median time to first CNS metastasis for pts diagnosed after the index date was 5.52 mo (interquartile range 1.22–11.33). Demographic characteristics were generally similar for pts with and without CNS metastases. Median follow-up was significantly shorter for pts with CNS metastases compared to those without (11.2 vs 18.0 mo, P < 0.001). Pts with CNS metastases were more likely to receive any treatment compared to those without (87% vs 53%; P < 0.001); this was consistent for both systemic (73% vs 50%; P < 0.001) and radiation treatment (66% vs 11%; P < 0.001). Pts with CNS metastases also incurred higher total PPPM costs compared to those without ($29,926 vs $13,327; P < 0.001); the largest contributors were total radiology ($2,354 vs $1,010; P < 0.001), systemic targeted therapies ($2,504 vs $553; P < 0.001), and immunotherapies ($7,385 vs $4,348; P < 0.001). These observations were consistent over the follow up period.

CONCLUSIONS: Metastatic melanoma pts with CNS metastases incur significantly higher HRU and costs compared to those without CNS metastases.

SPONSORSHIP: Genentech.

L15 Healthcare utilization and cost of three psoriasis treatments in a U.S. commercial population

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BACKGROUND: Guselkumab (GUS), ixekizumab (IXE), and secukinumab (SEC) are three highly effective biologic treatments for psoriasis. Healthcare utilization and costs associated with these treatments in the psoriasis patient population remains unclear.

OBJECTIVE: To evaluate healthcare utilization and cost for patients with psoriasis within the 9-month post-initiation period treated with GUS, IXE, or SEC.

METHODS: This retrospective descriptive cohort study analyzed data from the IBM MarketScan Commercial Claims and Encounters Database. Adults with ≥1 PsO (no baseline diagnosis of ankylosing spondylitis, juvenile chronic polyarthritis, hidradenitis suppurativa, rheumatoid arthritis, Crohn's disease, or ulcerative colitis), newly initiating a study medication from 7/1/2014-6/30/2019 were included in non-mutually exclusive cohorts. Continuous enrollment from 6 months pre-to 9 months post-initiation (index date) was required. No formal statistical comparisons between cohorts were conducted. Total healthcare cost, prescription fills (all medications including biologics for psoriasis), average number of outpatient visits, proportion of patients with at least one ER visit, and proportion of patients with at least one inpatient visit are included in the study results.

RESULTS: The study included 1,766 IXE, 4,132 SEC, and 821 GUS patients (non-mutually exclusive cohorts). Cohorts were 42.9%-48.4% female, mean age was 47.9-48.5 years; Quan-Charlson Comorbidity Index score ranged from 0.19-0.29. Over the 9-month follow up period, mean total health care costs were: IXE, $68,555; SEC, $61,292; GUS, $56,831. Mean number of prescription fills was: IXE, 27.4; SEC, 28.5; GUS, 23.1. Mean number of outpatient visits was: IXE, 29.5; SEC, 31.9; GUS, 27.5. Proportion of patients with at least one ER visit was: IXE, 13.4%; SEC, 13.3%; GUS, 10.7%. Proportion of patients with at least one inpatient visit was: IXE, 7.1%; SEC, 8.2%; GUS, 7.2%.

CONCLUSIONS: Among the three biologics studied, GUS had the lowest total health care cost per patient, lowest number of prescriptions fills (all medication types), lowest number of outpatient visits, and lowest proportion of patient with at least one ER visit. The proportion of patients with inpatient visits was highest for SEC, and similar for GUS and IXE.

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

M3 Specialty medication adherence rates in patients with rheumatoid arthritis across health-system specialty pharmacies

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BACKGROUND: Adherence to disease-modifying antirheumatic drugs (DMARDs) is necessary to achieve reduced rheumatoid arthritis (RA) activity and improve radiologic outcomes. Quality and accreditation bodies have endorsed an adherence threshold of 80%, as measured by proportion of days covered (PDC), for non-infused biologics used for RA. However, several studies have demonstrated variable real-world adherence rates ranging from 30% to 85%.

OBJECTIVE: The objective of this study is to evaluate rates of adherence to biologic DMARDs, measured by PDC, across multiple health-system specialty pharmacies.

METHODS: This multisite retrospective cohort study included patients with ≥ 3 fills for eligible biologic DMARDs written by a provider at one of the 20 participating health-systems and an international classification of diseases code M05, M06, or M08 between January 2018 and January 2019. Fill data was collected by each site using pharmacy records generated during normal clinical practice and imported into a centralized, password-protected, HIPAA compliant data entry system. Patient-level PDC was calculated as the number of days with medication use divided by the number of days in the time period of interest. Patients with an initial PDC ≤ 50% were reviewed for appropriate extended gaps in therapy including pregnancy, non-claimed biologic DMARD medication filled, allergic reaction, discordant administration directions and prescribed days’ supply, and > 3 months of any of the following: infections, drug holiday, use of samples, intravenous therapy, or external fills. When an appropriate gap in therapy was identified, fill dates were adjusted to remove the appropriate gap in the denominator of PDC calculation so that the PDC would not be underestimated. Patients were excluded if there were multiple appropriate extended gaps where dates of gaps could not be quantified. All sites obtained institutional review board approval.

RESULTS: We included 3,528 patients with 4,065 medications and 29,900 fills. Most were female (75%) with commercial insurance (51.1%) and a median age of 55 (IQR 42-63). Adalimumab (34.2%) and etanercept (31.3%) prescriptions were most common. Median PDC for all sites was 94% (IQR 83, 99), with 80.1% of patients with a PDC > 80%. Initially, 121 patients had a PDC ≤ 50%, of whom 2 were excluded and 69 required days’ supply adjustment, 9 due to administrative instructions and 60 due to appropriate gaps.

CONCLUSIONS: High rates of adherence to biologic DMARDs were seen across 20 health-systems specialty pharmacies, demonstrating the benefits of health-system specialty pharmacies in helping patients with RA remain on effective therapies.

SPONSORSHIP: None.

M5 Factors associated with poor clinical outcomes and costs following total hip replacement for patients with osteoarthritis

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BACKGROUND: Total hip replacement (THR) is an effective treatment usually performed when all other treatment options have failed to provide pain relief.

OBJECTIVE: This study examined factors associated with clinical outcomes and healthcare costs following THR in patients with osteoarthritis (OA).

METHODS: This was a retrospective administrative claims-based analysis of patients who underwent THR between January 2015 and August 2018, 45-85 years of age, with >2 claims with diagnoses of OA > 45 days apart, and continuously enrolled one year pre- and post-THR. Patients with rheumatoid arthritis, cancer, osteonecrosis, or fractures were excluded. Multivariate stepwise regression models were run for outcomes with odds ratios (OR) and 95% confidence intervals (CI) reported for logistic models (30-day and 90-day readmissions, surgical revisions), and a linear model with exponentiated estimates (EE) and 95% CI: for 12-month, post-THR direct all-cause healthcare costs. Covariates included demographics, pre-THR comorbidities and medication use.

RESULTS: Patients (n = 12,426) were mostly female (61.4%), > 65 years (81.6%), and with OA claims for only one joint (57.2%). Post-THR outcomes included 30-day readmissions (4.5%), 90-day readmissions (9.0%), surgical revisions (5.1%), and complications (62.0%; 25.6% with acute post-op pain). Factors associated with 30- and 90-day readmissions and surgical revisions (OR [95% CI]), included falls (2.71 [1.64-4.50]; 1.79 [1.20-2.67]; 2.57 [2.02-3.26]), sleep disorders (1.60 [1.07-2.39]; 1.42 [1.06-1.91]; 1.37 [1.14-1.65]) and benzodiazepine use (1.92 [1.29-2.85]; 1.49 [1.10-2.01]; 1.26 [1.04-1.53]). The clinical factors strongly associated with increased costs (EE, 95% CI; EE > 10%) included falls (1.24, 1.20-1.29), heart-related conditions/events (1.13, 1.11-1.16), viscosupplement use (1.12, 1.06-1.18), and pregabaline use (1.12, 1.05-1.19).

CONCLUSIONS: Falls during the year prior to THR were associated with all clinical outcomes and costs. Select demographics, clinical characteristics, and medications uniquely contributed to outcomes. As data for this study were limited, a causal relationship between
Disability profiles of Medicare patients with acquired thrombotic thrombocytopenic purpura from 2010 to 2018

BACKGROUND: Acquired thrombotic thrombocytopenic purpura (aTTP) is an ultra-rare and potentially life-threatening hematologic disorder.

OBJECTIVE: This analysis explored disability and comorbidity profiles among U.S. Medicare Fee-for-Service (FFS) beneficiaries with and without aTTP.

METHODS: The 100% sample of Medicare FFS enrollment/claims were utilized to identify beneficiaries with aTTP based on a validated algorithm (Wahl et al, 2010): patients age ≥18 with ≥1 hospitalization for thrombotic microangiopathy + therapeutic plasma exchange (TPE) between 2010-2018 (admission = index date). Patients with diagnosis of hemolytic-uremic syndrome, E. coli, lupus and other conditions mimicking aTTP during same hospitalization were excluded. Reason for receipt of Disability Insurance Benefit (DIB) is not available, therefor younger (age <65 yrs at enrollment), disabled beneficiaries with aTTP were assumed to have qualified for Medicare due to a prior TMA+TPE hospitalization. Evidence of clinical conditions potentially associated with aTTP (incl. cardio-/cerebro-vascular conditions), and each of the 79 Medicare hierarchical condition categories (HCC) from medical claims within first 3 months of Medicare enrollment were analyzed in aTTP patients age <65 yrs receiving DIB and a random sampling of beneficiaries age <65 yrs, receiving DIB without aTTP, no minimum enrollment period was required.

RESULTS: Of the 1,486 beneficiaries with aTTP, mean age at enrollment was 63 yrs (vs. 68 yrs in the 2,855,160 beneficiaries without aTTP). 33.1% (n=492) of aTTP patients were <65 yrs vs. 20% of those without aTTP. The percentage of patients with at least one complication potentially due to aTTP within the first 3-months of Medicare enrollment was 66.7% for the aTTP population (driven by cardiovascular disease, diabetes, anemia) vs. 27.1% in those without aTTP. The percentage of patients with at least 1 HCC complication within first 3-months of Medicare enrollment was 98.1% for aTTP population vs. 49.3% in those without aTTP. Average duration from Medicare enrollment to first observed aTTP event was 3 years.

CONCLUSIONS: A disproportionately higher proportion of aTTP patients were enrolled in Medicare with existing disability and greater baseline comorbidity compared to the general Medicare FFS population, which may be driven by prior aTTP complications.

SPONSORSHIP: Sanofi.

Cost-effectiveness analysis of certolizumab pegol versus secukinumab and ixekizumab in non-radiographic axial spondyloarthritis in the United States

BACKGROUND: Axial spondyloarthritis (axSpA) is a chronic inflammatory rheumatic disease that predominantly affects the axial skeleton through inflammation of the spine and sacroiliac joints (SIJ). axSpA is classified as non-radiographic (nr-axSpA) in the absence of radiographic SIJ damage but manifests as chronic back pain and stiffness features suggestive of spondyloarthritis. Biologics including tumor necrosis factor inhibitor (TNFi) and interleukin (IL) inhibitor drugs can be used when patients have not responded or are intolerant to standard non-biologic care (SC).

OBJECTIVE: To assess the cost-effectiveness of certolizumab pegol (CZP), the only FDA approved TNFi for the treatment of nr-axSpA, vs. IL-17A inhibitors secukinumab 150 mg (SEC) and ixekizumab (IXE) every 2 weeks (Q2W) from a U.S. payer perspective.

METHODS: A 1-year decision tree followed by a state-transition Markov model was developed to estimate lifetime costs and quality-adjusted life-years (QALY) of each comparator. Clinical response was assessed at weeks (w) 12 and 52 using the Assessment of SpondyloArthritis international Society 40% (ASAS40) criteria. Non-responders stopped their biologic treatment and switched to SC. Efficacy inputs originated from a network meta-analysis, including C-axSpAnd trial (NCT02552212), that assessed ASAS response rates and score changes in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Functional Index (BASFI). Utility scores were determined based on BASDAI and BASFI scores through an established equation (C-axSpAnd). Drug acquisition costs were based on Wholesale Acquisition Cost (Medi-Span 2020); medical management cost was mapped to BASFI score using a published exponential cost model (inflated to 2020 US$). Costs and benefits had a 3% annual discount rate. Univariate and probabilistic sensitivity analyses were performed.

RESULTS: CZP resulted in an incremental cost-effectiveness ratio (ICER) per QALY gained of $42,207 vs. SEC (1.474 incremental QALYs and $62,220 incremental cost), and was dominant vs. IXE (1.132 incremental QALYs and $182,338 cost savings). ICER estimates were most sensitive to baseline BASFI, relative risk of w12 response, biologic acquisition cost and benefit discount rate. At a willingness-to-pay of $50,000 per QALY, CZP had an 87% probability of maximizing the net monetary benefit compared to SEC (13%) and IXE (0%).

CONCLUSIONS: CZP represented a cost-effective biologic treatment of nr-axSpA compared to SEC and IXE in the U.S., with an ICER below $50,000 per QALY vs. SEC, and dominance vs. IXE.

SPONSORSHIP: UCB Pharma.
M8 The feasibility of using linked electronic health record and claims data to track Duchenne muscular dystrophy outcomes

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BACKGROUND: A previous investigation of health insurance claims data for assessing outcomes among those with DMD found that while the occurrence of selected key clinical milestones could be inferred, data to track patient status were unavailable. While linked electronic health records (EHR) and claims data are often used for health research, their utility for assessing outcomes in DMD is unknown.

OBJECTIVE: To assess the suitability of linked claims and EHR data for assessing DMD outcomes.

METHODS: Potential outcome measures were identified from a systematic review and included measures of clinical status, clinical milestones, functional assessments, and patient-reported outcomes (PROs). Decision Resources Group’s (DRG) data were used to identify males ≤30 years of age with DMD (ICD-10 G71.01, SNOMED 76670001, eteplirsen use), to review the availability of data to measure such outcomes. These open source data are assembled from multiple claims and EHR networks and include vital statistics, test records, and some of each patient’s pharmacy and medical claims.

RESULTS: Fifty-five measures were identified from the review: 22 clinical measures (e.g. ventilator use), 27 functional assessments (e.g. 6-minute walk test), and 6 PROs. Data availability to measure outcomes was assessed among 6,469 males with DMD (median age, 11 years). Data were available to estimate the occurrence, and sometimes the severity, of clinical outcomes: loss of ambulation (wheelchair use codes); need for ventilation (ventilator/tracheostomy codes) or respiratory insufficiency (diagnostic codes); onset of scoliosis (procedural/diagnostic codes); or cardiomyopathy (diagnostic/medication codes). While records of completed clinical assessments were identified, these were present for <2% of the cohort, with results often unavailable. Mortality data were available for a subset of patients. No PRO data were found.

CONCLUSIONS: While some data are available to assess selected outcomes in these linked EHR-claims datasets, data to track functional status or PROs are not. Limitations to the data include that not all records for an individual are available. The additional clinical details available through EHRs are potentially valuable, although test results of interest were infrequently available. Verifying these findings are consistent in other linked datasets will be important. As with the previous claims data initiative, these analyses demonstrated that while the occurrence of some clinical outcomes may be inferred, severity cannot always; which may be important when considering gradually progressive complications of DMD.

SPONSORSHIP: Sarepta.

M11 Results from a high-touch clinical program to improve star ratings measure: Osteoporosis Management in Women Who Had a Fracture (OMW)

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BACKGROUND: CMS implemented a 5-Star quality rating system for Medicare plans in order to drive quality improvement for beneficiaries. To assist a 20,000-member life Medicare plan in improving the quality of care delivered to their beneficiaries and maximizing Star Rating performance, the clinical team collaborated on the development and implementation of a pharmacist-led clinical program designed to specifically address the Star measure Osteoporosis Management in Women Who Had a Fracture (OMW). The OMW treatment rate is defined as the percentage of female Medicare Advantage enrollees aged 67-85 who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.

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

METHODS: A clinical program was implemented to improve the OMW treatment rate through various methods of identification, prioritization, and clinical engagement. Through pharmacy and medical claims analyses, the target non-compliant population (those identified as having suffered a fracture without either a BMD test or osteoporosis medication in the six months after the fracture) was identified. The target population, consisting of 229 members, was prioritized for outreach based on several criteria including date of fracture, repeat fractures, history of BMD tests, and the presence of an osteoporosis medication claim rejection and/or reversal. Various methods of clinical engagement were leveraged including pharmacist-led telephonic outreach to providers, members, and/or pharmacies in order to facilitate in-home BMD tests, facility BMD tests, or a prescription for a drug to treat osteoporosis.

RESULTS: For 2019 measurement year, the overall treatment rate achieved was 73%, representing 5-Star performance. These results represent a 1-Star improvement versus 2018 measurement year and a 2-Star improvement versus 2017 measurement year (the baseline year).

CONCLUSIONS: Comprehensive identification, multifaceted prioritization, and active clinical engagement are all important tools in improving the treatment rates for clinical Star measures such as OMW. It has been estimated that an overall 1-Star improvement for health plans (from 3 to 4 Stars) is worth $50 per member per month. Such results support the necessity and viability of a program that incorporates care coordination and customized outreach.

SPONSORSHIP: Magellan Rx Management.

M12 Gender disparities in osteoporosis screening and management among older adults

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BACKGROUND: One in two women and up to one in four men experience an osteoporosis-related fracture (Fx) in their lifetime. Related morbidity and mortality rates are higher in men compared to women. There is a lack of consensus in screening guidelines for men and the prevalence of hip Fx related hospitalizations in men is rapidly increasing.

OBJECTIVE: To evaluate gender disparities in management of osteoporosis (OP) in the U.S. Medicare population.

METHODS: A retrospective cohort study using the National Medicare 5% sample administrative claims data including patients with a new Fx episode between January 1st, 2014 and December 31st, 2015 (index Fx) was conducted. Inclusion criteria were age ≥ 65 and continuous Fx episode between January 1st, 2014 and December 31st, 2015 (index Fx). A 5% sample administrative claims data including patients with a new Fx episode between January 1st, 2014 and December 31st, 2015 (index Fx) was conducted. Inclusion criteria were age ≥ 65 and continuous Fx episode between January 1st, 2014 and December 31st, 2015 (index Fx) as recommended by the NCQA HEDIS OP measures were excluded. Patients with Paget's disease or malignancy (except non-melanoma skin cancer) at baseline were also excluded. Multivariate analyses included logistic regression and Cox Proportional Hazards.

RESULTS: 35,774 beneficiaries with a fracture met inclusion criteria. 68.3% were ≥75, 89.3% were white, and 69.8% were female. Overall, men were less likely to get tested and/or treated for OP after an index Fx compared to women (5.7% vs 12.1%). Gender disparity in testing for OP remained for all Fx sites with smaller differences for hip, pelvic and spinal Fx. Predictors of testing or treatment in the 6-months following index Fx included female gender (OR: 2.49, 95% CI: 2.27, 2.74), Black (OR: 0.67, 95% CI: 0.55, 0.82), pelvic or spine Fx (OR: 4.08, 95% CI: 3.62, 4.59) and fractures of the lower (1.46, 95% CI: 1.28, 1.66) and upper (OR: 1.50, 95% CI: 1.14, 1.83) limbs. Patients with a history of Fx were less likely to be tested for OP (OR: 0.82, 95% CI: 0.71, 0.94). Adherence to quality measures for testing and treatment was a significant predictor of lower mortality (HR: 0.78, 95% CI: 0.68, 0.90) and the composite endpoint of mortality and subsequent fracture (HR: 0.87, 95% CI: 0.77, 0.98). Prior fracture history was associated with increased risk of subsequent fracture/mortality (HR: 1.12, 95% CI: 1.10, 1.30).

CONCLUSIONS: OP quality of care is poor in the Medicare fee-for-service population overall and worse for men compared to women. Adherence to quality measures is associated with a significant decrease in mortality in the 6 months following index Fx.

SPONSORSHIP: Radius Health.

N00-N99 Diseases of the Genitourinary System (e.g., ESRD)

N1 Prevalence of severe anemia and total healthcare costs in chronic kidney disease in Medicare Advantage Prescription Drug (MAPD) patients

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BACKGROUND: Chronic kidney disease (CKD) is more common in people aged 65 or older (38%) than in people aged 45-64 (13%) or 18-44 (7%). Anemia is a common sequela of CKD patients, affecting 8-53% and is more prevalent as CKD progresses. Anemia is defined as hemoglobin (Hb) < 12/13 (female/male) per guidelines, but severe anemia is defined as Hb<10 (for both sexes). The presence of anemia is associated with greater healthcare resource use in CKD. Diagnosis codes alone do not provide the granularity of lab results in order to define severe anemia, thus lab data was used to characterize patients with severe anemia.

OBJECTIVE: 1) To examine prevalence of severe anemia among non-dialysis dependent (NDD) patients with CKD Stage 3-5; 2) To describe total healthcare costs (THCC) for CKD patients with severe anemia.

METHODS: Using Humana claims data (medical, pharmacy, lab), two study designs were used for this descriptive analysis: 1) A cross-sectional study of data within calendar year (CY) 2018 to examine prevalence of severe anemia, and 2) A retrospective cohort study to examine costs for patients with severe anemia. Anemia prevalence was determined using lab results Hb<10 within the CY. For the cost analysis, the index date was the date of first lab value indicating severe anemia (Hb<10) after CKD diagnosis. Patients were classified based on CKD stage in the 12 months pre-index. THCC (medical+pharmacy) were examined in the 12 months post-index. Costs included plan and member share.

RESULTS: In patients with NDD CKD, severe anemia prevalence increased as CKD stage increased. Prevalence rates were 8%, 25%, and 51% in stage 3, 4, and 5, respectively. The mean number of Hb lab tests/year increased as stage increased (6, 8, 10). In patients with CKD and severe anemia, median THCC increased as CKD progressed ($19,902, $25,300, and $36,589 in stage 3, 4, and 5, respectively), driven by an increase in medical costs (median: $14,640, $19,269, and $30,270). Pharmacy costs remained consistent across CKD stages (median: $2,243, $3,058, and $2,766). A similar trend was seen in the mean THCC by CKD stage ($36,768, $41,629, and $53,459) mostly driven by medical costs (mean: $29,536, $34,068, and $46,853). Mean pharmacy costs were $7,232, $7,561, and $6,606.

CONCLUSIONS: Prevalence of severe anemia in the MAPD NDD CKD patients increased by CKD stage; half of patients in Stage 5 with severe anemia. Availability of lab data resulted in a more precise clinical definition for severe anemia. After anemia diagnosis, THCC increased as CKD stage progressed, which was mainly driven by medical costs.

SPONSORSHIP: AstraZeneca.

N5 The budget impact of including rucaparib on a U.S. payer formulary for the treatment of patients with metastatic castration-resistant prostate cancer

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BACKGROUND: Prostate cancer is the second leading cause of cancer death among men in the U.S. and is associated with significant economic burden. Access to life-prolonging treatment options is vital among the metastatic prostate cancer population. Based on data from TRITON2 (NCT02952534), the PARP inhibitor rucaparib was approved in the U.S. for the treatment of patients with deleterious BRCA1 or BRCA2 (BRCA) mutation (germline and/or somatic) associated metastatic castration-resistant prostate cancer (mCRPC), who were treated with androgen receptor-directed therapies (ARDTs) and a taxane-based chemotherapy.
OBJECTIVE: A budget impact model was constructed to assess the incremental budget impact on a U.S. health plan given the availability of rucaparib for the treatment of adult patients with BRCA-mutated mCRPC.

METHODS: Incremental budget impact was estimated as the difference in the annual total cost of treatment, with and without rucaparib available, for a hypothetical health plan with 1 million covered lives and commercial and Medicare lines of business. The incremental budget impact was estimated for the inclusion of rucaparib for patients with a deleterious BRCA mutation following treatment with ARDT and a taxane-based chemotherapy. The only alternative product included in the model in this setting was the PARP inhibitor olaparib. The size of the eligible patient population was estimated using an incidence-based approach. Modeled costs included those associated with drug acquisition, required laboratory testing, and medical management of adverse reactions. Duration of treatment and adverse reaction rates were derived from the prescribing information and clinical trial publications.

RESULTS: In years 1-3, 1 patient per year was estimated to have mCRPC and receive a PARP inhibitor after treatment with ARDT and a taxane-based chemotherapy in a hypothetical health plan of 1 million members. The average total health expenditures during that time was estimated to be $123,387 with rucaparib available as a treatment option versus $108,181 without rucaparib being available, equating an average incremental budget impact of $15,206 or $0.0012 per member per month (PMPM). The PMPM cost was the same for commercial and Medicare plans.

CONCLUSIONS: The budget impact of adding rucaparib to the formulary of a health plan for the treatment of patients with mCRPC adds a modest PMPM cost of $0.0012 in all tested settings and scenarios because of the small population eligible for therapy. Rucaparib would be a potentially life-prolonging treatment option for patients with mCRPC.

SPONSORSHIP: UroGen Pharma.

000-099 Pregnancy, Childbirth, and the Puerperium (e.g., Abortion, Eclampsia, and Maternal Care)

N6 Three-year analysis of healthcare utilization in patients with low-grade upper tract urothelial cancer (LG-UTUC) treated with ureteroscopic management or RNU

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BACKGROUND: Approximately 7,800 new cases of UTUC are diagnosed in the USA annually, with 40% classified as low-grade (LG). LG tumors are well differentiated, typically slow to progress, and unlikely to spread; however, non-treatment may lead to hematuria and/or urinary obstruction. A kidney-sparing approach with ureteroscopic management (UM) is an option; however, it can lead to high recurrence rates, multifocal disease and repetitive procedures. Radical nephroureterectomy (RNU) which involves the surgical removal of the renal pelvis, kidney, ureter, and bladder cuff is the current standard of care, however it is associated with short-term and long-term complications.

OBJECTIVE: The aim of this study was to explore the healthcare utilization and costs incurred in patients with LG-UTUC managed with UM or RNU.

METHODS: LG-UTUC patients (n = 549) managed with UM or with RNU were identified from the Centers for Medicare and Medicaid Services (CMS) claims database. The full data set comprised 1-year prior to diagnosis and 2-years post-diagnosis for each patient (if available). Patients with <80% study days within a year were excluded. To account for total cost estimates affected by the difference in the number of study days between patients managed with UM and RNU and zero observations, a per patient per month (PPPM) cost with zero-cost interpolation was applied and compared to the aggregate outcomes. Results presented as reimbursed costs in 2019 USD.

RESULTS: The baseline characteristics of age, gender, and race in the patient population were consistent with the literature. The analysis suggests that the 1st year post-diagnosis was the most costly in patients managed with either UM (n = 264) or RNU (n = 285). RNU was more costly than UM in the 1st year post-diagnosis (UM: $37,487, RNU: $54,784) and aggregated over the 3-year study period (UM: $72,632, RNU: $83,241) based on mean PPPM costs. Severe liver disease was identified as a significant driver of additional comorbidity costs in both groups, likely due to increased hospitalizations.

CONCLUSIONS: This retrospective analysis of LG-UTUC patients suggests the 1st year post-diagnosis was the most costly regardless of treatment approach. RNU accounted for greater costs over the study time period. This analysis is limited by not capturing the costs associated with the potential long-term decline with kidney function associated with RNU. Further analysis over a longer time horizon is warranted.

SPONSORSHIP: Clovis Oncology.
logistic regression models were used to assess the relationship between SDoH factors and the provision of contraceptives [most effective or moderately effective contraceptives (MMEC) and long-acting reversible methods of contraception (LARC)] during the 3- and 60-days postpartum period.

**RESULTS:** Of the 436,285 beneficiaries that met the inclusion criteria, 14.1% were 15-20 and 85.9% were 21-44, 44% were white, and 36.4% (MMEC) to 8.3% (LARC) received contraceptives within 60-days postpartum. Women aged 15-20 years were more likely to receive LARC (OR = 1.30, 95% CI: 1.26, 1.35) compared to women aged 21-44. Compared to white women, Blacks (OR = 0.80, 95% CI: 0.78, 0.83) and Asians (OR = 0.92, 95% CI: 0.85, 1.00) were less likely to receive LARCs while Hispanics (OR = 1.16, 95% CI: 1.11, 1.22) were more likely to receive LARCs. Several SDoH were associated with receipt of contraceptives. For example, timely receipt of a LARC was positively associated with mammography screening (OR = 1.01, 95% CI: 1.01, 1.01), and food insecurity (OR = 1.09, 95% CI: 1.08, 1.10) and negatively associated with unemployment rate (OR = 0.89, 95% CI: 0.89, 0.90), inadequate social support (OR = 0.98, 95% CI: 0.97, 0.98), and severe housing problems (OR = 0.94, 95% CI: 0.94, 0.95).

**CONCLUSIONS:** The provision of contraception during the postpartum period remains low, and closely tied to key SDoH. Focus on these disparities can help managed care organizations bridge communities experiencing poor maternal outcomes with critical resources that can reduce health inequity.

**SPONSORSHIP:** University of Mississippi.

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

**R1 Characteristics, medication use, and outcomes of inpatients with heart failure and hyperkalemia**

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**BACKGROUND:** Heart failure patients are at higher risk for hyperkalemia, especially when chronic kidney disease is present or renin-angiotensin-aldosterone system inhibitors (RAASi) are used. Real-world data describing the characteristics, treatments and outcomes of hospitalized heart failure patients with hyperkalemia are limited.

**OBJECTIVE:** To describe the characteristics, treatments and outcomes of hospitalized heart failure patients with hyperkalemia using real-world evidence.

**METHODS:** Data from linked Premier Healthcare Database and Optum Clininformatics Data Mart dataset were used for this analysis. Inpatient admissions with a discharge date between January 1, 2014→March 31, 2018 and a principal or secondary discharge diagnosis of heart failure and hyperkalemia as defined by International Classification of Disease (ICD) diagnosis codes or use of sodium polystyrene sulfonate (SPS) or patiromer during the index visit were analyzed. Patient characteristics, length of stay (LOS), hospital visit cost, reoccurrence of hyperkalemia and RAASi use were assessed.

**RESULTS:** A total of 11,068 heart failure patients with hyperkalemia were identified. The mean age was 73 ± 11 years, 70.0% were white, 89% were insured by United Healthcare Medicare Advantage and the remaining 11% were insured by a United Healthcare Commercial plan. Comorbid conditions were common in this population: 55.0% had chronic kidney disease, 11.9% had end stage renal disease, 59.3% had ischemic heart disease and 60.3% had diabetes. The median LOS during index hospitalization was 6 days (interquartile range: 4, 10 days) with a mean total hospital cost of $21,821 ± $31,427. RAASi was used in 51% and 39% of patients within 90 days before and after index hospitalization, respectively. Within 90 days following index discharge, 18.3% of patients had at least one hyperkalemia-related inpatient or outpatient encounter and only 1.9% of patients used SPS or patiromer.

**CONCLUSIONS:** This analysis demonstrates the significant burden of illness faced by heart failure patients with hyperkalemia. Our data also suggest possible gaps between clinical need and current therapy and highlight potential opportunities for advancing therapy and management strategy for hyperkalemia.

**SPONSORSHIP:** AstraZeneca.

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

**T1 Opioid analgesic use among Texas Medicaid enrollees: trends in potential inappropriate prescribing practices from 2013 to 2016**

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**BACKGROUND:** The ongoing opioid epidemic in the United States is characterized by an increase in the misuse of prescription opioids resulting in an increase in opioid overdose deaths. Inappropriate prescribing is a risk factor for overdose. Medicaid enrollees are more likely to receive opioid prescriptions and are at greater risk of opioid overdose compared to non-Medicaid enrollees.

**OBJECTIVE:** To examine trends in the prevalence of indicators for potential inappropriate prescribing (PIP) of opioids among Texas Medicaid enrollees.

**METHODS:** This retrospective study used Texas Medicaid prescription claims data from July 2013 to June 2016. Non-cancer patients who were aged 18 to 64 years and had ≥1 opioid prescription claim were included in this study. Opioid and benzodiazepine prescriptions not dispensed as capsules or tablets were excluded. PIP was identified by: (1) opioid prescriptions overlapping by ≥7 consecutive days; (2) opioid and benzodiazepine prescriptions overlapping by ≥14 consecutive days; (3) high daily opioid doses (≥100 Morphine Milligram Equivalents); (4) opioid prescriptions dispensed by ≥4 distinct pharmacies in a quarter; and (5) opioid prescriptions prescribed by ≥4 distinct prescribers in a quarter. Analyses were stratified by age, gender, public health region, prescriber type, and urban-rural status.
Descriptive statistics were calculated and logistic regression analyses were conducted using SAS 9.4.

**RESULTS:** A total of 267,855, 255,122, and 238,051 enrollees met the inclusion criteria in years 1 to 3, respectively. The percentage of enrollees with ≥1 PIP indicator decreased over the study period from 23.8% in year 1 to 19.2% in year 3. The percentage of enrollees with PIP decreased for each additional PIP event per enrollee (0-5) across all years (e.g., 76.2% for no PIP to 0.01% for 5 PIP events in year 1). The most common indicator of PIP across all years was opioid-opioid overlapping prescriptions (19.9%, 15.1%, and 15.0% in years 1, 2, and 3, respectively), while opioid-benzodiazepine overlapping prescriptions ranked second (10.5%, 10.4%, and 9.8% in years 1, 2, and 3, respectively). Logistic regression results showed that older, male, and rural-dwelling enrollees were more likely to have PIP compared to younger, female, and urban-dwelling enrollees for all years during the study period. Across all years, anesthesiologists and pain physicians were more likely to be associated with PIP compared to primary care physicians (P < 0.001).

**CONCLUSIONS:** Although PIP decreased over the 3-year study period, the use of Prescription Drug Monitoring Programs could further reduce PIP.

**SPONSORSHIP:** None.

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A U.S. commercial claims analysis of characteristics and healthcare costs of patients with anaphylaxis prescribed Auvi-Q versus other epinephrine auto-injectors

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**BACKGROUND:** Anaphylaxis is a potentially life-threatening condition that requires immediate injection of epinephrine. Auvi-Q (epinephrine injection, USP) is designed with audible and visible cues for use, a compact size, and an auto-retractable needle. Real-world health economic outcomes of patients prescribed Auvi-Q vs. other epinephrine auto-injectors (EAIs) have not been previously explored.

**OBJECTIVE:** To compare patient characteristics and real-world costs of care for non-matched and propensity-score matched (PSM) patients who experienced anaphylaxis and had previously been prescribed Auvi-Q or another EAI.

**METHODS:** The IBM MarketScan Commercial Claims and Encounters Database (January 1, 2016-October 31, 2019) was used to identify patients who experienced anaphylaxis based on a previously validated algorithm. The date of initial anaphylactic episode was set as the index date. Continuous medical and pharmacy coverage was required 12 months pre-index and 3 months post-index, and a filled EAI prescription was required in the pre-index period. Patients were assigned to a treatment cohort—Auvi-Q vs. other EAI—based on the last prescribed EAI before the index date. Baseline characteristics of patients were described. Costs of care were assessed in non-matched and PSM patients, independent of prescription costs.

**RESULTS:** A total of 18,791 patients were identified who were prescribed an EAI during the pre-index period and experienced anaphylaxis (Auvi-Q, n=416; other EAI, n=18,375). Patient characteristics and costs of care were compared between the Auvi-Q and other EAI cohorts. Both genders were equally affected in each cohort. Auvi-Q-prescribed patients were significantly younger (mean 12.3 vs. 17.9 years, P < 0.001), due to a higher proportion of patients younger than 4 years (28% vs. 11%, P < 0.001) and a lower proportion of patients older than 25 years (10% vs. 22%, P < 0.001). A larger proportion of Auvi-Q patients resided in the North Central region (30% vs. 19%, P < 0.001) and had a high-deductible health plan (21% vs. 12%, P < 0.001). In the non-matched cohort, all-cause costs of care were significantly lower among Auvi-Q patients ($1,155 vs. $1,918, P < 0.001) due to lower costs of outpatient visits, hospitalization, and emergency care. In the PSM cohort (Auvi-Q, n = 340; other EAI, n = 934), differences in patient characteristics diminished; however, significantly lower all-cause costs of care ($1,155 vs. $1,582, P = 0.036) and in-patient costs ($27 vs. $189, P = 0.042) were seen among Auvi-Q patients.

**CONCLUSIONS:** Independent of prescription costs, costs of care may be lower among patients prescribed Auvi-Q vs. other EAIs.

**SPONSORSHIP:** Kaleo.

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Healthcare costs associated with anaphylaxis episode in patients prescribed Auvi-Q versus other epinephrine auto-injectors experiencing mild-to-moderate or severe anaphylaxis in a United States commercial claims database study

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**BACKGROUND:** Auvi-Q (epinephrine injection, USP) is designed with audible and visible cues for use, a compact size, and an auto-retractable needle. Comparison of healthcare resource use (HRU) and healthcare costs (HC) between patients with anaphylaxis who were prescribed Auvi-Q vs. a different epinephrine auto-injector (EAI) has not been previously studied. Additionally, studies have not evaluated the impact of anaphylaxis severity on HRU and HC in such patients.

**OBJECTIVE:** To compare real-world costs of care for propensity score-matched (PSM) patients who experienced mild-to-moderate (I, IIA, IIB) or severe (IIIA, IIB, IIIC) anaphylaxis and had previously been prescribed Auvi-Q or another EAI.

**METHODS:** This study was conducted using the IBM MarketScan Commercial Claims and Encounters Database from January 1, 2016 to October 31, 2019. The event of anaphylaxis was identified based on a previously validated algorithm. Date of the first anaphylaxis episode was defined as the index date. Patients were required to have continuous medical and pharmacy coverage for 12 months pre-index and 3 months post-index, and an EAI prescription during the pre-index period. Patients were assigned to a treatment cohort based on the last prescribed EAI before the index date: Auvi-Q or other EAI. Anaphylaxis severity was evaluated using a defined grading system. In each severity subgroup, PSM was performed to diminish the selection bias. The 3-month post-index HRU and HC independent of prescription costs were compared within these subgroups.

**RESULTS:** In the mild-to-moderate anaphylaxis group, 83 patients prescribed Auvi-Q were matched to 207 patients prescribed a different EAI during the pre-index period. Patients in the Auvi-Q cohort had a significantly lower proportion (12% vs. 27.5%, P = 0.005) and...
number (1.1 vs. 1.4, \(P = 0.032\)) of emergency department (ED) visits. All-cause costs of care were significantly lower in the Auvi-Q vs. other EAls cohort (\$621 vs. \$1,412, \(P < 0.001\)). In the severe anaphylaxis subgroup, 166 patients prescribed Auvi-Q were matched to 406 patients prescribed a different EAI. A significantly lower number of hospitalizations was observed in the Auvi-Q cohort vs. other EAls cohort (0.006 vs. 0.035, \(P = 0.023\)), which was reflected in the lower all-cause costs of care ($1,476 vs. $2,836, \(P = 0.024\)).

CONCLUSIONS: These data suggest that regardless of anaphylaxis severity and independent of prescription costs, patients with Auvi-Q had lower HRU and HC associated with the episode of care when compared to patients with other EAls.

SPONSORSHIP: Kaleo.

RESULTS: Generalized linear regression model from R package was built from the training dataset with average adjusted \(R^2 = 0.679\). The validation datasets were used to forecast future pharmacy expenditures with a comparable adjusted \(R^2 = 0.681\). Independently, the PMPM drug cost from the test dataset provided an unbiased evaluation of model fit with an average adjusted \(R^2 = 0.637\) with the inclusion of prior year pharmacy cost, and adjusted \(R^2 = 0.32\) without prior year pharmacy cost.

CONCLUSIONS: The novel model can forecast commercial pharmacy cost with enhanced predictive performance for members with or without prior year pharmacy cost, and across all the disease conditions.

SPONSORSHIP: None.

U22 Forecast pharmacy cost using demographics, therapeutic conditions, and historical pharmacy cost

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BACKGROUND: Predicting health care costs for individuals is essential for managing care. By identifying high cost members, plan sponsors can perform targeted interventions designed to address each member’s unique needs and improve patient outcomes. Numerous forecast pharmacy models exist, but not all adequately address the complex needs of each plan sponsor and their members. Currently, the pharmacy cost models to forecast future drug expenditure include Medicaid CDPS pharmacy model, Medicare RxHCC model and others. This analysis is to explore an alternative model with Rx data only.

OBJECTIVE: The study objective is to develop a new economic model to use patients’ prior information to predict future pharmacy cost.

METHODS: This forecast analysis was based on a sample of 622,199 distinct members and their paid pharmacy claims during the 2017, 2018 and 2019 years who were enrolled in the employer sponsored pharmacy benefit plans. To be included in the eligible sample, members must have been continuously enrolled in the employer client sponsored pharmacy coverage plan for two consecutive years or more. Age, gender and 57 therapeutic condition groupings follow the framework from CDPS pharmacy model. Pharmacy cost was normalized on a per member per month (PMPM) basis. In addition to age, gender and drug therapeutic condition variables, brand drug indicator, specialty drug indicator and previous year member specific PMPM variables were included in a one year shifted model. The data was then randomly split into training, validation and testing datasets by 2:1:1 ratio. The employer clients in the testing dataset were mutually exclusive from those in training and validation datasets. Data was processed and analyzed by Netezza SQL and R programming.

RESULTS: Analyzed members included: 40,407 DM, 143,308 statin, and 132,358 RAS. After covariate adjustment, 1 percentage point PDC increase was associated with $46 PPPY TCC decrease for DM members; $21 PPPY TCC decrease for statin members; and $38 PPPY decrease for RAS members, all findings \(P < 0.001\). For all three Star drug categories, using < 50% PDC as reference group, there was a statistically significant TCC PPPY decrease, \(P < 0.01\), with each progressively improving adherence quintile. For example, the DM members in the 80%-95% PDC group had $2,164 lower TCC PPPY compared to the < 50% PDC group. Medical events followed the same patterns as TCC PPPY, for all Star three drug categories, \(P < 0.01\).
CONCLUSIONS: In this real-world, large Medicare integrated medical and pharmacy claims study, we found a strong association between increasing adherence within Medicare Star rating drug categories and lower TCC, as well as medical events. Limitations include the retrospective study design and potential confounding by the healthy adherer effect.

SPONSORSHIP: Prime Therapeutics.

**U24** Identifying nonadherence to specialty medications: comparing pharmacy claims data and individual reasons for nonadherence

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**BACKGROUND:** Pharmacy claims data are often used to calculate medication adherence by pharmacies, accreditation bodies, payors, and manufacturers, but are unable to discern true nonadherence from clinically appropriate gaps in therapy frequently required with specialty medications.

**OBJECTIVE:** To identify reasons for nonadherence, defined as proportion of days (PDC) covered < 90%, and determine the rate of misidentified nonadherence to specialty medications.

**METHODS:** This was a single-center, prospective cohort study of patients with at least 4 specialty medication fills between 05/10/2019 and 09/10/2019 at an integrated health-system specialty pharmacy with a PDC < 90% in the previous 4 months. Patients were excluded if they were no longer seen by a Vanderbilt provider or deceased at the time of review. PDC was calculated as the number of covered days from the supply diary divided by calculated number of days in the study period. Reasons for nonadherence were identified via electronic health records or patient interview and used to classify patient nonadherence as either misidentified (provider-directed treatment holds or external pharmacy fills) or true. Individual patients may have > 1 reason for nonadherence. Descriptive statistics were performed.

**RESULTS:** Of the 677 patients reviewed, most were female (72%), white (86%), with a median age of 52 (IQR 41, 64). Common medications included adalimumab (13%), etanercept (13%) and evolocumab (13%). More than half of patients (59%) were determined to be misidentified as nonadherent for the following reasons: clinically appropriate holds (39%), medication discontinuation (32%), and medication from a source not captured by our pharmacy claims database (14%). Reasons for true nonadherence included memory (49%), patient unreachable for refill (30%), patient unresponsive to unfilled prescriptions (9%), medication discontinuation (9%), and clinical (11%).

**CONCLUSIONS:** Our study demonstrates that a common adherence calculation using pharmacy claims data, when applied to specialty medications, results in high rates of misidentified nonadherence. Better methods to assess true nonadherence in this population are needed to identify patients for possible interventions and to more accurately assess specialty pharmacy’s impact on adherence.

**SPONSORSHIP:** None.

**U25** Impact of a value-based program on the utilization and adoption of oncology biosimilars

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**BACKGROUND:** Biosimilars are similar to the existing licensed biologic products with no clinically meaningful differences in terms of safety and efficacy. Filgrastim-sndz is a short acting myeloid growth factor (SA-MGF) that was available in September 2015. Epoetin alfa-epbx is an erythropoiesis-stimulating agent (ESA) that was available in November 2018.

**OBJECTIVE:** This study was conducted to evaluate the utilization of SA-MGF and ESA biosimilars in two value-based management Medicare Advantage groups, one that actively promoted (AP) by offering the biosimilar as a preferred choice and one that passively promoted (PP) by offering the biosimilar as an equal alternative.

**METHODS:** For SA-MGFs, approved treatment requests for cancer patients were evaluated from September 2015 to October 2018 (n = 8,459). For ESAs, approved treatment requests for cancer patients were evaluated from November 2018 to December 2019 (n = 7,917). The primary outcome was the biosimilar utilization rate which was calculated by taking the number of requests for the biosimilar divided by the number of requests for the biosimilar and non-biosimilar. The secondary outcome was time to adoption, the time point when the utilization rate reached 50%. Chi-square statistics were performed to examine group differences. Post-hoc analyses evaluated the impact of demographic and contextual factors.

**RESULTS:** The findings suggested that the active promotion of biosimilars can impact the utilization rate for SA-MGF and ESA biosimilars. The utilization rate for filgrastim-sndz (AP: 62.62%, PP: 36.81%, χ² = 387.16, P < 0.01) and epoetin alfa-epbx (AP: 75.22%, PP: 65.22%, χ² = 69.82, P < 0.01) were higher in the AP as compared to the PP group. The time to adoption for filgrastim-sndz (AP: 19 months, PP: 28 months) and epoetin alfa-epbx (AP: 3 months, PP: 5 months) was shorter in the AP as compared to the PP group. After the point of adoption, the average utilization rate for the SA-MGF (AP: 93.75%, PP: 73.33%) and ESA (AP: 89.08%, PP: 77.34%) was higher for AP as compared to the PP group.

**CONCLUSIONS:** Oncology biosimilars are rapidly becoming important and provide value by delivering similar efficacy at a lower cost. The current study showed that actively promoting biosimilars within a valued-based program can have an impact on the utilization rate and time to adoption for SA-MGF and ESA biosimilars.

**SPONSORSHIP:** New Century Health.

**U26** Trends in manufacturer perceptions and practices regarding pre-approval information

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**BACKGROUND:** Pre-approval information exchange (PIE) is communication of information regarding medical products not yet approved/cleared for use or unapproved uses of approved/cleared medical products to payers. PIE is particularly valuable to payers facing increased challenges to appropriately forecast budgets and set premium rates.

**SPONSORSHIP:** None.
Manufacturers benefit from PIE by increasing awareness of impending product launches and informing earlier formulary review. The current study compared 2018 to 2020 manufacturer survey responses to explore evolving needs and considerations for PIE.

**OBJECTIVE:** Assess trends for U.S. biopharmaceutical manufacturers on their perceptions and practices regarding PIE.

**METHODS:** Two online surveys were conducted (2018 and 2020) to understand manufacturer perceptions and practices related to PIE. Trends in responses were analyzed where possible.

**RESULTS:** For 2018 (N=41) and 2020 (N=57) surveys, respondents were mostly at the Director level (76% vs 68%) and worked in health economics and outcomes research or market access (78% vs 68%), respectively. The number of respondents who reported having a specific process in place to approve materials for PIE increased (43% vs 68%, for 2018 to 2020, respectively; P<0.05). Increased rates of proactive communication of PIE with payers were reported, though non-significant (61% vs 65%, for 2018 to 2020, respectively; P>0.05). There was no significant difference between years in the types of approved PIE, although some categories of information (i.e., pricing) were rated as more difficult to disseminate in 2020. In 2020, PIE materials were most frequently disseminated (63%) 4 to 12 months prior to the anticipated approval. Manufacturers (26%) noted an increase in the frequency of payer requests for pre-approval dossiers. Additionally, 70% of manufacturers in 2020 were required to verify the audience for PIE and reported that barriers exist to the provision of PIE, such as confidentiality concerns (39%), internal education needs (35%), and lack of functional alignment on the need for PIE (30%).

**CONCLUSIONS:** From 2018 to 2020, manufacturers have adapted to payer needs for PIE, although there is continued need for legislative clarity to provide appropriate guardrails. Meanwhile, manufacturers will continue to remain heterogeneous in their approach and require a customized approach for effective pre-approval communications.

**SPONSORSHIP:** None.

**U27 Impact of different price reduction mechanisms for specialty prescription drugs on patient out-of-pocket costs**

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**BACKGROUND:** Manufacturers have recently employed a number of different approaches to reduce the cost of pharmaceuticals, however the impact of these price reduction mechanisms on patient out of pocket (OOP) costs is unknown.

**OBJECTIVE:** To describe the impact of different list price reduction mechanisms on patient OOP costs, using the introduction of new national drug codes (NDCs) for the PCSK9 inhibitor class of therapies (evolocumab (E), alirocumab (A)) and the introduction of early generic versions of hepatitis C medications (ledipasvir/sofosbuvir (LS), sofosbuvir/velpatasvir (SV)) as case studies.

**METHODS:** A retrospective analysis including adjudicated claims through 11/2019 was conducted using the IQVIA PharMetrics Plus claims database. Descriptive analyses at the claim level were conducted to describe the mean and median OOP costs by calendar month and the average across months. Generalized linear models using a log link and gamma distribution were conducted to estimate the mean change in OOP costs accounting for calendar months.

**RESULTS:** After introduction of the new NDCs, mean allowed amounts reflecting the list price reduction for E and A were both reduced by 61%, from approximately $1,190 to $460 while mean OOP costs were reduced to a lesser extent in both E (from $188 to $111, 38% (P<0.01) and A (from $157 to $121, 23% (P<0.01)). Similarly, the introduction of early generic versions of SV and LS resulted in mean allowed amounts reducing by 68% (from $23,237 to $7,537) and 61% (from $29,378 to $11,485) respectively, however mean OOP costs for SV were reduced by only 15% (from $659 to $554, P<0.01) and while LS had an increase in OOP by 5% (from $748 to $770) but was not statistically significant (P=0.25). In both price reduction approaches, the mean OOP cost differences varied by months, with some months demonstrating higher OOP costs post list price reductions (Range: E: -48% to -28%, A: -30% to -11%, SV: -33% to 11%, LS: -19% to 38%). In contrast to the mean OOP costs, median OOP costs for A, SV and AV were the same or larger for a majority of the calendar months post price reduction (A: 9 out of 9 months, SV: 8 out of 10 months, AV: 7 out of 10 months), indicating that for many prescriptions, patient OOP costs may not have changed or may have increased.

**CONCLUSIONS:** Savings from list price reductions were only partially passed through to patients in the form of OOP costs, with many calendar months having similar or higher OOP costs, indicating a multifaceted approach, beyond only considering list prices, may be required to reduce patient OOP costs.

**SPONSORSHIP:** Genentech.

**U28 AWP and NADAC price trends from 2015 to 2020: a retrospective analysis**

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**BACKGROUND:** Average Wholesale Price (AWP) is the pricing benchmark in most major pharmacy benefit manager contracts, though AWP price changes are not clearly connected with increased drug costs. In contrast, the National Average Drug Acquisition Cost (NADAC) price list of national drug codes (NDCs) reflects actual retail pharmacy acquisition costs of drugs. NADAC prices are available for more than 95% of all active NDCs, is publicly available, managed by the Center for Medicare and Medicaid Services (CMS), and updated weekly. While studies have looked at implied AWP discounts at a moment in time, price trends associated with these two price sources have not been reviewed longitudinally or studied comparatively.

**OBJECTIVE:** This study aims to establish across-time price trends for AWP and NADAC unit prices, hypothesizing that NADAC unit prices inflate at a slower rate.

**METHODS:** To examine price changes in AWP and NADAC retrospectively, we created price indices for each cost basis using Medi-Span’s AWP and CMS’ NADAC unit price lists from 2015 to 2020. Each price index comprised identical groupings of drugs where both NADAC and AWP unit costs existed. To ensure generalizability, we captured NDC codes that made up 95% of total spend, and, accounted for 80% of Capital Rx’s 2019 commercial book of business total spend when
excluding drugs without both NADAC and AWP prices. Price index changes were evaluated in aggregate and at the sub-classification-generic, brand, and specialty drug-level from 2015-2020.

RESULTS: Between 2015-2020, we found that AWP prices inflated at a faster rate than NADAC, with yearly increases of 2.46% and 1.85%, respectively. NADAC and AWP price trends for brand and specialty drugs were similar- NADAC price increases were 0.1% and 1.34% lower, respectively. However, generic price trends across these two indices displayed substantial divergence: generic AWP prices slightly increased over the period (+0.76%), while NADAC prices decreased by 44%.

CONCLUSIONS: Currently, the standard pricing metric—AWP—does not reflect the decreasing generic price trends reflected in NADAC. In a healthcare system where high drug costs are a barrier to care, lower drug prices could impact adherence and outcomes for patients with a high cost responsibility. This study demonstrates that a NADAC based pricing model could: enhance pharmacy pricing transparency, decrease the burden of medication expenses for patients, and enable richer benefit designs for clients.

SPONSORSHIP: None.

U30 Healthcare economic information and patient experience information in immuno-oncology: is the research being conducted and communicated effectively to U.S. payers?

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BACKGROUND: The FDA has released current guidance on healthcare economic information (HCEI) use and a series of guidance documents on patient-focused drug development. Payers are challenged with how to use this information effectively, while manufacturers are challenged with generating data to meet payer needs.

OBJECTIVE: This study investigates the current impact of immuno-oncology (IO) HCEI and patient experience information (PEI) on U.S. payer decision-making. Gaps in payer information needs and more effective communication of HCEI and PEI are explored.

METHODS: A targeted literature review of IO HCEI and PEI in the U.S. was conducted to inform in-depth interviews with 5 senior-level U.S. payers, with the goal of gauging payer awareness and impact of HCEI and PEI on decision-making.

RESULTS: Payer opinions varied on the impact of HCEI and PEI on payer decision-making. Some believed PEI was more relevant, while others focused on HCEI. All agreed HCEI or PEI could support differentiation when multiple treatment options exist. Where PEI was important, payers indicated PEI incorporated into registrational trials, manuscripts, and treatment guidelines could be reviewed alongside FDA labeling for payer reimbursement consideration. Payers also indicated summarizing PEI as part of total cost of patient care is particularly useful. Post-progression PEI can help justify treatment continuation and coverage decisions. Clear, concise communication of PEI is critical. Payers would value guidance from manufacturers to better understand PEI in order to appropriately incorporate into reimbursement decision-making. Greater transparency in HCEI such as healthcare resource utilization, including supportive medication costs and cost impact of adverse events, would be helpful. Publication in peer-reviewed journals is essential for HCEI and PEI to be considered by payers. Despite identification of 11 relevant IO HCEI and PEI publications as part of the strategic literature review, U.S. payer interviewees were unaware of the publications.
CONCLUSIONS: Communication of HCEI and PEI in clear, concise ways, in accordance with FDA guidance, is critical for U.S. payers to consider in their decision-making. This information can be impactful for payers, particularly where efficacy and safety are comparable among treatment options, and can help justify continued treatment after progression. Improved education of payers on PEI will maximize impact. Interactive, visually appealing summaries of peer-reviewed publications that tell compelling value stories from a total cost of care perspective have the most impact on payer decision-making.

SPONSORSHIP: EMD Seronzo Research & Development Institute.

U31 Evaluation of providers’ response to polypharmacy program outreach
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BACKGROUND: Polypharmacy is a common issue among patients with chronic conditions who take multiple medications to manage their diseases. According to the British Journal of Clinical Pharmacology, increasing the number of drugs used by a patient linearly increases the number of drug related problems (DRPs) (Viktil et al, 2006). Since there is no standardized threshold that defines what constitutes polypharmacy, 11 or more medications was used in this program. Polypharmacy puts patients at a higher risk of experiencing DRPs such as adverse drug events, drug-drug/drug-disease interactions, duplication of therapy. This could also result in unnecessary pharmacy drug spend for health plans.

OBJECTIVE: The objective of this program was to identify and resolve DRPs in patients taking 11 or more medications per month and result in pharmacy cost savings for the health plan.

METHODS: From July to December of 2019, 43,034 members taking 11 or more medications were enrolled in the polypharmacy program. The RxCellent Care program was used to identify the following DRPs: therapeutic duplications, deprescribing opportunities (such as long-term use of a proton pump inhibitor, a benzodiazepine, an antibiotic or a non-benzo hypnotic), drug-age interactions, and overutilization of a non-benzo hypnotic), drug-age interactions, and overutilization of a non-benzo hypnotic). Since there is no standardized threshold that defines what constitutes polypharmacy, 11 or more medications was used in this program. Polypharmacy puts patients at a higher risk of experiencing DRPs such as adverse drug events, drug-drug/drug-disease interactions, duplication of therapy. This could also result in unnecessary pharmacy drug spend for health plans.

RESULTS: Of the 43,034 members enrolled in this program, 29,990 unique DRPs were identified. Of the 16,092 DRPs with at least 6 unique DRPs were identified. Of the 16,092 DRPs with at least 6 months post intervention to measure outcomes, 5,320 (33.1%) were resolved (drugs discontinued) yielding to approximately $1,952,440 savings in pharmacy drug spend for the health plan.

CONCLUSIONS: Health plans should consider multimodal outreach (letter, call) in engaging providers to help resolve drug related problems (discontinue unnecessary medications), simplify medication regimens for patients and result in reduced pharmacy drug spend.

SPONSORSHIP: Envolve Pharmacy Solutions.

U32 Characterizing health plan evidence review practices: an empirical analysis
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BACKGROUND: Best-practice guidelines require that health plans base their drug coverage decisions on the best available evidence. However, how often plans update their coverage decisions and how comprehensively they review the available evidence is unclear.

OBJECTIVE: First, to examine the how frequently health plans update their specialty drug coverage decisions. Second, to determine the proportion of published evidence cited by plans in their specialty drug decisions.

METHODS: We relied on the Specialty Drug Evidence and Coverage (SPEC) Database for this research, which includes coverage decisions issued by 17 large commercial health plans. First, we used a sample of 201 drugs to determine how often plans updated their coverage decisions over a two-year period. Second, for 20 drugs randomly selected from SPEC, we systematically searched the PubMed Database for relevant clinical and economic studies. We compared the studies identified from the systematic literature search with the studies cited by plans in their coverage policies.

RESULTS: Between August 2017 and August 2019, plans updated 97% (4,468/4,597) of their coverage decisions (median = 100%; range = 70-100%). On average, plans added or removed restrictions in 16% of decisions (median = 13%; range = 7-52%). Plans updated the evidence they cited 81% of the time (median = 88%, range = 47%-99%). We identified 6,145 studies in our literature search, of which 2,760 were clinical or economic studies. Overall, plans cited only 1% of the available evidence (range ≤1-3%). Plans cited a larger percentage of available HTAs (3%) and RCTs (3%), than RWE studies (<1%) and economic evaluations (<1%). Plans cited a larger percentage of the available evidence for some drugs than others (median = 0.8% of available evidence; range = 0-24%). Plans cited the largest percentage of the available evidence for etoposide for Duchenne muscular dystrophy (24%), and the smallest percentage for crizotinib for patients with metastatic non-small cell lung cancer (0%) and palonosetron for nausea and vomiting associated with chemotherapy (0%).

CONCLUSIONS: We found that the included health plans updated 97% of their coverage decisions over a two-year period, but added or removed coverage restrictions in only 16%. On average, plans cited only 1% of the available evidence for the included sample of drugs, although some plans cited a larger percentage than others. Future research should examine the characteristics of studies that health plans cite in support of their coverage decisions.


U33 Digital therapeutics as a medical benefit: emergence of published policies by managed care organizations
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BACKGROUND: Digital therapeutics (DTx) are software programs designed to be administered digitally to support treatment of a disease, disorder or condition. In recent years, DTx have emerged as a medical benefit, with many payers developing policies to cover these treatments. However, the landscape of DTx policies remains inconsistent and fragmented, with few studies examining the factors that influence the development of these policies.

OBJECTIVE: To examine the characteristics of DTx policies published by managed care organizations (MCOs) and to identify the factors that influence the development of these policies.

METHODS: A systematic search of the literature was conducted to identify DTx policies published by MCOs. The characteristics of these policies were then examined to identify the factors that influence the development of these policies.

RESULTS: A total of 12 DTx policies were identified, with varying levels of detail and specificity. The factors that influenced the development of these policies included the availability of evidence, the cost of the DTx, and the potential for clinical improvement.

CONCLUSIONS: The development of DTx policies by MCOs is influenced by a variety of factors, including the availability of evidence, the cost of the DTx, and the potential for clinical improvement. These factors should be taken into account when developing DTx policies, in order to ensure that the policies are effective and efficient.

BACKGROUND: Digital therapeutics (DTx) are software-based interventions that deliver a clinical mechanism of action, either alone or in combination with other standard-of-care treatments to improve outcomes. DTx products can collect patient data to help healthcare providers deliver personalized care for better outcomes. However, due to the nascent marketplace, there is a rising debate for an appropriate reimbursement model that aligns with and captures the full value of DTx products. Although the pharmacy benefit has been recommended for DTx coverage, published medical policies can offer a detailed glimpse into the qualifications and evaluation for a DTx product for medical necessity.

OBJECTIVE: To identify current DTx products with published medical policies by managed care organizations (MCOs) in the U.S. in order to elucidate trends for coverage determination and status.

METHODS: A search was conducted on Canary Insights (Lakewood, CO) with companies that were members of the Digital Therapeutics Alliance (DTA) and have products on the market, as well as pending regulatory review. Policies were segmented by parent vs derivative policy to be analyzed across key parameters assessing total policy count, unique payers, state and national plan coverage, and percent coverage of the DTx product.

RESULTS: A total of 7 of the 37 DTx companies reviewed were found to have a published policy on at least 1 of their DTx products. There were 114 total policies analyzed with 24 parent policies identified. 62.5% of the companies showed coverage from a single unique payer; 65% of the policies were state-specific vs 24% that were national; 4% of all policies provided coverage within the payer organization. The covered policies indicated that the DTx product may be considered medically necessary for specified patient populations, while another was under consideration for coverage of the DTx product.

CONCLUSIONS: Our analysis indicates that payers are still developing a uniform foundation for their coverage policies of DTx products. Additional evidence gathered through direct payer insights would provide further insights to elucidate DTx product coverage efforts. By referencing existing policies, DTx innovators may be able to help guide conversations with payers regarding coverage of their product.

SPONSORSHIP: None.

U34 Treatment cost analysis in the U.S.: conceptual framework and comparison with budget impact model

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BACKGROUND: Despite the growing prominence of the ICER Review, the absence of a national U.S. HTA with a broad mandate to evaluate new technologies and guide coverage and pricing decisions has manifested in limited health economic evidence for many new treatments in the U.S. Payer ambivalence regarding the use of quality-adjusted life years has also contributed to underuse of conventional cost effectiveness analyses (CEA), resulting in budget impact analyses (BIA) often constituting the only economic evidence available to payers. Treatment cost analysis (TCA) seeks to bridge the divide between the two methodologies, preserving the focus on short-term decision-making while considering comparative treatment effects and the implications of treatment sequencing, which BIAs commonly fail to address.

OBJECTIVE: The study objective is to compare decision analytics approach of TCA with BIA.

METHODS: TCA estimates the number of patients responding to alternative treatments over short term and the resultant cost. The model typically uses a decision tree structure, with nodes corresponding to treatment response outcomes, and considers patient pathways through multiple lines of therapy. Outcomes include cost per member per month (PMPM), total number of responders and cost per responder. We developed de novo BIA and TCA models within the context of a hypothetical new product alongside three existing treatments in a plan with 1M members. Both models shared equal inputs, including population size, costs, medical resource utilization, and adverse events rates, but the BIM also included market shares, while the TCM incorporated treatment-specific response rates. The BIA compared a current and new market mix, while the TCA compared alternative treatment strategies with three lines of therapy each.

RESULTS: Over three years, the TCM and BIM produced similar results: total cost of $63M and $61M and average cost PMPM of $1.73 and $1.70, respectively. Additionally, the TCA compared alternative positioning for the new treatment, resulting in cost PMPM ranging from $1.69 to $1.75, number of responders from 173 to 157, and annual cost per responder from $118,468 to $131,394, for first line and third line use respectively, demonstrating that earlier use of the new treatment in the patient pathway produces greater value for money.

CONCLUSIONS: TCA can supplement traditional BIMs by adding novel insights into short-term affordability and value for money, by examining alternative positioning in patient pathways. As such, it represents a promising tool in communicating the economic impact of innovative treatments to U.S. payers.

SPONSORSHIP: Evidera.

U35 Structure and implementation environment of performance-based pharmacy payment models

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BACKGROUND: There has been a recent shift in the United States (U.S.) towards value-based health care models which seek to improve patient outcomes while reducing health care spending. As a part of this trend, many payers have implemented performance-based pharmacy payment models (PBPPMs) which incentivize pharmacists to improve patient care by tying reimbursement to performance measures. However, the design and implementation of PBPPMs in pharmacy lacks transparency and has not been described in the literature.

OBJECTIVE: To (1) describe the current structure of PBPPMs in the U.S. and (2) identify the contextual and motivational influences that need to be considered when implementing these models.

METHODS: A literature search of peer-reviewed and grey literature on value-based care, pay-for-performance, and performance-based models in pharmacy settings was conducted. Additionally, semi-structured stakeholder interviews were conducted with a convenience sample of 17 individuals who were selected to ensure representation across the socio-ecological model. Participants included
community pharmacists, payers, quality measure developers and vendors, academics, and pharmacy advocacy organization leaders. Data were analyzed to facilitate a greater understanding of PBPPMs and how they can be improved in the U.S., as well as the contextual conditions and motivational pressures of the environments in which the PBPPMs are currently implemented.

**RESULTS:** Four major components of PBPPMs in the U.S. were found: 1) performance and quality measures; 2) incentive structures; 3) patient care services; and 4) attribution. The analysis highlighted major barriers (e.g., lack of alignment) and interviewees made recommendations to improve current structures of PBPPMs. When implementing PBPPMs it is important to consider individual and relational factors (e.g., organizational culture, information technology, and workflow operations), broader contextual factors, and other motivations and pressures. Notable implementation considerations included: 1) having a quality driven, innovative, and flexible organizational culture; 2) ensuring engagement of pharmacists, payers, and patients; and 3) utilizing necessary workflow and IT infrastructure (e.g., data sharing through use of EQuIPP).

**CONCLUSIONS:** To better develop and implement PBPPMs, it is first critical to understand their key components and needed changes, as well as the contextual and motivational influences that impact their implementation.

**SPONSORSHIP:** PharmAlliance.

**U36 Inequality in value assessment across health care sectors**

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**BACKGROUND:** Spending on health care in the U.S. continues to rise, reaching nearly $3.6 trillion in 2018. (CMS, 2020) As such, policymakers and payers have grown increasingly dependent on economic evaluations of health technologies and services to optimize their investments. Among all U.S. health care sectors, the pharmaceutical sector is facing the most stringent economic evaluation expectations. To date, similar economic evaluative requirements have not been implemented in a standard way for other health care services, despite pharmaceuticals accounting for approximately 14.7% of U.S. health care expenditures in 2018 while other health care sectors account for a far higher share of spending. (CMS, 2020; Buxbaum et al., 2017; Mafi et al., 2017; Reid et al., 2016; Roehrig, 2017).

**OBJECTIVE:** To quantify the extent to which the evaluation burden varies by U.S. health care sector relative to health care spending.

**METHODS:** To gain a better understanding of the burden of value assessment on the U.S. health care system, we estimate the count of cost-effectiveness analyses (CEAs) for each health sector included in the Tufts CEA Registry (CEAR) using multivariate Poisson regressions. We then compare sector-level CEA counts with each sector’s share of national health expenditures as reported in the National Health Expenditure Accounts (NHEA).

**RESULTS:** In 1990, 43.8% of reported CEAs were in the pharmaceutical sector (n=256). The next most common sectors evaluated in 2015 were medical procedures, surgical procedures, and health screenings, at 14.3%, 9.5% and 9.3% respectively. Using multivariate analysis for CEAs reported during this 25-year period, compared to the pharmaceutical sector, all other health sectors had between 94% and 87% fewer CEAs performed. Immunizations had the lowest CEAs relative to pharmaceuticals (85% fewer), while surgical procedures had the most CEAs relative to pharmaceuticals (54% fewer evaluation). Between 2000 and 2015, pharmaceuticals accounted for 10.4% (in 2000) to 11.9% (in 2015) of health spending, 12.4% at the high point in 2006. Over this same period, pharmaceuticals were subject to an average of 36.7% of CEAs conducted annually.

**CONCLUSIONS:** The economic evaluative burden on the pharmaceutical industry relative to other sectors is imbalanced considering its share of health care spending. To best optimize investments in health care, policymakers and payers may benefit from economic evaluations on under-evaluated sectors responsible for higher proportions of expenditures.

**SPONSORSHIP:** Amgen.

**U37 How are curative therapies defined by United States payers?**

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**BACKGROUND:** Curative therapies are generally described as one-time, or short-term, treatments for patients with diseases that would otherwise require treatment for the duration of a patient’s life. Coverage decisions for curative therapies can differ from traditional therapies because the potential long-term benefit/risk profiles of newly approved curative therapies are often determined over time. The Institute for Clinical and Economic Review (ICER) recently published its “Value Assessment Methods and Pricing Recommendations for Potential Cures: A Technical Brief,” which outlines considerations for the assessment of potential curative therapies.

**OBJECTIVE:** This study aimed to evaluate coverage decision patterns for curative therapies, as well as familiarity with and utilization of ICER’s technical brief, among United States payers.

**METHODS:** Data was collected from qualified users registered with FormularyDecisions (FD) using a double-blinded, 10-item survey. FD is an online platform that facilitates access to critical product evidence and supports a bidirectional exchange between payers and manufacturers via syndicated surveys and other innovative methods. The survey was fielded in March 2020.

**RESULTS:** A total of 152 payers from national and regional health plans, integrated delivery networks, and pharmacy benefit managers participated in the survey. Respondents (83%) were at least somewhat familiar and knowledgeable about curative therapies; however, very few (5%) had a standard definition for curative therapies. Cost-effectiveness data, comparator data, and post-launch real-world evidence were noted as the biggest drivers for potential decision making for curative therapies (77%, 75%, and 72%, respectively). Among known payment models, outcomes-based payments were the most
frequently considered (53%) and implemented (20%) by organizations to mitigate the high costs of curative therapies. When asked about familiarity with ICER’s brief, 62% were not at all or not very familiar, however, a majority (88%) were at least somewhat likely to consider utilizing it to assess the value of curative therapies.

**CONCLUSIONS:** Although payers were generally familiar with curative therapies, very few payers reported their organization having standard definitions for curative therapies. Manufacturers should work closely with payers to better define curative therapies, since these definitions may impact payer coverage decisions, development of alternate payment models, and value assessment methods. With an increasing number of curative therapies in the pipeline, future research should examine factors that impact payer decision making for curative therapies.

**SPONSORSHIP:** Xcenda.

**U39 Impact of electronic-directly observed therapy (eDOT) on medication adherence: results of a systematic literature review**

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**BACKGROUND:** The electronic-Directly Observed Therapy (eDOT) intervention requires trained health care professionals to video-monitor patient adherence, via computer or smartphone, to the entire course of their prescribed medication at the right time and right dose. Video monitoring can be synchronous (live video) or asynchronous (recorded video). There is a paucity of literature studying the utility of eDOT in patient adherence.

**OBJECTIVE:** To conduct a systematic literature review evaluating the treatment completion rate and medication adherence rate of eDOT across different therapeutic areas.

**METHODS:** We performed a systematic literature search on PubMed database (2001-2020) and Google Scholars search engine for English language publications for the treatment completion and adherence of electronic-Directly Observed Therapy intervention in adults and pediatric population within the U.S. Both clinical trials as well as real-world, observational studies were included. Completed/ongoing research studies evaluating the feasibility, acceptability/user satisfaction, and adherence rate of eDOT in different therapeutic areas were included. Measurement methods for feasibility and acceptability of eDOT included were semi-structured interviews or patient experience survey questionnaires. Patient adherence measurement scales included were proportion of eDOT sessions attended, MMAS (Morisky Medication Adherence Scale), MPR (Medication Possession Ratio), and ASK-20 (Adherence Starts with Knowledge).

**RESULTS:** Eight studies comprising 195 patients and 56 CDC programs were included in the literature review. Among the observational studies (n = 7 studies), the adherence using eDOT intervention in the treatment of tuberculosis (TB, n = 3) was ≥90%, sickle cell disease (SCD, n = 1) was 93.3%, acute lymphoblastic leukemia (ALL, n = 1) was 90%, mild dementia (n = 1) was 81%. The treatment completion rate in TB was ≥90%, SCD was 93%, and ALL was 82%. In addition, the observational study (n = 1) on the feasibility of eDOT for treatment adherence in opioid use disorder suggested mixed attitudes towards eDOT. Finally, the randomized clinical trial (n = 1) to measure the adherence in depression patients is currently ongoing.

**CONCLUSIONS:** Findings from this systematic literature review indicate that the usage of eDOT as a medication adherence intervention demonstrates that patients show a high adherence. The adherence rates vary across therapeutic areas.

**SPONSORSHIP:** None.

**U38 Patient-related factors: a prevalent barrier dimension in adherence to oral oncolytic treatments literature review**

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**BACKGROUND:** Oral oncolytic treatments can be complex and often costly for payers and patients. In 2003 the World Health Organization (WHO) created the 5 dimensions of adherence which are: social and economic, healthcare system, condition-related, therapy-related, and patient-related. Understanding patient-related factors impacting medication adherence is critical.

**OBJECTIVE:** To identify prevalence and impact of patient-related adherence to oral oncolytic adherence based upon the WHO framework.

**METHODS:** A targeted literature review was conducted for oral oncolytic treatments from 2014-2019. Twenty-one of the patient-related barriers categorized using the WHO classification for oral oncolytic treatments were ranked by type, prevalence, and impact on adherence. Outcomes for adherence were defined by the following: in-person or phone interviews, Chew’s health literacy questionnaires, various types of surveys, claims data analysis, Rx refill data, and assessment scales such as, memorial symptom assessment scale (MSAS) and morisky medication adherence scale (MMAS-8).

**RESULTS:** Twenty-four articles were specific to barriers in oral oncolytic adherence. Of the 24 articles, patient-related adherence barriers were consistent across 13 of the 21 factors. Four of the most prevalent factors were 1) negative health and medication belief (34%), 2) forgetfulness (17%), 3) lack of knowledge and negative perceived risk and benefit associated with disease and treatment (17%), 4) increased psychosocial stress, anxiety, anger, fear or frustration with healthcare professionals (HCPs) or healthcare system (HCS) (17%). Impact of negative health and medication belief was seen to lower adherence by 30%-89% across the reporting studies. While forgetfulness lowered adherence by a range of 30%-47%. Lack of knowledge and negative perceived risk and benefit associated with disease and treatment had a larger variation with negative impact on adherence ranging from 9.5%-80%. Finally increased psychosocial stress, anxiety, anger, fear, or frustration with HCPs or HCS reported a range of 35%-60.8% lowered adherence. Many studies did not achieve statistically significant adherence outcomes that directly impacted treatment safety, efficacy, or cost.

**CONCLUSIONS:** When developing medication adherence strategies for oral oncolytic treatments, healthcare practitioners should consider addressing patient-related factors that can be modified to create effective long-term results. Further research is necessary to fill gaps in this analysis.

**SPONSORSHIP:** None.
U40 Analyzing trends in new molecular entities and biologics approved by the FDA from 2015 through 2019

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BACKGROUND: At its core, the American healthcare system grants exclusivity to drug manufacturers enticing them to bring new and innovative products to the market. The FDA on average has approved 20-25 drugs per year over the past two decades. However, in the last 5 years, except for a dip in 2016, new drug approvals have been in the range of 50-60 each year. The rapidly evolving environment is a sign of significant market potential resulting in significant competition and innovation.

OBJECTIVE: To study the trend in new molecules and biologics approved by the FDA between 2015-2019.

METHODS: Created an excel framework of newly approved molecules and biologics between the years 2015 and 2019 using the FDA-Approved Drugs database. Additional information on Company, Therapeutic Area and Mechanism of Action were added by studying the prescribing information of these products.

RESULTS: The average approvals between 2015-2019 was 50 new drugs per year. The highest number of approvals was in Oncology (N = 71, 38%), followed by Infectious Diseases (N = 32, 17%), Neurology (N = 19, 10%) and Immunology and Inflammation (N = 18, 10%). 41% (N = 104) of the new drugs had a priority review and over 75% (191) have a unique mechanism of action. 58% (N = 145) had a Type -I New Molecular Entity (NME) classification and 36% (N = 90) were Biologics (BLA). 52% (N = 71) of the companies were in Oncology, 23% (N = 32) in Infectious Diseases, 15% (N = 21) in Immunology and Inflammation and 14% (N = 19) in Neurology.

CONCLUSIONS: Pharmaceutical companies recognize the unmet need and market potential in Oncology, Infectious Diseases, Immunology and Inflammation and Neurology, which has led to significant innovation and increased drug approvals.

SPONSORSHIP: Apperture Health.

U52 United States payer perceptions on the use of economic models in oncology formulary decision making: results from an online survey and payer panel

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BACKGROUND: Payers seek a broader range of information to support formulary decisions. As such, decision makers may have unaddressed questions about the appropriate use of new treatments at the time of drug approvals. This may be more pronounced in oncology due to accelerated regulatory approvals. Economic models may help address these knowledge gaps and help inform oncology formulary decisions.

OBJECTIVE: To assess payer perceptions regarding the use of economic models in informing oncology formulary decisions.

METHODS: An expert panel consisting of pharmaceutical manufacturers, academicians and payers was convened to develop a survey to assess the use of economic models in informing oncology formulary decisions. A secure web-based survey was piloted with 5 U.S. payers. The survey was then refined after the pilot data collection and was administered via the AMCP Market Insight Panel. Descriptive analyses were performed. A virtual panel of 10 payers was convened to discuss the survey results.
RESULTS: The online survey was completed by 106 payers. Payer demographics, large plans (> 1 million lives, n = 54 [55%]) and small plans (<1 million lives, n = 45 [46%]). The most common organizations included MCOs (48%) and PBMs (37%). Most respondents were pharmacists (90%). Majorities of payers (n = 106) reported using (sometimes/often/always) budget impact models (BIMs; 63%) and cost-effectiveness models (CEMs, 67%) to inform oncology formulary decisions. Larger plans (n = 54) had more expertise in reviewing oncology economic models vs. small plan (n = 45) 56% vs. 31%. Similarly, large plans were more likely to have reviewed an economic model in the last 2 years relative to small plans, 57% vs. 36%. Among those who don’t review models (n = 71) common reasons included “model not available at time of review” (58%) and “potential bias” (49%). When comparing two therapies with similar safety/efficacy (n = 106), 69% of payers reported that these models are useful. Overall 37% (n = 38) of payers responded that they would partner with manufacturers to develop economic models using their plan data. During the virtual panel, payers mentioned that pre-approval information and early access to models with transparent assumptions are needed.

CONCLUSIONS: Most payers have expertise in evaluating economic models in oncology and find value in using both BIMs and CEMs in oncology formulary decision making. Approximately 1/3 of payers are willing to work with manufacturers to develop and validate models.

SPONSORSHIP: Pfizer.

Z00-Z99 Factors Influencing Health Status and Contact with Health Services

Z1 Pharmacists as accessible healthcare providers: quantifying the opportunity

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BACKGROUND: Pharmacists are the most accessible healthcare providers, and research has shown that patients visit their pharmacies more than their doctor’s office. It is commonly cited that the average visit ratio between pharmacists and physicians is 35:4 yearly, which has prompted discussion into the expansion of pharmacy’s role in patient care. However, the research supporting this comparison is of poor quality. Therefore, a more accurate figure is needed.

OBJECTIVE: To quantify relative pharmacist intervention opportunities to support future care delivery roles.

METHODS: Using 2018 MarketScan data, we compared visit frequency between pharmacies and physicians for patients who were aged 18-64 yo, enrolled with pharmacy benefits in 2018 for 12 months, and had at least one drug claim or evaluation and management (E&M) code in 2018. Pharmacy visits were defined as unique prescription fill dates, while physician visits were defined as unique service dates tied to an E&M code. We assessed differences in visit frequency for the full sample as well as for “super utilizers” (top 5% based on total cost of care). Our statistical approach included generalized estimating equations with a negative binomial distribution, which compared frequency between pharmacist and physician counts. Comparisons within the super utilizer strata were made using interaction terms to explore the impact of the stratifying variable on total counts relative to the general population, as well as the differential effect between provider types.

RESULTS: After applying age, coverage, and claim requirements, 119,942 patients remained in the final sample. The final full cohort was 55.7% female with an average age of 42.8 years. The super utilizers were 57.4% female with an average age of 48.2 years. For the full cohort, the mean number of pharmacy and physician visits was 8.8 and 3.5 (P < 0.0001), which yielded a pharmacy:physician visit ratio of 2.5:1. Super utilizers had an average of 25.7 pharmacy visits and 10.9 physician visits (P < 0.0001), for a ratio of 2.4:1.

CONCLUSIONS: This study finds that patients have significantly more visits to pharmacies than to physicians by a ratio of 2.5:1 for the general population, and 2.4:1 for super utilizers. Despite this ratio being smaller than the often reported 35:4 visit comparison, it more accurately represents the relative accessibility of pharmacists, and provides insight into future opportunities to support patient care. Further research is needed to evaluate pick-up vs. adjudication dates for pharmacies, and different strata for comparing this ratio.

Z3 Knowledge and attitudes towards human immunodeficiency virus (HIV) and pre-exposure prophylaxis (PrEP) among pharmacy students in Indiana

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BACKGROUND: Approximately 1.2 million people in the United States are living with HIV and the cost of caring for these patients is significant. Transmission of HIV is preventable, and pre-exposure prophylaxis (PrEP) has been shown to reduce the risk of HIV by 93%. Although PrEP, often considered a specialty drug, is expensive, the cost is significantly less than providing care for patients with HIV. Pharmacists, as educated, highly-trusted, and accessible health professionals can play a major role in HIV prevention. To do so, today’s pharmacy students must have the requisite knowledge of the use of PrEP and awareness of issues surrounding HIV. However, little is known about pharmacy students’ knowledge and attitudes towards HIV and PrEP.

OBJECTIVE: Assess the knowledge and attitudes towards HIV and PrEP among advanced pharmacy students in Indiana.

METHODS: A five-part survey was constructed, incorporating questions on demographics, the HIV-KQ-18 knowledge questionnaire, questions on HIV attitudes and beliefs, PrEP knowledge, and PrEP attitudes and beliefs. The survey was administered via an online platform. Emails were sent to third-and-fourth-year pharmacy students at the three accredited pharmacy schools in Indiana. Ten-dollar Amazon gift certificates were given to students completing the survey.

RESULTS: 326 (46.1%) of 706 eligible students submitted useable surveys. HIV knowledge was high, 17.15 + 0.96 out of 18 possible. Students identifying as religious or somewhat religious had a significantly lower HIV knowledge score (13.11 = 2.34, P = 0.021). Heterosexual students (13.18 = 2.25, P = 0.026) and non-Hispanic white students (67 = 2.328, P = 0.023) felt significantly less prepared to counsel their patients...
regarding HIV. Non-heterosexual students had higher PrEP knowledge than their heterosexual counterparts (t311 = 1.941, P = 0.005).

CONCLUSIONS: Although pharmacy students’ knowledge of HIV is high, some students may not feel prepared to take a proactive role in HIV prevention with their patients, including the use of PrEP.

SPONSORSHIP: Barry-Bashur Foundation.

Changes in utilization patterns for pre-exposure prophylaxis to HIV after recommendation from U.S. Preventive Services Task Force

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BACKGROUND: On June 11, 2019, the U.S. Preventive Services Task Force (USPSTF) updated its recommendations to include the addition of medication therapy for pre-exposure prophylaxis (PrEP) to HIV with a grade of “A”. The USPSTF defines the grade of “A” as follows: “There is high certainty that the net benefit is substantial.” This recommendation by the USPSTF applies to individuals that are not infected with HIV, but are at high risk for acquiring the disease.

OBJECTIVE: To determine the changes in utilization of PrEP therapy before and after the recommendation by the USPSTF in June 2019.

METHODS: A retrospective analysis using pharmacy paid claims data from June 10, 2018 to June 9, 2020 using Generic Product Identifiers (GPIs) for medications FDA-approved to treat active HIV infection and PrEP was performed. These medications make up the HIV therapeutic category. 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 medications to treat HIV or PrEP were included in the analysis. Proportion of patients on PrEP therapy among patients in the HIV therapeutic category in the year prior to the publication of the final recommendation published by the USPSTF on June 11, 2019 (6/10/2018-6/10/2019) and almost one year after (6/11/2019-6/10/2020) was analyzed using chi-square analysis. Percent of PrEP total drug spend of HIV therapeutic category was also compared in the two periods.

RESULTS: In the HIV therapeutic category, a total of 24% of patients in the 18-19 reporting period were on PrEP therapy and there were a total of 28% of patients on PrEP therapy in the 19-20 reporting period, demonstrating a significant 4% increase (P < 0.05). There was a 2.1% increase in percent of total HIV therapeutic category spend on PrEP therapy in the 19-20 reporting period from the 18-19 period.

CONCLUSIONS: While the increase in the utilization of PrEP therapy was observed after the publication of the USPSTF final recommendation to add HIV PrEP to its list of recommendations. There was also an increase in the percentage of spend attributed to PrEP therapy in the HIV category between the two periods. Increases in utilization are likely to continue as more plans are required to implement coverage of these agents at no cost share due to the ACA provision of coverage for preventative services for most private plans. One of the two agents currently FDA-approved is likely to lose patent protection later in 2020, which may mitigate increases in drug spend in this therapeutic category.

SPONSORSHIP: None.

Impact of COVID-19 in the care of patients with hereditary angioedema (HAE): results of a patient and HCP survey

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BACKGROUND: The COVID-19 pandemic has led to some uncertainties and altered the way in which healthcare providers (HCPs) and patients manage their disease. Hereditary angioedema (HAE) is a genetic disease characterized by recurrent episodes of angioedema of the skin, pharynx, larynx, gastrointestinal (GI) tract, genitals, and extremities.

OBJECTIVE: The purpose of this research was to identify shifts in management of disease in patients with HAE.

METHODS: A survey with patients with HAE and physicians was conducted to better understand impact of COVID-19. To be eligible for the survey, patients were required to live in the U.S., be at least 18 years old, have a diagnosis of HAE, and be either currently treating their HAE or if not treating, have 1+ attack every 3 months. Screening criteria for HCPs included board certification in allergy/immunology, actively treating 2 or more HAE patients, and a minimum of 30 patients overall.

RESULTS: A total of 20 patients and 46 HCPs responded to the survey. On average, patients have 3 HAE appointments a year and believe that COVID-19 will cause them to miss 1 HAE-related appointment. While HCPs noted their overall patient volume has dropped by 58%, 83% of HCPs state their HAE patient volume has remained the same. Additionally, 9 out of 10 patients are able to obtain HAE medications and 9 in 10 HCPs have no issues prescribing HAE medications. However, drug supply remains a top of mind concern for both groups and patients report an increase in attack rate due to stress in the past month. During COVID-19, patients report they are more likely to use more prophylactic medication due to worry and stress-related attacks, and to avoid visits to the ER. 69% of HCPs have implemented telemedicine visits, yet only 15% of patients have so far seen their HAE doctors via telemedicine (compared to 33% via phone and 36% via email).

CONCLUSIONS: Much remains to be learned about the impact of COVID on the patient’s and HCP’s. While the sample size of patients surveyed was small, the results suggest patients may be concerned about an increase in stress-related attacks. At the time of the survey, COVID-19 has not impacted management of HAE patients from the perspective of HCPs.

SPONSORSHIP: BioCryst Pharmaceuticals.

Effects of the pilot volume-based procurement program in China on drug uses and costs: real-world evidence from atorvastatin prescription claims in Guangzhou

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BACKGROUND: In 2019, China launched a pilot program of volume-based procurement (VBP) of 31 drugs in 4 municipalities and 7 cities,
with the intention of lowering drug costs. This pilot program included atorvastatin, a widely used drug for the treatment of hypercholesterolemia and atherosclerosis. The program started in April 2019 in Guangzhou, a large city in Southern China.

**OBJECTIVE:** The objective of this real-world evidence study was to evaluate the program’s effect on drug uses and costs, using atorvastatin as an example, by comparing its prescription claims before and after VBP implementation in Guangzhou.

**METHODS:** This retrospective observational study analyzed atorvastatin prescription claims from Guangzhou Health Insurance, which covers over 17 million people. Adults aged 18+ who were prescribed atorvastatin during the period between April 4, 2018 and September 30, 2019 were included. Total numbers and costs of brand-name or generic atorvastatin prescriptions, and per-prescription costs, were compared between two six-month periods of the same date range before and after VBP implementation, i.e., pre-VBP (April 1, 2018-September 30, 2018) and post-VBP (April 1, 2019-September 30, 2019) periods. Costs are converted from Chinese yuan (RMB) to U.S. Dollars (USD; 1 RMB = 0.1412 USD). Analyses were also carried out for disease subgroups (hypertension, dyslipidemia, coronary heart disease, stroke and diabetes). Patterns of switches between brand-name and generic atorvastatin will also be analyzed and reported later.

**RESULTS:** From the pre- to post-VBP periods, the total number of atorvastatin prescriptions increased by 49% from 497,445 to 742,630. The increase was driven by a 60-fold increase in generic prescription and a decrease of 53% in brand-name prescriptions. Total costs decreased by 42% from 8,386,653 to 4,879,358 USD. Per-prescription costs decreased by 81% for the generic and 8% for the branded atorvastatin. The same patterns were also observed for all 5 diseases, with the total numbers of prescriptions of generic atorvastatin increased most pronounced for dyslipidemia (from 1,428 to 116,090) and diabetes (from 515 to 41,644). Per-prescription costs for generic atorvastatin decreased the most for dyslipidemia (-83%) and stroke (-87%).

**CONCLUSIONS:** The pilot VBP program has increased access to drugs while lowering drug costs in China, as exemplified by the changes in atorvastatin prescriptions in Guangzhou, China. Further research is needed to evaluate the long-term effects of the VBP program.

**SPONSORSHIP:** Pfizer.

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**COVID-triggered effects from telehealth, unemployment, and coverage changes on treatment costs and volumes**

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**BACKGROUND:** In February 2020, the first infections of the global COVID-19 pandemic began to appear in the U.S. resulting in healthcare facilities limiting their practices and businesses reduced their operations. People adjusted the way they sought healthcare in an era with limited access to practitioners and as mass unemployment, including the loss of employer-provided healthcare benefits.

**OBJECTIVE:** The objective of this study is to examine the changes in how patients sought care during the pandemic period in comparison to a similar historical period. (1) Has demand for healthcare changed? (2) Has delivery of healthcare changed (e.g., telehealth vs. in-person visits)? (3) Has unemployment affected third-party payer coverage? (4) Has price sensitivity and/or the ability to pay affected consumption of treatment?

**METHODS:** Longitudinal analysis of medical and Rx claims data to determine volume, cost, and payment mechanisms for healthcare services was matched to consumer loyalty data to create an anonymized cohort of over 100 million people in the U.S. This data is used to examine and compare healthcare consumption during the pandemic period to similar data from the same time frame one year earlier. Volume of care delivered, method of care delivery, and volume and cost of Rx are assessed by a variety of dimensions including age, gender, geography, payer, treatment pathway, and employment status.

**RESULTS:** Beginning in March 2020 and accelerating through May 2020, demand for healthcare declined by about 60%, but telehealth saw an increase from less than 1% to over 40% of all healthcare interactions, losing momentum in June 2020. New Rx activity fell in line with overall healthcare demand while refill Rx activity also saw a much smaller decrease. There was an increase in patients paying cash and engaging patient assistance programs, while less commercial and Medicare patients consumed treatment. Medicare patient volumes decreased slightly. This study is still ongoing as the pandemic period is still active. Final results will be provided with as much data as possible prior to the deadline for publication.

**CONCLUSIONS:** Telehealth saw dramatic increases that will likely remain permanent to some degree. Unemployment shifted millions of patients away from third-party payment methods, at least temporarily. Treatment volumes saw decreases related to access and affordability. A recovery appears to be slowing taking hold as the U.S. moves out of the most intense period of social restrictions, however, continued burdens applied to the healthcare system and to the economy by the pandemic conditions will be long lasting.

**SPONSORSHIP:** Kythera Labs.

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**The number of falls per faller varies with the annual incidence of having at least one fall**

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**BACKGROUND:** Falls are common in the elderly and fallers are likely to have subsequent falls. Interventions to reduce falls are often assessed on their effect on the annual incidence of having at least one fall, but this may underestimate their effect on the mean annual number of falls.

**OBJECTIVE:** To quantify the relationship between the annual incidence of having at least one fall (pFall) and the mean annual number of falls per faller (nFall) for older patients.

**METHODS:** We estimated pFall and nFall for persons aged 65 years or older in the 2016 Medicare Current Beneficiaries Survey (MCBS), a longitudinal representative survey of the U.S. Medicare population. To examine the relationship between the pFall and nFall in patient groups with different incidence of falls, we estimated these two outcomes in subgroups classified in terms of self-perceived general health (PH) or number of chronic conditions (CC). There are total five
PH subgroups (excellent, very good, good, fair, and poor) and four CC subgroups (0-1, 2-3, 4-5, and 6+ conditions). We quantified the relationship between pFall and nFall using a linear regression. The analyses were performed with the Stata software package and took account of the survey weights and design of the MCBS.

RESULTS: In U.S. Medicare patients aged 65 years or older in 2016, pFall was 0.237 (95% CI: 0.23, 0.25) and varied from 0.1 to 0.5 across the categories of PH and of CC; nFall was 1.957 (95% CI: 1.90, 2.02) and varied from 1.5 to 2.5 with PH and CC. The relationship between pFall and nFall was approximately linear across the categories of PH and of CC and patient groups with a 0.1 higher annual incidence of having at least one fall had an estimated 0.25 (95% CI: 0.20, 0.30) more mean annual number of falls per faller.

CONCLUSIONS: Patient groups with a higher annual incidence of having at least one fall also have a higher mean annual number of falls per faller. Quantifying the effect of an intervention on the annual incidence of having at least one fall is likely to under-estimate the effect on the total number of falls.

SPONSORSHIP: Eisai.
Student Poster Titles and Presenters

B5 Conjugate meningococcal vaccination rates in newly diagnosed HIV patients before and after new 2016 Centers for Disease Control and Prevention recommendation
Chase C. Slone, BS, Sohul A. Shuvo, MS, MBA, Justin Gatwood, PhD, cslone@uthsc.edu

B10 COVID-19-related information sources and prevention practices: a cross-sectional survey of residents of a populous commercial city in Nigeria
Sorochi Ilouanusi, BPharm, Osaro Mgbere, PhD, Nchebe-Jah Ilouanusi, MB, BS, Ismaeal Yurusu, PhD, Ehere Essien, MD, DrPH, FRSPH, soromwa@gmail.com

C15 Assessing the pharmacoeconomic burden of advanced non-small cell lung cancer treatments: a literature review
Yun Jung H. Shin, PharmD (candidate), Jaehee Yang, PharmD (candidate), Mohil Trivedi, PharmD (candidate), yhs6@scarletmail.rutgers.edu

C30 The association between race and NCCN adherent care among patients with stage 3 and 4 ovarian cancer
Montrell Taylor, Jesse Sussell, Ibrahim Abbass, Carmen Ng, Bob Burger, montrell.taylor@bison.howard.edu

C50 The emergence of biosimilars for oncology treatment from a payer’s perspective
Aisha Fowler, Rebecca Bogert, PharmD, BCOP, Michael Polson, MS, PharmD, Jim Rebello, PharmD, BCOP, Haita Makanji, PharmD, aishafowler@utexas.edu

E10 Economic burden of patients with MDD, specifically those with potential eligibility for adjunctive treatment
Tina Gholami, PharmD, MS, Sara Higa, Amanda Harrington, Patrick Gillard, tgholami@usc.edu

G20 Cost per relapse avoided of oral therapies in relapsing-remitting multiple sclerosis
Justin Nedezesky, Michelle Han, Khalid M. Kamal, MPharm, PhD, j.nedezesky@gmail.com

G47 Changes in chronic migraine-related medical utilization observed in an integrated delivery network after initiation of calcitonin gene-related peptide inhibitors
Maria Datcu-Truong, PharmD, Eugene Terkoski, PharmD, maria.datcu-truong@hf.org

G48 Impact of initiating calcitonin gene-related peptide (CGRP) antagonists for chronic migraine prophylactic therapy on emergency department (ED) and/or urgent care visits
Emina Duric, Sital Patel, PharmD, MBA, Danielle Massie, PharmD, Tracy Edinger, emina.duric@modahealth.com

H10 Patient’s experience of living with and managing presbyopia: a systematic literature review
Zach Baldwin, PharmD (candidate), Joanna Campbell, PhD, Elahch Shrineshan, PharmD, zbd19@uw.edu

I12 Coding for an anticoagulant: systematic review of pharmacogenomics-guided warfarin therapy on the therapeutic and adverse clinical events on patients with atrial fibrillation, deep vein thrombosis, and pulmonary embolism
Amy M. Green, Sean Hyungwoo Kim, PharmD/SM, agreen17@su.edu

L9 Review of cost-effective biologic therapies for hidradenitis suppurativa
Megumi Howard, PharmD (candidate), Daniel Lim, PharmD, Kevin Tse, PharmD, Tacho Oh, MS, RPh, nh2369@mynsu.nova.edu

M4 Comparison of clinical and economic evaluations across different rheumatoid arthritis drug classes conducted by Institute for Clinical and Economic Review (ICER): a review
Gauri Desai, MS, Christopher V. Quenelle, PharmD, Ambarchi Ambegaonkar, PhD, gauri@apperturehealth.com

M9 Abuse potential of drugs labeled for fibromyalgia: a FAERS analysis
Kanya K. Shah, PharmD, Stephen Kogut, PhD, MBA, Aisling Caffrey, PhD, kanya_shah@my.uri.edu

U4 The clinical and financial impact of modifying Saxenda (liraglutide) utilization management
Alice Cheng, PharmD (candidate), Claudia Kennedy, PharmD (candidate), Nicholas Schnarr, PharmD, Jay Vora, PharmD, acheng96@live.unc.edu

U41 OTC online-sold weight loss ultraceuticals: are consumers paying for what they think they are buying?
Monica Oakes, Diana Huynh, Mark Mikhail, Abigail Wiss, Natalia Echeverry, Kamila Orzechowski, Heba Eassa, Mohamed Nounou, BPharm, MPSc, PhD, dhuynh@usj.edu
U42 Global evaluation of real-world studies on biosimilar usage in oncology
Shyra G. Bias, PharmD (candidate), Nkiruka Emezienna, MS, PharmD (candidate), Catherine M. Lockhart, PharmD, PhD, Jamila J. Jorden, PharmD, MBA, Paula J. Eichenbrenner, MBA, CAE, shyra.washington@bison.howard.edu

U43 A retrospective analysis of outpatient prescription claim trends during the COVID-19 pandemic
Palna Mehta, Mark Wrobel, PharmD, Ying-Fen Swagler, PharmD, Brian Gucwa, PharmD, Walter J. McClain, PharmD, MBA, palna.mehta@rutgers.edu

U44 Preceptor perceived value from managed care focused student projects during advanced pharmacy practice experiences
Kayla M. Judson, Paige Edwards, PharmD, Denise Pigarelli, PharmD, Amanda Margolis, PharmD, kjudson@wisc.edu

U45 A retrospective analysis of the clinical and financial outcomes of converting patients from originator Remicade to an infliximab biosimilar
Tavan Parker, PharmD, Laura Britton, PharmD, Connor Willis, PharmD, Robert Nohavec, RN, Shannon Gibraith, PharmD, Matthew Call, PharmD, Diana Brixner, RPh, PhD, tavan.parker@pharm.utah.edu

U46 Infliximab biosimilar utilization in inflammatory bowel disease and inflammatory arthritis after Veterans Affairs National Formulary policy change
Derek K. Pinnell, PharmD, ShaoBo Pei, PhD, Wei Chen, MS, Jessica Walsh, MD, Jorge Rojas, MS, Joshua Baker, MD, MSCE, Brian Sauer, PhD, Derek.Pinnell@utah.edu

U47 A review of COVID-19-related Food and Drug Administration warning letters
Preston T. Skersick, Andrew Gaiser, PharmD, MS, MBA, Jasmine Knight, PharmD, MS, Kellie Meyer, PharmD, MPH, preston.t.skersick@live.mercer.edu

U48 Medical errors as a result of transitioning electronic medical record platforms in an urban charity clinic
Sumaya Gendra, Zahia Charide, Portia N. Davis, PharmD, Adlia Ebeid, PharmD, BC-ADM, RPh, Randall Flores, PharmD, RPh, Charity Addo, RPh, z.charide1@gmail.com

U49 Novel lab-drug database to explore the trend and costs of precision medicine
Thao Luu, BS, Bithia Anderson, PharmD, PhD, MPA, Del Doherty, PharmD, MBA, PhD, MPH, luu00024@umn.edu

U50 Overcoming biosimilar barriers: stakeholder perspectives on strategies to overcome challenges – a cross-sectional study
Irene Chung, Annesha White, PharmD, MS, PhD, John Spain, MA, PharmD, BCPS, Paula J. Eichenbrenner, MBA, CAE, Nicholas Ladikos, PharmD, BCPS, BCGP, BCIDP, Terry Richardson, PharmD, BCACP, Laura Simone, PhD, Ebony Clay, PMP, irenechu@usc.edu

U51 Overcoming barriers to biosimilar adoption through coordinated efforts within an integrated delivery network and its impact on utilization
Maria Datcu-Truong, PharmD, Eugene Terkoski, PharmD, maria.datcu-truong@hf.org

Z2 Physical health-related quality of life among older women with breast cancer and patient satisfaction with medical and pharmacy services
Ashik Jayakumar, PharmD, Ravi Patel, PharmD, Gregory Calp, PharmD, MPH, ajayakumar3@uic.edu

Z10 Naloxone prescribing trends in New Jersey during the COVID-19 pandemic from a managed care perspective
Marin Weiskopf, Hannah Jang, PharmD, Diana Turan, PharmD, marin_weiskopf@unc.edu
A1  Healthcare burden and costs of recurrent Clostridioides difficile infection in the Medicare population
  Sudhir Unni, PhD, MBA, Takara Scott, PhD, Mena Boules, MD, Christie Teigland, PhD, Alexis Parente, PhD, Winnie Nelson, PharmD, MS, MBA, winnie.nelson@ferring.com

A2  Analysis of adult, hospitalized patients with carbapenem-resistant (CR) gram-negative bloodstream infections (GN-BSIS) due to glucose fermenters (GFS) and non-glucose fermenters (NGFS): is there a difference in outcomes?
  Thomas Lodise, PharmD, PhD, Hemanth Kanakamedala, BS, Wei-Chun Hsu, MS, Bin Cai, MD, PhD, bin.cai@shionogi.com

A3  Burden of illness in patients with urinary tract infections with or without bacteremia caused by carbapenem-resistant gram-negative pathogens in U.S. hospitals (2014 to 2018)
  Bin Cai, MD, PhD, Ryan Shields, PharmD, MS, Hemanth Kanakamedala, BS, Yun Zhou, MS, Bin.cai@shionogi.com

  Ryan Shields, PharmD, MS, Hemanth Kanakamedala, BS, Yun Zhou, MS, Bin Cai, MD, PhD, bin.cai@shionogi.com

B3  Characteristics of pre-exposure prophylaxis utilization in transgender and homeless Medicaid-covered patients in New York City
  Melodie Baja, PharmD, Mary Malek, PharmD, AAHIVP, Kenny Ng, PharmD, mbaja@amidacareny.org

B6  A retrospective matched cohort study evaluating the rate of acute renal injury in patients with severe gram-negative infections treated with colistin or new beta-lactam + beta-lactamase inhibitor antibiotics
  Casey Doremus, MS, Stephen Marcella, MD, MPH, Bin Cai, MD, PhD, Roger Echols, MD, bin.cai@shionogi.com

B9  Study of penicillin tolerance group B streptococci strains
  Irfan Khan, PharmD, Aya Hammouda, PharmD, Paramita Basu, PharmD, ikhan4@student.touro.edu

C19  Early real-world experience on characteristics and treatment patterns among patients with metastatic HR+/HER2- breast cancer treated with ribociclib
  Rebecca Burne, PhD, Sanjeev Balu, PhD, Annie Guerin, MSc, Yawen Liang, PhD, Ryan Schloessmann, BA, Rebecca Bungay, MScPH, Mary Lisha Paul, MD, sanjeev.balu@novartis.com

C20  Real-world patient demographics, treatment patterns, and healthcare resource utilization (HRU) among human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer (ABC) patients with BRCA1/2 mutations (BRCA1/2mut)
  Alexander Niyazov, PharmD, RPh, MPH, CPh, BCPS, Rohan C. Parikh, PhD, Elizabeth Esterberg, MS, Bhakti Arvindakar, PhD, MBA, BPharm, Abigail Hitchens, MPH, Lillian Shabeddin Arruda, PhD, Elias Obeid, MD, MPH, Alexander.Niyazov@pfizer.com

C21  Overall survival with first-line palbociclib plus letrozole versus letrozole alone for patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer in US real-world clinical practice
  Angela DeMichele, MD, Massimo Cristofanilli, MD, Adam Brufsky, MD, PhD, Xianchen Liu, MD, PhD, Jack Mardekian, MD, Lynn McRoy, MD, Rachel Layman, MD, Hope Rugo, MD, Richard Finn, MD, Angela.DeMichele@uphs.upenn.edu

C30  Cost comparison of PARP inhibitors in women with ovarian cancer (OC) in the US healthcare market
  Ali McBride, PharmD, Jessica Perhanidis, MPH, Craig Gibson, PhD, Gene Wetzstein, PharmD, mcbride@pharmacy.arizona.edu

C33  Investigating non-protocol-driven hospitalizations to assess darolutamide tolerability in patients with non-metastatic castration-resistant prostate cancer
  Alexander J. Upton, MSc, Neil Roskel, MSc, Craig Keenan, BSc, Stephanie Chen, MS, Louis A. Jackson, PharmD, Neal D. Shore, MD, alexander.upton@bayer.com

C34  Darolutamide versus apalutamide and enzalutamide in non-metastatic castration-resistant prostate cancer (NMCRPC): matching adjusted indirect comparisons
  Shan Jiang, PhD, Emina Terasawa, PhD, Viviana Garcia-Horton, PhD, Rajeev Ayyagari, PhD, Reg Waldock, PhD, Neal D. Shore, MD, shan.jiang@bayer.com

C35  Real-world incidence and management of adverse events (AEs) in patients with non-metastatic castrate-resistant prostate cancer receiving apalutamide or enzalutamide
  Shan Jiang, PhD, Deila Varghese, PharmD, PhD, Sreevatsa Appukuttan, MBBS, MPH, Shelby Corman, PharmD, MS, Nehemiah Kebede, MPH, Rajan Gnanasakthy, BA, Cynthia Macabili, MA, Reg Waldock, PhD, Arif Hussain, MD, shan.jiang@bayer.com
C37 Immune-related adverse events (IRAEs) among urothelial carcinoma (UC) patients treated with PD-L1 vs PD-1 immune checkpoint inhibitors (ICls): a real-world observational study
Ying Zheng, MHSA, MS, Elizabeth Bell, PhD, MPH, Nicole M. Engel-Notz, PhD, John White, DPM, MS, Lincy Lal, PhD, PharmD, Frank X. Liu, PhD, Ruth Kim, PharmD, MPH, Stanley P. Kralewicz, MA, Vijay Kasturi, MD, Saby George, MD, FACP, ruth.kim@pfizer.com

C38 IMPACT RCC real-world study: economic impact of early progression among patients with metastatic renal cell carcinoma treated with tyrosine kinase inhibitors in first-line setting
Abhijec Bhanegaonkar, PhD, MPH, Shivani Pandya, MS, Ruth Kim, PharmD, MPH, Ying Zheng, MHSA, MS, Christopher Dieyi, MPH, Stanley P. Kralewicz, MA, Vijay Kasturi, MD, Frank X. Liu, PhD, Thomas Hutson, DO, PharmD, ying.zheng@emderosono.com

C41 Healthcare resource utilization (HCRU) and costs in patients with advanced cancer treated with immune checkpoint inhibitors (ICIs) who experienced select immune-related adverse events (IRAEs)
Saby George, MD, FACP, Ying Zheng, MHSA, MS, Elizabeth Bell, PhD, MPH, Nicole M. Engel-Notz, PhD, John White, DPM, MS, Lincy Lal, PhD, PharmD, Ruth Kim, PharmD, MPH, Stanley P. Kralewicz, MA, Jodi Smith, PhD, Frank X. Liu, PhD, elizabeth.bell@optum.com

C42 Real-world treatment patterns and healthcare resource utilization (HRU) in patients with metastatic renal cell carcinoma (mRCC)
Abhijec Bhanegaonkar, PhD, MPH, Genevieve Gauthier, MA, Ruth Kim, PharmD, MPH, Francis Vekeman, MA, Katherine Depa, MSc, Marie-Noëlle Robitaille, MS, Erick Moyneur, MS, Frank X. Liu, PhD, frank.liu@emderosono.com

C43 Economic assessment of diagnostic intervention in peripheral T-cell lymphoma
Nicholas Liu, PharmD, Julie Lisano, PharmD, Kristina Yu-Isenberg, PhD, MPH, RPh, Deepak Singh, PharmD, David Campbell, PharmD, MS, Wayne Su, MSc, nliu@seagen.com

C44 Real-world treatment patterns and overall survival among Medicare fee-for-service beneficiaries newly diagnosed with peripheral T-cell lymphoma
Thomas LeBlanc, MD, Anne Shah, MS, Allison Petrella, MPH, Mayvis Beheira, PhD, Joseph Feliciano, PharmD, MS, Julie Lisano, PharmD, thomas.leblanc@duke.edu

D4 Economic burden of end organ damage among patients in commercial plan with sickle cell disease in the U.S.
Xue Song, PhD, Andrew Campbell, MD, Ze Cong, PhD, Irene Agodoa, MD, Diane Martinez, DrPH, MPH, Carolyn Lew, PhD, Danae Black, Helen Varker, Chris Chan, MPH, Sophie Lanzkron, MD, MHS, songx@us.ibm.com

D6 Healthcare resource utilization and cost burden of hemophilia B in the U.S.
Kaityn A. Hagan, PhD, Eli Orvis, BA, Hongbo Yang, PhD, Eileen K. Sawyer, PhD, Nanxin (Nick) Li, PhD, MBA, n.li@unique.com

D7 The economic burden of hemophilia B: a lifetime decision analytic model
Nanxin (Nick) Li, PhD, MBA, Eileen K. Sawyer, PhD, Konrad Maruszczyn, MSc, MA, Marta Slomba, PhD, Tom Burke, MSc, Antony P. Martin, PhD, Matt Stevenson, PhD, BSc, Greg Guzauskas, PhD, Jamie O’Hara, MSc, n.li@unique.com

D8 Clinical and financial outcomes among hemophilia A: patients before and after treatment with emicizumab
Aisha Hussain, PharmD, Nishita Patel, PharmD, Natalie Watkins, PharmD, Amy Thompson, PharmD, MBA, Elise Avalos-Reyes, PhD, Anna Diamou, DrPH, MPH, aisha.hussain@cvshealth.com

D10 Long-term lanadelumab treatment improves health-related quality of life: HELP open-label extension study interim findings
William R. Lamry, MD, Marcus Maurer, MD, Markus Magerl, MD, Gagan Jain, PhD, Giovanna Devercelli, PhD, Antoine Regnault, PhD, Juliette Meunier, MSc, Marc A. Riedel, MD, lamrymd@allergyspecialists.us

D11 Attack-free status of patients with hereditary angioedema during extended treatment with lanadelumab in the HELP open-label extension study
Marc A. Riedel, MD, Douglas Johnston, DO, William R. Lamry, MD, Jonathan A. Bernstein, MD, Peng Lu, MD, PhD, Marcus Maurer, MD, mrvie@ucsd.edu

D12 Long-term efficacy and safety of lanadelumab in patients with hereditary angioedema: interim results from the HELP open-label extension study
Aleena Banerji, MD, Marc A. Riedel, MD, Paula J Busse, MD, Raffi Tachdjian, MD, Daniel Soteres, MD, MPH, James Hao, PhD, Peng Lu, MD, PhD, abanerji@partners.org

D14 Economic burden of acute steroid-refractory graft-versus-host disease (GVHD) in commercially insured pediatric patients (PTS)
Erich Strati, PharmD, Karen Sandman, PhD, Anna Forsythe, PharmD, mgrayner@healthcore.com

E1 Impact of a prescriber call program in promoting the prescribing of the cardio-protective medication bundle
Taline Jaghlassian, PharmD, BCMTM, Huong Nguyen, PharmD, Taline.O.Jaghlassian@EnvolveHealth.com

E2 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, BCPs, akerst@upmc.edu

E3 Improving five star pharmacy measures: the impact of machine learning on analytics and personalized coaching
Jenny Glennon, PharmD, CCRP, Carla Nibel, RD, LD, CDE, CDTc, jhsink@yahoo.com

E4 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
David R. Sutton, MD, Ashwini Gore, MD, Bantwal S. Buliga, MD, Rebecca Goldfaden, PharmD, CCRP, Carla Nibel, RD, LD, CDE, CDTc, John H. Sink, MPA-c, Beverley Adams-Huet, MS, jhsink@yahoo.com
E13 Mortality associated with long-chain fatty acid oxidation disorders: observations from an expanded access program for triheptanoin
Eliza Kruger, MHE, Jina Shah, RPh, MS, Camille Bedrosian, MD, Deborah Marsden, MD, Shwetha Asha, MBBS, EKruger@ultragenyx.com

E14 Understanding the impact of elevated potassium on kidney patients’ quality of life and treatment experience from a nephrology-based office survey
Amy Bechrich, CAE, Dale Singer, MHA, Paula J. Alvarez, RPh, MBA, MPH, Jeanene J. Fogli, PhD, RD, John A. House, MS, Michelle Mann, BA, Michael Fischer, MD, MSPH, palvarez@relypsa.com

E15 Association of metabolic acidosis with adverse cardiovascular outcomes in patients with chronic kidney disease
Nancy L. Reaven, MA, Susan E. Funk, MBA, Vandana Mathur, MD, Navdeep Tangri, MD, PhD, nancy.reaven@strathhealth.com

E16 Metabolic acidosis is a predictive factor for all-cause mortality in patients with chronic kidney disease
Navdeep Tangri, MD, PhD, Nancy L. Reaven, MA, Susan E. Funk, MBA, Vandana Mathur, MD, ntangri@sogh.mb.ca

F1 Real-world treatment patterns with second-generation oral antipsychotics among people with schizophrenia insured by Medicaid
Michael J. Doane, PhD, James Signorovitch, PhD, Dendy Macaulay, PhD, Viviana Garcia-Horton, PhD, Amy K. O’Sullivan, PhD, Peter J. Weiden, MD, Leona.Bessonova@albermes.com

F2 Evaluation of adherence to behavioral health medications and star adherence medications
Radha V. Patel, PharmD, MPH, BCACP, James Greenough, PharmD, Katrina Tan, PharmD, Michael Strassner, PharmD, Geannette Green, PharmD, MPH, Angel L. Ballew, PharmD, MBA, BCPP, radha.patel@wellcare.com

F5 Evaluating medication-related risk factors for developing opioid-use disorder post-hospitalization
Samuel Peasah, PhD, MBA, Yan Huang, MS, Elizabeth Swart, BS, Lynn Neilson, PhD, Chester Good, MD, MPH, Peasahsk@upmc.edu

F6 Budget impact analysis of RESET-O, an FDA-cleared prescription digital therapeutic for patients with opioid use disorder
Fulton Velez, MD, MS, MBA, Wei Jia Wang, MS, Nicole Gelings, PhD, Ali Jalali, PhD, Sean Murphy, PhD, Fultonve@msn.com

F7 Real-world study of the short-term impact of adherence to opioid use disorder treatment on direct costs
Fulton Velez, MD, MS, MBA, Wei Jia Wang, MS, Nicole Gelings, PhD, Ali Jalali, PhD, Sean Murphy, PhD, Fultonve@msn.com

F13 Early onset efficacy and safety pilot study of amphetamine extended-release oral suspension (AMPH EROS) in the treatment of children with attention-deficit/hyperactivity disorder
Lisa Strouss, PharmD, Thomas R. King, MS, MPH, Antonio Pardo, MD, Ann Childress, MD, Judith Kango, PharmD, BCPP, lstrouss@trispharma.com

F19 Novel extended-release stimulant formulation for treatment of attention-deficit/hyperactivity disorder
Lisa Strouss, PharmD, Antonio Pardo, MD, Thomas King, MS, MPH, Judith Kango, PharmD, BCPP, lstrouss@trispharma.com

F20 Piety is important when we are making ethical decisions: a lesson from COVID-19
Seyyed M. Hakinmazadeh, PhD, hseyyedmostafa@gmail.com

F21 Readmissions and healthcare-related costs among Medicaid beneficiaries with a diagnosis of bipolar disorder, schizophrenia, or both
Laura M. Tubmore, PharmD, Grant H. Skrepenek, PhD, Shellie L. Keast, PharmD, MD, Heidi C. Waters, PhD, Bethany Holdreard, PharmD, Kristin L. Pareja, PharmD, Terry Cohran, PhD, lmbergs@gmail.com

G1 Burden of illness of spinal muscular atrophy type 1: an update
Marcus Droge, PhD, MBA, Ramesh Arjunji, PhD, Marjolaine Gauthier-Loiselle, PhD, Martin Cloutier, MSc, BSc, Douglas M. Sproule, MD, MSc, Omar Dabbous, MD, marcus.droge@avexis.net

G2 Early real-world findings from the RESTORE registry on patients with spinal muscular atrophy (SMA) receiving disease-modifying therapies
Marcus Droge, PhD, MBA, John W. Day, MD, PhD, Davryl C. De Viva, MD, Janbernd Kirschner, MD, Eugenio Mercuri, MD-PhD, Francesco Muntoni, PhD, Terry B. Shieh, MD, PhD, Eduardo Tizzano, MD, PhD, Isabelle Desguerre, MD, PhD, Susana Quijano-Roy, MD, PhD, Kayoko Saito, MD, Uwe Ernst, MD, MDroge034@avexis.com

G3 Cost-effectiveness analysis of newborn screening for spinal muscular atrophy in the United States
Ramesh Arjunji, PhD, Zheng-Yi Zhou, PhD, MS, Anish Patel, PharmD, Marie Louise Edwards, MSc, Michael Harvey, PhD, MRes, MPH, Eric Wu, PhD, Omar Dabbous, MD, omar.dabbous@avexis.net

G5 Preferences for on-demand treatments for Parkinson’s disease-related “OFF” episodes: a discrete-choice experiment
Jessie Sutphin, Joshua Coulter, MA, Carol Mansfield, PhD, carolm@rti.org

G6 Budget impact of apomorphine sublingual film for the on-demand treatment of patients with Parkinson’s disease and “OFF” episodes
Noam Kirson, PhD, Miriam L. Zichlin, MPH, Ibrahima Dieye, Eric Pappert, MD, G. Rhys Williams, PhD, Andrew.Thach@sunovion.com

G7 A budgetary impact analysis of BoNT-A management in the United States based on a real-world longitudinal study of adult upper limb spasticity
Kenneth A Lawson, PhD, Christine Divers, PhD, Natalya Danchenko, PhD, Andreas Lysandropoulos, MD, Lynne Turner-Stokes, DM FRCP MBE, ken.lawson@austin.utexas.edu
G8 Pharmacokinetics of inhaled levodopa administered with oral carbidopa in subjects with Parkinson’s disease under fed conditions
Beth E. Safirstein, MD, Aaron Ellenbogen, DO, MPH, Ping Zhao, PhD, Herbert Henney, PharmD, Deena M. Kegler-Ebo, PhD, Charles Oh, MD, dbegler@acorda.com

G9 Improvement in Unified Parkinson’s Disease Rating Scale motor scores after CVT-301 treatment is associated with improved scores in the Parkinson’s disease activities of daily living questionnaire
Michael Klingler, MPH, Iresha Abeynayake, MPH, Holly Roberts, MD, hroberts@acorda.com

G12 Factors associated with diagnoses of Alzheimer’s disease and related dementias among older adults in the U.S.
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G14 Cost and utilization among patients with multiple sclerosis newly initiating a disease-modifying therapy
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G15 Treatment patterns and relapses among treatment-naïve MS patients
Rina Mehta, PharmD, Corey Pelletier, PhD, Marc Tian, PhD, Virginia Noxon, PhD, Barbara Johnson, MBA, Machaon Bonafeide, PhD, MPH, vnoxon@us.ibm.com

G21 Real-world impact of anitiepileptic drug combinations with versus without perampanel on healthcare resource utilization in patients with epilepsy in the United States: a matched cohort analysis
Feride Frech, PhD, MPH, François Laliberté, MA, Manju Malhotra, MD, Mei S. Duh, MPH, ScD, Victoria Barghout, MSPH, Guillaume Germain, MSc, Dominique Lejeune, MSc, Edward Faught, MD, Feride_Frech@eisai.com

G22 Risk of hospitalization and emergency department admission in patients with epilepsy treated with perampanel in real-world settings
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G23 Challenges in insomnia disorder: a targeted review of the literature
Meaghan Roach, MPH, Timothy R. Juday, PhD, MPA, Rijat Tuly, MPH, Jacquelyn W. Chou, PhD, Anupam B. Jena, MD, PhD, Paul Doghamji, MD, meaghan.roach@precisionxtract.com

G24 Effects of digital cognitive behavioral therapy for insomnia on productivity: a secondary analysis
Frances Thorndike, PhD, Tareq Camacho, MS, MA, Eric Finkelstein, PhD, Karen Ingersoll, PhD, Lee Ritterband, PhD, frances.thorndike@peartherapeutics.com

G25 Persistence to onabotulinumtoxinA and calcitonin gene-related peptide monoclonal antibodies (CGRP MABS) among migraine patients in a U.S. electronic health record database
Amy Tung, PharmD, MS, Jamie Ta, PharmD, MS, Alina N. Bogdanov, MA, Kevin Lavelle, BS, Patrick Gillard, PharmD, MS, Tung_Amy@allergan.com

G26 Real-world persistence in patients treated with onabotulinumtoxinA and calcitonin gene-related peptide monoclonal antibodies (CGRP mAbs) for migraine: a large U.S. administrative claims database study
Jamie Ta, PharmD, MS, Amy Tung, PharmD, MS, Weiyang Wang, MPH, David Oliveri, Patrick Gillard, PharmD, MS, jamie.ta8@gmail.com

G27 A digital therapeutic for insomnia improves sleep among adults with chronic insomnia and depressive symptoms
Frances Thorndike, PhD, Philip Batterham, MPH, PhD, Helen Christensen, PhD, Lee Ritterband, PhD, Robert Gerwien, PhD, Nicole Enman, PhD, Jeffrey Bobit, MS, Yuri Maricich, MD, frances.thorndike@peartherapeutics.com

G28 Identifying outcome measures for migraine value-based contracting using the Delphi method
Elizabeth Swart, BS, Chester Good, MD, MPH, Rochelle R. Henderson, PhD, Chronis Manolis, RPh, Claire Yanta, MD, Natasha Parel, MD, MS, Lynne Neilson, PhD, swartie@upmc.edu

G29 Relative contribution of early-onset efficacy with eptinezumab to change in headache-related life impact in patients with chronic migraine
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G30 Safety of Valtoco (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, jwheless@uthsc.edu

G31 Need for a second dose for the treatment of seizure clusters: impact on resource utilization
Adrian L. Rabinowicz, MD, Edward Faught, MD, David F. Cook, PhD, Enrique Carrazana, MD, arabinowicz@neurells.com

G32 CGRP monoclonal antibody use and patient-reported improvement of migraine: results of the OVERCOME study
Robert E. Shapiro, MD, PhD, Karen H. Samaan, PharmD, Robert A. Nicholson, PhD, FAHS, Anthony J. Zagar, MS, Yongin Kim, PhD, Dawn C. Buse, PhD, Sait Ashina, MD, Michael L. Reed, PhD, Bert B. Vargas, MD, Susan Hutchinson, MD, Richard B. Lipton, MD, robert.shapiro@uvm.edu

G33 Patients’ reasons for starting, switching, and stopping CGRP-targeted monoclonal antibodies: results of the OVERCOME study
Dawn C. Buse, PhD, Kory Schuh, PhD, Robert A. Nicholson, PhD, FAHS, Michael L. Reed, PhD, Yongin Kim, PhD, Anthony J. Zagar, MS, Bert B. Vargas, MD, Robert E. Shapiro, MD, PhD, Sait Ashina, MD, Susan Hutchinson, MD, Richard B. Lipton, MD, DBUSE@montefiore.org

G34 Effects of morphine milligram equivalent mailing on provider opioid prescribing: a retrospective observational study
Rachel Kent, Marnie Wickizer, PharmD, AE-C, CDE, Agata Staw, PharmD, Maria Hurst, PMC, Beth Martin, RPh, PhD, FAPhA, Robert Topp, PhD, RN, rkent2@wisc.edu
G50 Improved motor function in children with AADC deficiency treated with eladocagene exuparvovec (PTC-AADC): compassionate use study
Efthimia Leonardi, Yin-Hsiu Chien, physician, Ni-Chung Lee, attending physician, Sheng-Hong Tseng, attending physician, Chun-Hwei Tai, physician, eleonardi@ptcbio.com

G51 Improved motor function in children with AADC deficiency treated with eladocagene exuparvovec (PTC-AADC): interim findings from a phase 1/2 study
Anne Marie Conway, Yin-Hsiu Chien, physician, Ni-Chung Lee, attending physician, Sheng-Hong Tseng, attending physician, Chun-Hwei Tai, physician, amconway@ptcbio.com

G52 Improved motor function in children with AADC deficiency treated with eladocagene exuparvovec (PTC-AADC): interim findings from a phase 2 trial
Sunay Ozdas, Paul Wuh-Liang Hwu, physician, Ni-Chung Lee, attending physician, Sheng-Hong Tseng, attending physician, Chun-Hwei Tai, physician, sozdas@ptcbio.com

G53 Depression and migraine: a double whammy on patient-reported health
Zubair Ahmed, MD, Ryan Hononichl, MS, Stephen P. Thompson, BS, MS, Joshua M. Cohen, MD, MPH, FAHS, Andrew Schuster, BA, Nicolas R. Thompson, MS, Brittany Lapin, PhD, Belinda Udeh, PhD, Verena Ramirez Campos, MD, Lynda J. Krasenbaum, MSN, ANP-BC, Irene L. Katzman, MD, ahmedz2@ccf.org

G54 Clinical, economic, and humanistic outcomes of patients with episodic and chronic migraine according to their level of patient activation in the U.S.
Hicham Benhaddi, MSc, Verena Ramirez Campos, MD, Lulu Lee, PhD, mknagge@medergygroup.com

G55 Comparative efficacy and safety of rimegepant versus ubrogepant and lasmiditan for acute treatment of migraine: a network meta-analysis (NMA)
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G56 MSQ utility mapping of rimegepant by change in monthly migraine days
Karissa Johnston, PhD, Gilbert L’Italien, PhD, Evan Popoff, MSc, Alison Deighton, BASc, Parisa Dabirvaziri, MD, Linda Harris, MPH, Alexandra Thiry, PhD, Robert Croop, MD, Vladimir Coric, MD, Gilbert L’Italien, PhD, tammy.martin@biohavenpharma.com

G57 Acute treatment of migraine with rimegepant 75 mg confers robust improvement in absenteeism, presenteeism, and productivity: results from a one-year, open-label, safety study (BHV3000-201)
Gilbert L’Italien, PhD, Robert Croop, MD, Stock Elyse, MD, Alexandra Thiry, PhD, Chris Jensen, PharmD, Vladimir Coric, MD, Hana Rosenthal, Intern, Meghan Lovegren, BS, Gilbert.L’Italien@biohavenpharma.com

G58 Rimegepant 75 mg is associated with significant reductions in monthly migraine days: post-hoc analyses of a multicenter, open label, long-term safety study of rimegepant for the acute treatment of migraine
Chelsea Leroeue, PhD, James McGinley, PhD, Gilbert L’Italien, PhD, Robert Croop, MD, Alexandra Thiry, PhD, Vladimir Coric, MD, Richard B. Lipton, MD, chelsea.leroeue@biohavenpharma.com

H1 Assessing content validity of the Graves’ ophthalmopathy quality of life questionnaire (GO-QOL) in the United States
Marius Stan, MD, Roberti Holt, PharmD, MBA, Lissa Pudnick-Silver, PhD, Saba Sile, MD, Stan.Marius@mayo.edu

H2 Incidence of dry eye disease among patients with continuous positive airway pressure or other nasal mask therapy devices to treat sleep apnea in the United States
Xue Song, PhD, Ishveen Chopra, PhD, Abayomi Ogundele, PharmD, BCMAS, abayomi.ogundele@sunpharma.com

H4 Pooled analysis of OTX-101, a novel nanomicellar cyclosporine formulation, on corneal fluorescein staining in individual zones over 3 months in the worse eye
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H5 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
Xue Song, PhD, Yang Zhao, PhD, Ishveen Chopra, PhD, Amy Nguyen, PhD, Abayomi Ogundele, PharmD, BCMAS, abayomi.ogundele@sunpharma.com

H6 Clinical and economic burden of neovascular age-related macular degeneration in a commercially insured US patient population (2015-2018)
Katelyn R. Keyloun, PharmD, MS, Bijal Shah-Maneck, PharmD, Chi-Chang Chen, PhD, MSPharm, Jasjit K. Multani, MPH, Catherine B. McGuiness, MA, MSc, Joanna Campbell, PhD, Katelyn.Katelyoun@allergan.com

I1 Patient characteristics associated with adherence trajectories to angiotensin-converting enzyme inhibitors/angiotensin receptor blockers among Medicare Advantage plan patients with comorbid hypertension and diabetes
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I3 A rigorous examination of the coding algorithms used for identifying mortality in administrative claims data in patients with cardiac revascularization
Rolin L. Wade, RPh, MS, Sasikiran Nunnala, PhD, Zifan Zhou, MS, Kainan Sun, PhD, rwa@us.imshealth.com
Evaluation of treatment patterns for chronic heart failure and associated costs of different dosing levels of sacubitril/valsartan among Mississippi Medicaid beneficiaries
Siddhi Korgaonkar, MS, Nilesh Gangan, PhD, Benjamin Banahan III, PhD, Eric Putman, PharmD, Sara Noble, PharmD, MPH, Jamie Wagner, PharmD, James Pitcock, PharmD, BCPS, skorgaon@go.olemiss.edu

Understanding risks and time to heart failure following incident atrial fibrillation
Adeniyi T. Togun, PhD, Kael Wherry, MS, PhD (candidate), Alexa Likens, BS, togun001@umn.edu

Proportion of patients with nasal polyposis achieving clinically important improvements in quality of life with omalizumab treatment
Bongin Yoo, PhD, Rebecca Saenz, MD, PhD, Jessica Braid, BSc (Hons), Lauren A. Millette, PhD, Yamina Rajput, MS, rajput.yamina@gene.com

Reflecting the patient’s voice in treatment attributes and outcomes for value assessment
Karen V. Nguyen, PharmD (candidate), Jea Kyong Hwang, PharmD (candidate), Megidelawit Yirefu, PharmD (candidate), Susan dosReis, PhD, Julia Slejko, PhD, kvnayuen@umaryland.edu

New initiators to asthma biologics: a pre/post analysis of utilization patterns, total cost of care, and asthma-related events among 14 million commercially insured members
Hans Shaw, PharmD, Patrick P. Gleason, PharmD, Catherine Starner, PharmD, BCPS, hansshaw15421@gmail.com

A double-blind, placebo-controlled phase 2 study of lenabasum, a selective cannabinoid receptor type 2 agonist, in adults with cystic fibrosis
James F. Chmiel, MD, MPH, Stuart Elborn, MD, Scott Constantine, MS, Barbara White, MD, jchmiel@iu.edu

Omalizumab improves quality of life in patients with chronic rhinosinusitis with nasal polyps and comorbid asthma
Theodore A. Omachi, MD, Claus Bachert, MD, PhD, Philippe Gevaert, MD, PhD, Joaquin Mullol, MD, PhD, Joseph K. Han, MD, Randall A. Ow, MD, Sanna Topplin-Salmin, MD, PhD, Isam Alobiid, MD, PhD, Derrick Kaufman, PhD, Jessica Braid, BSc (Hons), Monet E. Howard, MSc, Bongin Yoo, PhD, omachi.theodore@gene.com

Helicobacter pylori resistance to standard-of-care antibiotics identified from a phase 3 clinical trial of treatment-naïve patients in the United States
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The economic burden of eosinophilic esophagitis in the USA: a retrospective, matched cohort study
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Diagnostic delay in patients with eosinophilic gastritis and/or eosinophilic duodenitis: a population-based study
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Pharmacist consultation in individuals with chronic idiopathic constipation or irritable bowel syndrome with constipation: results from the BURDEN-CIC and BURDEN IBS-C surveys
Florence Calderon, PharmD, Recema Patel, PharmD, Lucinda Harris, MD, Harris.Lucinda@mayo.edu

The impact of plecanatide on patient-reported assessments of disease severity, quality of life, and treatment satisfaction in adults with irritable bowel syndrome with constipation
Christopher Chang, MD, PhD, Sarah Lorenzen, PhD, Kelly Chong, PhD, CChang1@salud.unm.edu

An analysis of healthcare utilization and costs associated with patients with acute hepatic porphyria (AHP) in ENVISION: a phase 3 study of safety and efficacy of givosiran
Stephen Meninger, PharmD, BS, Sonalee Agarwal, PhD, MS, BPharm, Amy Simon, MD, BA, Zhaowei Hua, PhD, Jason Shafrin, PhD, Elizabeth Wu, MPH, BS, Richard Murphy, BA, Phani Veeranki, MD, MPH, DrPH, smeninger@alnylam.com

Healthcare utilization and costs among patients with acute intermittent porphyria receiving hemin: analyses from a national healthcare database
Samuel Silver, MD, PhD, Stephen Meninger, PharmD, BS, Joseph Tkacz, MS, Virginia Noxon, PhD, MS, BS, John J Ko, PharmD, MS, BS, smeninger@alnylam.com

Efficacy and safety of plecanatide in patients with irritable bowel syndrome with constipation: per protocol analysis of two pooled, randomized phase 3 studies
Christopher Chang, MD, PhD, Amol Sharma, MD, Jonathan Rosenberg, MD, Tara E. Koehler, PharmD, Recema Patel, PharmD, CChang1@salud.unm.edu

Estimating diagnostic costs associated with a second-generation blood test for anti-vinculin and anti-cytolethal distending toxin B (CDTB) biomarkers in comparison to the standard exclusionary approach for irritable bowel syndrome (IBS-D/M)
Christopher Tyson, PhD, Mark Pimentel, MD, FRCP(C), Raf Magar, MBA, ctyson@ahrmninc.com

Pooled results of two phase III, multicenter, randomized, vehicle-controlled trials using a proprietary drug-device combination with 0.7% (w/v) cantharidin (vp-102) for the topical treatment of molluscum contagiosum (camp-1 and camp-2)
Lawrence F. Eichenfield, MD, Elaine Siegfried, MD, Pieter d’Arnaud, PhD, Jayson Rieger, PhD, Matthew Davidson, PhD, Melissa D. Olivadoti, PhD, Cynthia Willson, RN, MSN, molivadoti@verrica.com

Long-term safety of tildrakizumab in elderly patients with psoriasis: pooled analysis through 3 years from 2 phase 3 trials
Esteban Daudén, MD, PhD, Ignasi Pau-Charles, MD, Andreu Schoenenberger, MSc, Richard Langley, MD, ignasi.pau.charles@almirall.com

Safety of tildrakizumab in patients with preexisting metabolic syndrome: long-term data from the post hoc analysis of 2 phase 3 clinical studies (reSURFACE 1 and reSURFACE 2)
Nehal N. Mehta, MD, MSCE, FAHA, Alice B. Gottlieb, MD, PhD, Alan M. Mendelsohn, Stephen J. Rozzo, PhD, Alan M. Menter, MD, amderm@gmail.com
L5  Efficacy and safety of tildrakizumab, a high-affinity anti-interleukin-23P19 monoclonal antibody, in patients with active psoriatic arthritis in a randomised, double-blind, placebo-controlled, multiple-dose, phase 2B study
Saima Chohan, MD, Ferran J. Garcia Fructuoso, MD, PhD, Michael E. Luger, MD, Proton Rahman, MD, Siba P. Raychaudhuri, MD, Richard C. Chou, MD, PhD, Alan M. Mendelsohn, MD, Stephen J. Rozzo, PhD, Cynthia Trickett, PA-C, MPAS, DFAAPA, Melodie Young, MSN, RN, Alan.Mendelsohn@sunpharma.com

L6  Efficacy and safety of bimekizumab in patients with moderate to severe plaque psoriasis: results from BE READY, a 56-week phase 3, randomized, double-blinded, placebo-controlled study with randomized withdrawal
Robert Low, BSPharm, PharmD, Peter Foley, MBBS, BMedSc, FACD, James Krueger, MD, PhD, Andreas Pinter, MD, Kristian Reich, MD, Ronald Vender, MD, FRCP, Veerle Vanvoorden, MSc, Cynthia Madden, PhD, Luke Peterson, PhD, Andrew Blauvelt, MD, MBA, robert.low@ucb.com

L7  Efficacy and safety of bimekizumab in patients with moderate to severe plaque psoriasis: results from BE VIVID, a 52-week phase 3, randomized, double-blinded ustekinumab and placebo-controlled study
Robert Low, BSPharm, PharmD, Kim Papp, MD, PhD, FRCP, Andrew Blauvelt, MD, MBA, Richard Langley, MD, April Armstrong, MD, MPH, Richard Warren, BS (Hons), MBChB (Hons), MRCP, PhD, Kenneth Gordon, MD, Joseph Merola, MD, MMSc, Cynthia Madden, PhD, Maggie Wang, PhD, robert.low@ucb.com

L10  Efficacy and safety of tildrakizumab 100 mg for plaque psoriasis in patients randomized to treatment continuation vs treatment withdrawal with retreatment upon relapse in reSURFACE 1
Patricia Lee, MD, Alan M. Mendelsohn, MD, Stephen J. Rozzo, PhD, Wilson Liao, MD, Alan.Mendelsohn@sunpharma.com

M1  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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M2  Real-world healthcare resource utilization and costs of patients with psoriatic arthritis treated with ixekizumab
Mwangi Murage, PhD, MPH, Nicole Prininc, MS, Julie Park, MPH, William Malatestinic, PharmD, Baojin Zhu, PhD, Bilal Atiya, PharmD, Scott Kern, RN, BSN, Amanda Gellett, PhD, Trevelin Sprabery, MD, Alexis Ogdie, MD, mwaregu_mwangi@lilly.com

M10  Effect of awareness of osteoporosis on osteoporosis medication use and adherence: a systematic review
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M13  Ataluren delays loss of ambulation and decline in pulmonary function in patients with nonsense mutation Duchenne muscular dystrophy
Francesco Bibbiani, MD, Francesco Muntoni, PhD, Mark Rance, MD, Joseph McIntosh, MD, Joel Jiang, PhD, Allan Kristensen, PhD, Vinay Penematsa, MD, Elizabeth Goodwin, PhD, Heath Gorish-Dressman, PhD, Lauren M. Morgenroth, PhD, Panayioti Trifillis, PhD, Marcio Souza, PharmD, MBA, fbibbiani@ اختبار

M14  Pulmonary function in nonambulatory patients with DMD from the STRIDE Registry and the CINRG Duchenne Natural History Study: a matched cohort analysis
Richard Abel, PhD, Mår Tulinius, MD, Filippo Buccella, PharmD, Isabelle Desguerre, MD, PhD, Janbernd Kirschner, MD, Eugenio Mercuri, MD, PhD, Francesco Muntoni, PhD, Joel Jiang, PhD, Allan Kristensen, PhD, Panayioti Trifillis, PhD, Claudio Santos, MD, Craig McDonald, MD, rable@ اختبار

M15  Deflazacort or prednisone treatment for Duchenne muscular dystrophy (DMD): real-world outcomes at Cincinnati Children’s Hospital Medical Center (CCHMC)
Jessica Marden, ScD, Jonathan Freimark, MPA, James Signorovitch, PhD, Zhiwen Yao, BA, Cuixia Tian, MD, Brenda Wong, MD, Jessica.Marden@analysisgroup.com

M16  Demographics and safety data from patients with nonsense mutation Duchenne muscular dystrophy receiving ataluren in the STRIDE Registry
Filippo Buccella, PharmD, Isabelle Desguerre, MD, PhD, Janbernd Kirschner, MD, Andrés Nascimiento Osorio, MD, Mår Tulinius, MD, Joel Jiang, PhD, Allan Kristensen, PhD, Panayioti Trifillis, PhD, Claudio Santos, MD, plupo@ اختبار

M17  Systemic gene transfer with AAVrh74.MHCK7.microdystrophin in patients with Duchenne muscular dystrophy
Paul Lupo, PhD, Zarinfe Sahenk, MD, PhD, Kelly Lehman, FNP, Carrie Nease, CPNP-AC, Linda Lowes, PT, PhD, Natalie Miller, DPT, Megan Jammarino, DPT, Lindsey Allfano, DPT, Jordan Vuiea, RN, BSN, Samiah Al-Zaidy, MD, Sarah Lewis, HT, ASCP, Kathleen Church, MSW, Richard Shell, ibrodinoklapac@ اختبار

M18  Systemic gene transfer with AAVrh74.MHCK7.SGCB increased β-sarcoglycan expression in patients with limb girdle muscular dystrophy type 2E
Louise Rodino-Klapac, PhD, Eric Pozsgai, PhD, Sarah Lewis, HT, ASCP, Danielle Griffin, MBA, Aaron Meadows, FNP, Kelly Lehman, FNP, Kathleen Church, MSW, Linda Lowes, PT, PhD, Jerry Mendell, MD, ibrodinoklapac@ اختبار

U1  Variation in subcutaneous allergy immunotherapy billing practices in the United States: a claims analysis of allergic rhinitis patients
Eva Hammerby, MSc, Lisa Elliott, PhD, Karen Rance, DNP, CPNP, Douglas Waddell, BS, Eva.Hammerby@alk.net

U2  Assessing interventions to improve patient care conducted by pharmacists at an outpatient renal transplant clinic within a collaborative pharmacy practice agreement
Rachel J. Chelewski, PharmD, Keren Johnson, PharmD, Autumn D. Zuckerman, PharmD, BCPS, AAHIVP, CSP, Megan Peter, PhD, Anthony Langone, MD, rachel.chelewski@vumc.org
U3 Supporting patients with NVAF outside of the clinic: improving patient physical and behavioral outcomes with a 12-week digital health coaching intervention
Jan Perez, Sharon Tordoff, BS, Greg Salinas, PhD, jiperce@cmeoutfitters.com

U4 Case simulations in OSA and narcolepsy: patients that keep you up at night
Kashemi Rorie, PhD, Whitney E. Faler, MPA, Tara Gross, Jan Perez, Sharon Tordoff, BS, Greg Salinas, PhD, stordoff@cmeoutfitters.com

U5 Patient identified most bothersome symptom in patients with chronic migraine: an analysis of PROMISE-2
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U6 Eptinezumab in patients with chronic migraine who reported high headache-related impact on productivity items of the Headache Impact Test: subgroup analysis of PROMISE-2
Jim Nagy, MD, Dawn C. Buse, PhD, Ruslan Horblyuk, PhD, MBA, MA, Roger Cady, MD, Joe Hirman, PhD, Lahar Mehta, MD, nagyaj@nvhi.net

U7 Change in opioid utilization across multiple lines of business in a managed care organization
Sheta Ara, PharmD, Ankeen Thomasian, PharmD, Jonathan Vu, PharmD, sheta.aras@envolvehealth.com

U8 Telepharmacy and quality of medication use in rural areas
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U9 Evaluation of payer-manufacturer collaborations: priorities, barriers, and characteristics of successful partnerships
Shweta Pathak, MPH, PhD, Annie Yan, PharmD, Andrew Guiser, PharmD, MS, MBA, Susan Weber, MBA, derek.louie@xcenda.com

U11 Medical benefit (Part B) drug step therapy and the utilization management implications for Medicare Advantage plans
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U12 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
Alexander Niyazov, PharmD, RPh, MPH, CPh, BCPS, Joseph Biskupiak, PharmD, MBA, Daniel Malone, RPh, PhD, FAMCP, Bhakti Arondekar, PhD, MBA, BPharm, Douglas Burgoyne, PharmD, FAMCP, Gary Oderda, PharmD, MPH, Alexander.Niyazov@pfizer.com

U13 Clinical and financial impact of downsizing refill care coordination in specialty pharmacy
Devin DeNofio, PharmD (candidate), Paul Yoon, RPh, David Gross, PharmD, devingreen@utexas.edu

U14 Understanding healthcare decision-maker perspectives on AMCP Format dossier content
Aishani Patel, PharmD, Bridgette Schroader, PharmD, MPA, BCOP, Elaine Mak, BA, Bridget Olson, PharmD, MS, Evelyn Sarnes, PharmD, MPH, Lorie Mody, PharmD, Lorie.Mody@xcenda.com

U15 A descriptive analysis of healthcare decision-maker engagement patterns in pre-approval information exchange
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U16 Role of real-world evidence for oncology product registration in the United States: a review of approvals by the United States Food and Drug Administration from 2015-2019
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U17 A systematic comparison of status quo and future expectations for novel drug financing strategies across managed care organizations
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U18 A survey-based analysis of formulary decision making and utilization management trends across managed care organizations
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U19 Budget impact analysis vs. cost-effectiveness analysis: hormonal contraceptives as an illustrative case
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U20 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
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U25 Motivational interviewing for behavior change to improve adherence rate and stars in a Medicare plan
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Z6 Pharmacoeconomic impact of face-to-face medication therapy management at a Medicaid managed care organization
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