Meeting Abstracts

Academy of Managed Care Pharmacy
Nexus 2016
National Harbor, Maryland
October 3-6, 2016
Abstract Submission Process

The Academy of Managed Care Pharmacy (AMCP) Abstracts program provides a forum through which authors can share their insights and outcomes of advanced managed care practice through publication in AMCP’s Journal of Managed Care & Specialty Pharmacy (JMCP). Poster presentations are Tuesday, October 4, at 4:00 pm. The posters will also be displayed on Wednesday, October 5. The reviewed abstracts are published in the JMCP Meeting Abstracts supplement.

The AMCP Nexus 2016 Meeting in National Harbor, Maryland, is expected to attract more than 2,000 managed care pharmacists and other health care professionals who manage and evaluate drug therapies, develop and manage networks, and work with medical managers and information specialists to improve the care of all individuals enrolled in managed care programs.

Abstracts were submitted in the following categories:

Research Report: Describe completed original research on managed care pharmacy services or health care interventions. Examples include (but are not limited to) observational studies using administrative claims, reports of the impact of unique benefit design strategies, and analyses of the effects of innovative administrative or clinical programs.

Economic Model: Discuss models that support various clinical decisions before prospective studies using actual health plan data can be conducted. For example, an economic model could be used to predict the budget impact of a new pharmaceutical product on a health care system.

Solving Problems in Managed Care: Describe a problem or issue that exists in managed care, the goal for the intervention or practice, the intervention or best practice implemented to address a specific issue (e.g., introduce a needed change, develop and implement a new system or program, plan and organize an administrative function, or solve other types of problems in managed care settings). Describe what was observed after or when the intervention or best practice was implemented. Provide a general overview of subjective and objective findings and recommendations for future work/research. These descriptions are not as rigorous as a research report describing the outcomes of an intervention. These are not conducted at the level to conduct hypothesis testing, thus, they do not have firm conclusions.

Abstract Review Process

Thirty-six reviewers and 4 JMCP editorial reviewers were involved in the abstract review process for the AMCP Nexus 2016 Meeting. Each abstract (with author name and affiliation blinded) was reviewed by reviewers and scored using a 1-5 scale on the following 5 criteria (15 rating scores per abstract) used by JMCP to evaluate manuscripts for publication:

- Relevance
- Originality
- Quality
- Bias
- Clarity

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

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Medal Winning Abstracts

Each abstract was assessed by reviewers using a 1-5 scale on the following 5 criteria: relevance, originality, quality, bias, and clarity. These are the same criteria used by JMCP to evaluate manuscripts. The abstract's mean score on the 5 criteria was used to award Platinum, Gold, Silver, or Bronze medals.

**PLATINUM**

Sviatlana Ferri, PharmD Candidate, [U24] Reasons for Primary Medication Nonadherence in Specialty Pharmacy
Bijal M. Shah, BPharm, PhD, [D06] Value Frameworks for the Patient-Provider Interaction: A Comparison of the ASCO Value Framework Versus NCCN Evidence Blocks in Determining Value in Oncology
Andrew Sumner, PharmD, [U28] Cost Savings Analysis from a Fully Implemented Site of Service Management Program
Bingcao Wu, MS, [E22] Cost of Type 2 Diabetes in a Commercially Insured US Population: Comparison of Disease-Attributable and Matched Cohort Cost Estimation Methods

**GOLD**

Kim Boswell, MD, [U06] Value, Utility, and Challenges with the Academy of Managed Care Pharmacy Format Dossier: Implications of Version 4.0
Chi-Chang Chen, PhD, MSPharm, [U15] Evaluation of Patient Migration Patterns and Their Associated Costs Within a National Medicare Advantage Prescription Drug Plan Imposing an Oxycodone HCL Extended-Release Access Restriction
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Janelle Sheen, PharmD, [J13] Incidence of Acute Respiratory Distress Secondary to Opioid Morphine Equivalent Dose Among a Medicaid Population
W. Gerald Teague, MD, [J08] High Costs of Care for Children with Severe or Poorly Controlled Asthma in Privately Insured and Medicaid Populations
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Kevin Bowen, MD, MBA, [M24] Prevalence and Cost of Autoimmune Specialty Drug Use by Indication in a 4.4 Million-Member Commercially Insured Population Continuously Enrolled 4 Years, 2012 to 2015

Hrishikesh Kale, BPharm, MS, [U45] Dispensing Channel and Adherence to Specialty Drugs Among Medicare Part D Beneficiaries

Lee Kallenbach, PhD, [E16] Predictors and Clinical Outcomes of Treatment Intensification in Type 2 Diabetes Patients Uncontrolled on 2 or More Oral Antidiabetic Agents in a Real-World Setting

Daniel Kantor, MD, [G13] Real-World Persistence with Fingolimod for the Treatment of Multiple Sclerosis: A Systematic Review and Meta-analysis

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Sharon L. Larson, PhD, [E30] Primary and Secondary Nonadherence in Diabetic Patients

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Elizabeth A. Lyvers, [F07] Stocking and Dispensing of Opioids and Related Medications: A Survey of Community Pharmacists in a High Abuse Region

William Malatestinic, PharmD, MBA, [L05] Positive Predictive Value of an Algorithm to Identify Moderate-to-Severe Psoriasis in a Claims Database

Alexander C. Marshall, PharmD Candidate, [M09] Tofacitinib (Xeljanz) Utilization Patterns and Persistency Among 4.4 Million Continuously Enrolled Commercially Insured Members over 4 Years

Andrew David Norden, MD, MPH, [G32] A Real-World Claims Analysis of Glioblastoma Treatment Patterns by Lines of Therapy

Janice L. Pringle, PhD, [E42] Evaluating the Impact of Sample Medication on Subsequent Patient Adherence

Gurkirpal Singh, MD, [G24] Hospital Readmissions in Epilepsy: A Statewide Study

Marie Smith, PharmD, [U01] Survey of Medicaid Medication Therapy Management Programs: Variability in State Initiatives

David Stenehjem, PharmD, [M04] Patient and Provider Preferences for Melanoma Treatment: A Discrete Choice Experiment and Willingness-to-Pay Estimates for Immunotherapy and BRAF/MEK Inhibition

Brian Sweet, BSPharm, MBA, [U21] Branded Extended-Release Opioid Use in a National Health Plan: Adverse Selection or Adverse Retention?

Patty Taddei-Allen, PharmD, BCACP, [U03] Impact of Pain Guardian, a Fraud, Waste, and Abuse Program, on Opioid Utilization Using Pharmacy-Paid Claims Data

Tom Tencer, PhD, [L06] Quality-of-Life Benefit Achieved with PASI 75 and PASI 90 Response: Results from Phase III Trials of Apremilast

Thanh G.N. Ton, MPH, PhD, [M11] Patient Heterogeneity in Rheumatoid Arthritis Treatment

Podium Abstracts
(Presentations: Tuesday, October 4, 9:35 am-11:05 pm)

D06 Value Frameworks for the Patient-Provider Interaction: A Comparison of the ASCO Value Framework Versus NCCN Evidence Blocks in Determining Value in Oncology

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BACKGROUND: To address the rising concern about oncology drug costs, the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have recently developed tools to help providers and patients make informed decisions about the value of an oncology regimen. Currently, there is a gap in the literature discussing a head-to-head review of ASCO versus NCCN frameworks when comparing oncology regimens.

OBJECTIVE: To compare the characteristics of ASCO versus NCCN frameworks by applying each tool to the same clinical scenarios.

METHODS: ASCO’s Value Framework (AVF) allows users to generate a net health benefit (NHB) score along with drug acquisition costs for two regimens that have been compared in a prospective randomized clinical trial. The AVF generates scores for clinical benefit, toxicity, and bonus points that range from zero to 180. In contrast, the NCCN Evidence Blocks (NEB) visually depict consensus values from an expert panel in a 5 × 5 matrix representing treatment efficacy, safety, quality and consistency of evidence, and affordability. Scores for NEB range from 1-5, with 1 as the least favorable and 5 as the most favorable based on clinical trials from guidelines and expert panel assessment. We used two regimens as examples for comparing the AVF and NEB scores; enzalutamide for treatment of metastatic castration resistant prostate cancer (mCRPC) as well as nivolumab vs. docetaxel in treatment of advanced nonsquamous non-small-cell lung cancer (NSCLC).

RESULTS: The AVF for enzalutamide generated a total NHB score of 70.8 (high score; range 0-180) with a monthly cost of $8,494-$91, while the NPB scored at a 4 (very effective) for efficacy, 4 (occasionally toxic) for safety, and 2 (expensive) for affordability in the non-visceral metastases block and a score of 3 (moderately effective) for efficacy, 4 for safety, and 2 for affordability in the visceral metastases block. Nivolumab scored a 3.4 (medium score) out of 180 with a monthly cost of $7,009-$86 in AVF and was given a score of 4 for efficacy and safety and 1 (very expensive) for affordability in NEB.

CONCLUSIONS: Both AVF and NEB are novel tools that present oncology treatment values differently. An understanding of the characteristics and methodology of each tool is necessary for users to make a value decision on a given anticancer regimen.

SPONSORSHIP: None.

E22 Cost of Type 2 Diabetes in a Commercially Insured U.S. Population: Comparison of Disease-Attributable and Matched Cohort Cost Estimation Methods

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BACKGROUND: Type 2 diabetes (T2D) is a costly disease and different cost estimation methods (CEM) may yield different results with significant policy implications.

OBJECTIVE: To compare the cost of T2D estimated by 2 CEMs in a commercially insured U.S. population.

METHODS: This retrospective cross-sectional study took a series of 8 biennial snapshots of the HealthCore Integrated Research Database from 1/1/2006-12/31/2014 (cohorts 2007-2014). For each cohort, T2D patients were identified in the first calendar year and must have been continuously enrolled for both years. Each T2D patient was matched to a non-diabetic individual (control) based on age, sex, state of residence, and health plan type. All-cause and T2D-related (claims with a T2D diagnosis or an anti-diabetic medication) healthcare costs (adjusted to 2014 U.S. dollars), including both plan paid and patient paid, were examined in the second calendar year. Annual costs due to T2D were estimated as the difference in all-cause costs between T2D patients and controls using the matched cohort CEM, while the T2D-related costs using the disease-attributable CEM. Each biennial cohort was analyzed independently and differences were examined between the CEMs.

RESULTS: The study identified between 346,886 and 410,234 T2D patients in each biennial cohort. During 2007-2014, the prevalence of T2D increased from 4.9% to 6.4%. Average age of the yearly cohorts increased from 60.3 to 63.3 years old as annual share of Medicare Advantage Plan subscribers increased from 9.2% to 21.5%, while gender share remained stable (~47% were female). All-cause outpatient visits ($6,223-$6,448) were the main cost driver, followed by prescription ($3,687-$4,182) and hospitalization cost ($3,244-$3,445). Over the years, annual all-cause healthcare costs remained relatively steady in both T2D patients ($13,940-$14,330) and matched controls ($7,155-$7,470). However, T2D-related costs increased from $2,930 in 2007 to $3,651 in 2014, mainly driven by higher costs on T2D-related outpatient visits (from $1,502 in 2007 to $1,768 in 2014) and prescriptions (from $1,098 in 2007 to $1,432 in 2014). Annual costs due to T2D estimated by the matched cohort CEM ($6,528-$6,969) were around twice the estimates using the disease attributable CEM ($2,847-$3,651).

CONCLUSIONS: Healthcare costs attributed to T2D varied greatly depending on the estimation method selected. Payers should pay particular attention to the costing methodology used, as they may impact the interpretation and application of the findings.

SPONSORSHIP: Supported by Novo Nordisk.

U24 Reasons for Primary Medication Nonadherence in Specialty Pharmacy

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BACKGROUND: Primary medication non-adherence (PMN) has been recognized by Pharmacy Quality Alliance (PQA) as a high-priority measure for medication adherence. They define PMN as newly initiated medications not picked up from the pharmacy within 30 days of receipt of the prescription by the pharmacy. Rates of PMN reported in the literature vary widely from 1.94-75%; however, the definition used to assess PMN differed amongst these studies. Additionally, most studies were not designed to identify underlying reasons for PMN and very few evaluated PMN in specialty pharmacy. It’s theorized that because of the challenges unique to specialty medications including high cost, strict insurance requirements and specialized training needs, reasons for and rates of PMN may differ than those for non-specialty medications.
OBJECTIVE: To establish a quality management program with the purpose of identifying the frequency of and reasons for PMN in specialty pharmacy.

METHODS: A retrospective electronic health record review was performed from April 1, 2015 to March 31, 2016 to determine the rates and associated reasons for PMN with specialty medications managed by the University of Illinois Hospital and Health Sciences System Specialty Pharmacy Service (UI-SPS). The reasons for PMN were then further grouped into one of five categories: insurance- (e.g., denied claims); cost- (e.g., high out of pocket costs); clinical- (e.g., missing labs); patient- (e.g. patient refused to start); and coordination- (e.g. scheduling injection training) related factors.

RESULTS: The overall rate of PMN for all therapies was determined to be 18.6% using the PQA definition. A total of 87 records met the PQA criteria for PMN. The causes of PMN identified in the chart review in order of highest to lowest frequency included insurance- (33%), coordination- (32%), patient- (21%), clinical- (9%), and cost- (5%) related factors.

CONCLUSIONS: UI-SPS implemented a quality management program to identify the rates and reasons for PMN in specialty pharmacy. Specialty medications are often associated with high drug costs, complex administration, complicated diseases and stringent insurance criteria which may contribute to PMN. Because of this, it’s essential to identify the underlying reasons for PMN in order to address the issues and improve timely delivery of the life-changing therapeutic interventions.

SPONSORSHIP: None.

U28 Cost Savings Analysis from a Fully Implemented Site of Service Management Program

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BACKGROUND: Physician-administered medications have gained an increasing role in the management of many chronic diseases. These products are typically infused by a nurse and can be administered in several different sites including hospital outpatient facilities, physician offices, ambulatory infusion suites, and the patient’s own home. While most office-based practices and home infusion providers are subject to a standard fee schedule for reimbursement, hospital outpatient facilities are usually reimbursed based on the larger hospital contract, which may result in more than 100% increase in cost. Shifting utilization to more cost-effective sites can result in significant savings to health plans without compromising quality of care. In response, a Site of Service (SOS) Management Program was developed to address this need.

OBJECTIVE: To assess the impact of a SOS program for a health plan after 12 months.

METHODS: The SOS program was implemented on July 1, 2015 and included infliximab and all intravenous immune globulin products. When a prior authorization (PA) request is approved for an eligible product, a SOS case is automatically generated. Once the patient’s insurance benefits are confirmed, a nurse case manager will conduct member and provider outreaches to provide information related to different sites of care and help coordinate care to the new SOS. Data from July 1, 2015 to June 30, 2016 was analyzed. Cost is calculated by multiplying the number of approved units (based on PA) by the ASP for the drug and the ASP index for the site based on historical claims data. The ASP index represents the cost per unit at a given site compared to the ASP. Savings is estimated using the difference between the cost at the original SOS compared to the new SOS.

RESULTS: Data for a regional health plan with approximately 2.5 million covered lives was represented in this analysis. Over a course of 12 months, 480 eligible cases were received and 60 cases were successfully shifted. Estimated annual savings is $2,182,500 with an average savings of $36,375 per shift.

CONCLUSIONS: This SOS program offers unique potential to produce significant cost savings to the health plan without compromising the quality of care. The process of this program is designed to minimize patient and network disruptions. Within the current scope of the program, an annualized savings opportunity of $0.07 per member per month (PMPM) was realized. Expanding the program to include additional infusible drugs will allow for an opportunity to further increase the savings potential of this program.

SPONSORSHIP: Magellan Rx Management.
A00-B99 Certain Infectious and Parasitic Diseases (e.g., HIV, Hepatitis C)

B01 Assessing the Impact of Vaccine Coverage Under Medical and Pharmacy Insurance Benefit Versus Medical Only on the Herpes Zoster Vaccine and Pneumococcal Vaccination in a Commercially Insured Population

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1Center for Observational and Real World Evidence, Merck & Co; 2HealthCore

BACKGROUND: Adult vaccination rates are sub-optimal and well below Healthy People 2020 targets. Pharmacies have shown to be convenient settings for patients to receive vaccination. Vaccination reimbursement through an employer-sponsored pharmacy insurance benefit is expected to encourage patients to receive vaccinations in pharmacies. Few studies have evaluated the impact of pharmacy benefit coverage on vaccination rates.

OBJECTIVE: To compare vaccination rates for herpes zoster vaccine (HZV) and pneumococcal vaccine (PCV) among (1) commercially insured members with vaccine coverage via both a medical and pharmacy benefit, and (2) those with insurance coverage for vaccines via only a medical benefit.

METHODS: Commercially insured members within employer groups with ≥100 members that offered coverage for HZV and/or PCV in both medical and pharmacy benefit (exposed group), and in the medical benefit only (unexposed group) were identified in the HealthCore Integrated Research Database (HIRD). Vaccination rates were measured among vaccine eligible patients between 01/01/2013 to 12/31/2014. Vaccination rate was calculated as the number of vaccinations per 1,000 vaccine eligible member-years. Descriptive statistics were used to compare vaccination rates between exposed and unexposed groups.

RESULTS: 7,404 employer groups with 2.83 million members were identified. Mean age among exposed HZV vaccine recipients was 62 years with 55% females, and about 61 years among the unexposed with 51% females for members vaccinated in 2013 and 2014. For pneumococcal vaccines, mean age among the exposed was about 58 years with 49% females, and about 57 years among the unexposed with 48% females. The vaccination rate for HZV was 42 per 1,000 member-years among the exposed and 15 per 1,000 MM in the unexposed group (P<0.001). The vaccination rate for PCV was 22 per 1,000 MM in the exposed and 17 per 1,000 MM in the unexposed group (P<0.001). Vaccination rates for Zostavax and pneumococcal vaccines were higher among employer groups that offered vaccination coverage under medical and pharmacy benefit (exposed group).

CONCLUSIONS: Vaccination rates against herpes zoster and pneumococcal disease were higher among commercially insured members with vaccination coverage under medical and pharmacy benefit, compared to those with vaccination coverage under a medical benefit only. The receipt of vaccination at a pharmacy may reduce barriers to vaccine access and therefore improve vaccine uptake among eligible adults.

SPONSORSHIP: Funded by Merck & Co.

B02 A Medicaid Hepatitis C Prior Authorization Program Outcomes Evaluation

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Amida Care Health Plan

BACKGROUND: Amida Care is a Medicaid Special Needs Health Plan that provides comprehensive care to individuals living with HIV/AIDS in New York City. Upon the release of new DAA HCV drugs, Amida Care implemented a Prior Authorization Program to ensure that its members with Hepatitis C receive treatment that would optimize therapeutic outcomes. It is Amida Care's mission to treat all its coinfected members in a manner that is consistent with clinical guidelines, safe, and cost-effective. The intent of this analysis is to understand the reasons leading to the prior authorization denial of Hepatitis C treatment in the Amida Care population and to follow members who did not receive treatment in order to optimize outcomes.

OBJECTIVE: To determine the factors leading to denial of Hepatitis C medications in a Medicaid Health Plan for members living with HIV/AIDS.

METHODS: A cross-sectional analysis was performed using administrative and clinical data for one year of Prior Authorization (PA) requests.

RESULTS: The total number of Prior Authorization requests in 2015 was 450, of which 410 were approved upon initial request. The initial Hepatitis C drug PA approval rate was 91%. The denial reasons for the initial requests (n = 40) included unsuppressed HIV Viral Load (37.5%), Incomplete data received from provider (7.5%), alternative drug/regimen recommendation accepted by provider (42.5%), or insufficient evidence to support drug effectiveness (12.5%). Of the 40 denied cases, 22 were approved after an appeal. The approvals were due to the following reasons: member achieved unsuppressed HIV Viral Load (n = 9), additional data received from provider (n = 2), alternative drug/regimen recommendation accepted by provider (n = 11). Three members disenrolled from the plan and the prescriber withdrew the request for two of the cases which were initially denied. In 2015, 95% of Hep C requests were approved (included initial requests and appeals). The denial reasons for the 13 cases were denied after a second level of review were as follows: Unsuppressed HIV Viral Load (n = 5), insufficient evidence to support drug effectiveness (n = 4), missing data from provider (n = 1), and request for an alternative treatment regimen when there was insufficient justification documented (n = 3).

CONCLUSIONS: In order to drive health outcomes and support member adherence and engagement in a cost effective manner, Amida Care developed a Hep C prior authorization program to ensure members are treated appropriately. Denial reasons supported clinical appropriateness, member readiness as well as cost-effective therapeutic alternatives.

SPONSORSHIP: AmidaCare.
**B04 The Impact of a “High Touch” Patient Management Model on SVR12 in Chronic Hepatitis C Patients: A Comparative Study of Independent and Pharmacy Benefit Manager-Owned Specialty Pharmacies**

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**BACKGROUND:** The evolution of HCV medications has resulted in simplified treatment regimens and improved cure rates. However, these advancements have not addressed the continuing challenges of therapeutic management which, if unsuccessful, can result in treatment failure, increased patient mortality rates, and soaring payer costs. According to a Medscape article titled “Achieving Sustained Virologic Response in Hepatitis C,” “a U.S.-based study determined that follow-up costs for patients achieving SVR vs. non-responders have a mean annual cost of $6,301 vs. $10,149 for non-responders due to higher hospital and outpatient costs.” The value of achieving SVR is paramount and specialty pharmacies have an obligation to maximize this result.

**OBJECTIVE:** To compare the effect of independent and PBM-owned specialty pharmacy (SP) patient management programs on sustained virologic response (SVR12) rates in hepatitis C patients.

**METHODS:** A retrospective medical record review of >600 chronic hepatitis C patients serviced by independent and PBM-owned SPs was conducted to determine the percentage of patients achieving SVR12. The independent SP utilized a “high touch” patient management model. In this model, a comprehensive clinical evaluation and patient assessment (including baseline quality of life) was conducted to ensure therapy appropriateness and patient adherence. Baseline clinical data was recorded and pharmacists regularly followed up with clinical and QOL assessments to ensure continued therapy appropriateness and adherence. Patients from both SP types were categorized based on treatment history and extent of hepatic fibrosis.

**RESULTS:** Of the >600 patients reviewed, 98% of those managed by the independent SP “high touch” model achieved SVR12 compared to 95% of those serviced by PBM-owned SPs. Treatment-naïve patients achieved SVR12 rates of 98% and 94% through the independent SP model and PBM-owned SPs, respectively. Significant differences were seen in cirrhotic patients, with 99% achieving SVR12 through the independent model compared to only 91% in the PBM-owned SPs (P < 0.01).

**CONCLUSIONS:** This analysis shows that SVR12 rates for hepatitis C patients are improved with the use of an independent SP “high touch” patient management model. In particular, there is a substantial difference in the SVR12 rate of difficult to treat patients, such as cirrhotics. These significant improvements warrant additional research to determine the specific differences between SP models and how they directly influence SVR12 rates.

**SPONSORSHIP:** None.

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**B05 Long-Term Follow-up of Patients with Chronic HCV Infection Following Treatment with Direct-Acting Antiviral Regimens: Maintenance of SVR, Persistence of Resistance Mutations, and Clinical Outcomes**

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**BACKGROUND:** Significant advances in the treatment of chronic hepatitis C have been made with the introduction of direct acting antiviral (DAA) regimens. While sustained virologic response (SVR) rates may now be achieved in the majority of patients, data describing long-term virologic and clinical outcomes with these regimens are needed.

**OBJECTIVE:** To describe the long-term outcomes of patients with chronic hepatitis C treated with DAAs and enrolled in two 3-year registry studies.

**METHODS:** We report interim data from two 3-year registry studies capturing long-term outcomes in patients with chronic hepatitis C treated with DAAs. Subjects are enrolled into the two registries according to SVR status; SVR versus non-SVR (Sequence registry). We determined the durability of SVR, relapse rates and reinfection rates. The persistence of resistance associated variants (RAV) in treatment failures is followed. Liver disease progression is assessed by periodic clinical and laboratory evaluations.

**RESULTS:** 5,433 patients enrolled in the SVR registry with a median (range) follow-up of 71 (0-156) weeks. 536 patients enrolled in the Sequence registry with a median (range) follow-up of 44 (0-159) weeks. Demographic and disease characteristics are described. In the SVR registry, at the time of data analysis 99.7% (5,414/5,433) of patients have maintained SVR with 0.3% (19/5,433) having emergent virus (6 relapses, 8 new infections, 5 to be confirmed). Viral emergence occurred by Week 96 in all patients. In the Sequence registry, of 89 patients who received an NS5A inhibitor and had baseline sequencing data 91.0% (81/89) had NS5A RAVs at Week 96. Hepatocellular carcinoma (HCC) was reported in 0.3% (16/5,433) and 0.9% (5/536) of patients in the SVR and Sequence registries through Week 96 respectively. There were no significant changes in laboratory evaluations or liver disease assessments.

**CONCLUSIONS:** SVR achieved following treatment with direct-acting antiviral regimens is durable. In patients failing NS5A containing regimens, treatment-emergent NS5A RAVs persist. Rates of clinical disease progression and HCC are low. Ongoing reporting from the registry studies will be required to confirm these findings.

**SPONSORSHIP:** This research was funded by Gilead Sciences.
In this analysis, the phase-3 ION-3 data is compared with data from several diverse real world populations and one post-marketing investigator sponsored HIV/HCV trial. Patient demographics, characteristics, SVR12 and discontinuation data has been collated and compared.

RESULTS: The ION-3 post hoc analysis reported 123 patients who were TN, NC and VL <6M and treated with 8 weeks of LDV/SOF. Mean age was 52, 22% black, 72% genotype 1a (GT1a); the SVR12 was 97% (119/123). The overall SVR12 rate from six diverse real-world and postmarketing cohorts was also 97% (638/658). There was no significant impact of HCV genotypes or subtypes (GT1a, 1b versus GT4), prior treatment history, presence or absence of cirrhosis, high viral load (HCV VL >6M), or HIV/HCV co-infection.

CONCLUSIONS: LDV/SOF for 8 weeks yielded high SVR rates in ION-3. Analysis of RWE data from several diverse & heterogeneous cohorts from the U.S. & EU show SVR outcomes that were consistent with the Phase-3 ION-3 results and supports the use of 8 weeks LDV/SOF in treatment-naive, non-cirrhotic GT1 patients with a baseline HCV VL<6M and possibly in other populations including HIV/HCV co-infected patients. Discontinuation rates were low despite diverse patients and clinical settings. Data from the TARGET and TRIO cohorts also suggests that the 8-week regimen is underutilized.

SPONSORSHIP: This research was funded by Gilead Sciences.

B07 Real-World Analysis of Fee-for-Service State Medicaid Data to Compare Differences in Patient Demographics and Comorbid Medical Conditions Between Previously Treated and Untreated Patients Infected with Hepatitis C Virus

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BACKGROUND: Since the introduction of the first interferon-free regimens for the treatment of chronic hepatitis C virus (HCV) infection, the treatment landscape has been rapidly evolving. This analysis aims to examine a real-world Medicaid HCV population to understand current treatment patterns.

OBJECTIVE: To analyze real-world medical and pharmacy data to characterize demographics, comorbidities, and concomitant medication treatment received between patients treated for HCV and patients who remain untreated for HCV.

METHODS: This retrospective study examined real-world medical and pharmacy claims from six fee-for-service (FFS) state Medicaid programs. Qualifying participants had a diagnosis of chronic HCV on at least 2 separate medical claims, were at least 18 years old at index date, were continuously eligible throughout baseline period (1/1/10 to 12/31/14) and study period (1/1/15 to 12/31/15), and, in the treated population, at least 1 claim for HCV treatment during the study period. The index date for treatment cohort is first date with paid claim for HCV treatment and for non-treated cohort is first date with service date or medical claim tied to HCV diagnosis code. A six-month look back from the index date was used to assess baseline comorbidities and concomitant medications.

RESULTS: The prevalence of HCV in this Medicaid FFS study population was 4.2%. Of the 4,260 patient with HCV, 1,038 (19.6%) were treated. Depending on the state, HCV treatment rates varied between 16.5% and 22.3% of identified patients. Treated patients were significantly older (average [SD] in years 48.8 [11.0] vs. 44.8 [12.4]) and had more baseline comorbidities (24.5% vs. 17.1% with comorbidity index > 3). (P<0.0001 for all comparisons). In addition, treated patients had a significantly higher prevalence of cirrhosis (19.1% vs. 7.5%) and hepatocellular carcinoma (1.0% vs. 0.6%). In contrast, untreated patients had significantly higher prevalence of mental health conditions (74.6% vs. 70.2%), hepatitis B (2.7% vs. 1.9%), chronic kidney disease (4.0% vs. 3.6%), and use of anticonvulsants (57.3% vs. 51.8%). (P<0.0001 for all comparisons).

CONCLUSIONS: In a real-world Medicaid population, patients treated for HCV tended to be older and sicker overall. Specific comorbidities and/or concomitant medications identified in untreated patients may be barriers to HCV treatment, which would support earlier HCV treatment prior to the development of such comorbidities.

SPONSORSHIP: This research was funded by Gilead Sciences.

B09 Best Practices for a Hepatitis C Multidisciplinary Team

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BACKGROUND: With the advent of direct-acting antiviral agents (DAAs) and interferon-free treatment options, Hepatitis C virus (HCV) treatment has undergone a seismic shift. Cure rates now exceed 90%. DAA regimen choices continue to present challenges to HCV providers. The Veterans Health Administration (VHA) has a higher percentage of patients with chronic HCV than the general population and a high demand for HCV treatment. Pharmacists are uniquely positioned to collaborate with providers to manage patients.

OBJECTIVE: To describe best practices of a Hepatitis C Ambulatory Care Clinic.

METHODS: Pharmacists have been integrated into a multidisciplinary team (MDT) in the Infectious Disease Hepatitis C clinic at our VHA facility. This team includes an Attending Physician, Physician Assistants and Clinical Pharmacist Specialists. Additionally, the team is supported by a Medical Support Assistant for patient scheduling and a pharmacist for medication dispensing and inventory control. Clinical Pharmacist Specialists work within the team determining the most appropriate HCV treatment regimen for each patient based on medical history, previous treatment history, comorbidities, drug interactions, cost and management of patients on treatment.

RESULTS: The incorporation of Clinical Pharmacist Specialists within the MDT has, in addition to providing patient management, led to the development of management tools essential to the success of the clinic. A shared Outlook calendar optimizes communication within the MDT. The calendar includes patient HCV clinic appointments, follow-up telephone call appointments, urgent patient care issue reminders and weekly MDT meetings. An Excel template is used to monitor the progress of each patient throughout treatment. A SharePoint site for the MDT members contains pertinent resources for HCV treatment (guidelines, Criteria for Use, drug monographs, etc.), patient drug information pamphlets and Excel monitoring templates. Weekly MDT meetings (Hep C Huddles) are held to review patients starting treatment in the next week and to discuss issues. The inclusion of primary-care based Clinical Pharmacist Specialists further increased the capacity of the clinic.

CONCLUSIONS: Our facility has developed best practices for an effective and efficient MDT in the Hepatitis C Ambulatory Care clinic. Clinical Pharmacist Specialists are integral members of the team. Shared calendars and patient monitoring sheets are quick and effective tools for communication and workload management. Our HCV treatment success rate is above 90%

SPONSORSHIP: None.
**B10 Cost-Effectiveness of Elbasvir/Grazoprevir Compared with Ledipasvir/Sofosbuvir and Sofosbuvir/Velpatasvir for the Treatment of Chronic Hepatitis C Virus Genotype 1 in the United States**

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1Pharmerit International; 2Merck & Co.

**BACKGROUND:** An estimated 2.7 million patients are infected with chronic hepatitis C (CHC) virus in the U.S. Compared with interferon and ribavirin (RBV)-based regimens, direct-acting antivirals (DAAs) have shorter treatment durations, greater efficacy, and fewer adverse events. As new DAAs are introduced into the market, cost-effectiveness analyses are needed in order to identify the most efficient use of resources.

**OBJECTIVE:** To evaluate the cost-effectiveness of treatment with elbasvir/grazoprevir (EBR/GZR) regimens compared with ledipasvir/sofosbuvir (LDV/SOF) and sofosbuvir/velpatasvir (SOF/VEL) in patients with CHC virus genotype 1 (GT1) infection.

**METHODS:** A Markov model was constructed to evaluate the cost-effectiveness of EBR/GZR ± RBV, LDV/SOF, and SOF/VEL over a lifetime time horizon from the payer perspective. The target population was patients infected with CHC GT1a or 1b, stratified by treatment history (treatment-naïve [TN] or treatment-experienced [TE]), degree of fibrosis (cirrhotic or non-cirrhotic), baseline viral load (HCV RNA < or ≥6 million IU/mL), and presence of NS5A resistance-associated variants (RAVs). The model consists of 16 health states encompassing METAVIR fibrosis score (F0-F4), treatment success or failure, decompensated cirrhosis, hepatocellular carcinoma, liver transplant, and liver-related death. The proportions of patients achieving sustained virologic response (SVR) or discontinuing therapy early were obtained from clinical trials. Other inputs were obtained from published sources. The primary outcome was incremental cost-utility ratio (ICUR) for EBR/GZR ± RBV vs. LDV/SOF and EBR/GZR ± RBV vs. SOF/VEL. Results for subpopulations with and without RAVs and low or high viral load were combined into a single weighted average. One-way sensitivity analyses were conducted to identify drivers of results.

**RESULTS:** EBR/GZR ± RBV was cost-saving and produced more QALYs compared with LDV/SOF in all patient populations studied, regardless of subtype, treatment history, and presence of cirrhosis. EBR/GZR ± RBV was less costly than SOF/VEL in all populations, but produced fewer QALYs than SOF/VEL in GT1a cirrhotic (ICUR = $150,540/QALY for SOF/VEL vs. EBR/GZR in TN and $103,266/QALY in TE patients) and in GT1b TN non-cirrhotic patients (ICUR = $228,958/QALY for SOF/VEL vs. EBR/GZR). In the remaining populations, EBR/GZR ± RBV was cost-saving and more effective than SOF/VEL. In one-way sensitivity analyses, SVR rates in patients receiving EBR/GZR ± RBV most commonly impacted model conclusions, and at the upper bound resulted in dominance over SOF/VEL in GT1a cirrhotic and GT1b TN non-cirrhotic patients.

**CONCLUSIONS:** This study found EBR/GZR ± RBV to be less costly and more effective than LDV/SOF in patients with CHC GT1. EBR/GZR was less costly compared with SOF/VEL in all populations and was also more effective in most populations. In GT1a cirrhotic and GT1b-TN non-cirrhotic patients, EBR/GZR ± RBV was cost-effective compared with SOF/VEL when SVR was increased within sensitivity ranges.

**SPONSORSHIP:** Merck & Co.

**B11 Trends in HIV Antiretroviral Tablet Burden in Treatment-Naïve Patients in the United States**

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**BACKGROUND:** There has been a significant trend in prescribing ART with a lower pill burden in the last decade. More than two thirds of naïve patients now initiate on an STR, and notwithstanding differences in efficacy, adherence and tolerability of the various ARVs during the timeframe analyzed, significant trends were also noted in achieving viral suppression and reducing disease progression (new ADE) during the initial ART.

**OBJECTIVE:** To trend antiretroviral therapy (ART) pill burden and quality metrics in naïve patients.

**METHODS:** HIV+ patients initiating ART between 1/1/2007 and 12/31/2014 were identified in the OPERA database, a collaboration of HIV caregivers at 79 clinics in 15 states. Patients were followed from treatment start to regimen change, death, loss to follow-up, or study end. ART tablet burden was classified into STR, 2 (2PR) and 3+ pill regimens (3 + R). Linear regression models assessed the impact of time on the frequency of STR use. The likelihood of achieving viral suppression and experiencing an AIDS defining event (ADE) were as well as on the time to viral suppression.

**RESULTS:** Total sample was 9,190 (86% male, median age (IQR) 35 (27, 45, 39% African American). The percentage of patients initiating on a STR or 2PR increased from 57% and 2% in 2007 to 69% and 15% in 2014 (P = 0.02. 0.04 respectively) while those initiating on a 3+ R decreased from 41% to 16% (P < 0.01) during the same period. Over the same time period, the percentage of patients achieving viral suppression after ART initiation rose from 58% to 70% (P = 0.06) while those experiencing an ADE dropped from 6.0% to 2.2% (P < 0.001). Viral suppression rates increased in STR initiators from 67% to 75% (P = 0.15) and from 44% to 47% (P = 0.40) among 3+ R initiators. Median time to suppression dropped from 4.3 to 3.0 months (P = 0.06) driven primarily by the changes in time to suppression in STR initiators (4.3 to 2.1 months, P = 0.051). Time to suppression did not change significantly among 3+ R initiators during the same time frame (4.6 to 4.0, P = 0.7). Time trends in ADE reduction were also significant for STR (4.2% to 1.8%, P = 0.003) but not for 3+ R (8.8% to 5.8%, P = 0.16). Cell size for 2PR was too small to support analysis.

**CONCLUSIONS:** There has been a significant trend in prescribing ART with a lower pill burden in the last decade. More than two thirds of naïve patients now initiate on an STR, and notwithstanding differences in efficacy, adherence and tolerability of the various ARVs during the timeframe analyzed, significant trends were also noted in achieving viral suppression and reducing disease progression (new ADE) during the initial ART.

**SPONSORSHIP:** Funded by ViiV Healthcare.
defined as time from start date to end of first 90-day gap between fills for any ART in the index regimen, or the start date of an ART not in index regimen. Kaplan-Meier and Cox proportional hazard models evaluated persistence and discontinuation across treatments controlling for age, gender, health-plan type, region, Charlson Comorbidity Index (CCI), and baseline comorbidities.

RESULTS: 3,990 patients were included, predominantly male (82%), average age 41.1 years. Single tablet regimens (STRs) had superior persistence compared to multi-tablet regimens (MTRs). Hazard ratio for discontinuation/switch with STRs was 1.95 compared to STRs (P < 0.0001), and median time to discontinuation/switch was 37.5 months (STRs), compared to 21.4 months (MTRs, P < 0.0001). Controlling for baseline differences, FTC/TDF-backbone regimens demonstrated greater persistence compared to ABC/3TC. ABC/3TC/DTG had a higher propensity for discontinuation/switch compared to EVG/C/FTC/TDF (Hazard ratio 1.24). FTC/TDF+DTG had a decreased risk for discontinuation/switch compared to FTC/TDF+DRV/r (HR 0.75), an increased risk compared to EVG/C/FTC/TDF (HR 1.54), and a comparable risk compared to ABC/3TC/DTG (HR 0.98).

CONCLUSIONS: Among DHHS-recommended regimens, STRs had greater persistence compared to MTRs. However, ABC/3TC was comparable to the FTC/TDF+DTG MTR. Regimens containing FTC/TDF had greater persistence compared to regimens with ABC/3TC across third agents, STRs, and MTRs. As a third agent, DTG yielded greater persistence compared to DRV/r, but poorer persistence compared to EVG as part of the EVG/C/FTC/TDF STR. Persistence is likely to result in improved patient outcomes due to benefits associated with improved persistence.

SPONSORSHIP: Gilead Sciences sponsored this research.

C02 Patient Characteristics and Costs in Advanced Head and Neck Cancer: Retrospective Analysis of a Community Oncology Database

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BACKGROUND: Head and neck (H&N) cancers account for 3% of all cancers in the U.S., and it is expected that 61,760 new cases will occur in 2016.

OBJECTIVE: To describe patient characteristics, treatment patterns, and costs for advanced H&N patients in the community oncology setting.

METHODS: Clinical patient data from the 1/1/2007-10/1/2015 medical records of adults diagnosed with advanced H&N cancer (stage III/IV or metastatic) were retrospectively collected from a network of community oncology practices in the U.S. Comparisons across groups were conducted using ANOVA or Kruskal-Wallis test for continuous variables and chi-squared or Fisher’s Exact test for categorical variables.

RESULTS: The study included 462 patients (median age 61 years, range 26-99). Of these, 80.7% were male, 77% Caucasian, and 21% African-American. At initial diagnosis, the most frequent tumor locations were hypopharynx/larynx (31.1%) and oropharynx (30.9%). HPV testing was most frequent among the oropharynx group (21.7% tested, 51.6% positive). Overall, 41.8% were current tobacco users and 22.3% were current or past alcohol abusers/excessive users. First-line systemic therapy consisted of platinum combinations (41.8%), platinum monotherapy (26.4%), cetuximab monotherapy (11.3%), other (0.9%), or no chemotherapy (26.4%). Overall median monthly healthcare cost was $8,505 (95% CI: $12,739-$16,044). A significant effect was seen for alcohol use, with the highest median monthly costs among those with abuse/excessive use ($11,009 [95% CI: $967-$71,328]; P = 0.049). Median monthly cost for the first-line period was $6,406 ($12,592-$15,984). Significant variability was seen by treatment regimen, with highest cost in patients receiving cetuximab monotherapy ($12,429 [$12,506-$17,348]; P < 0.001). Median monthly cost
for second-line was $6,073 ($11,021-$14,433), with no significant variability based on tumor location, HPV status, and tobacco/alcohol use. Second-line cost varied by treatment regimen, with lowest median cost in patients receiving cetuximab monotherapy ($1,749 [$9,838-$18,415], P = 0.004), potentially due to different hospitalization costs (higher in other treatment groups).

**CONCLUSIONS:** Preliminary data in this “real-world” community oncology retrospective study suggest that costs of care in patients with advanced H&N cancer are related to patient characteristics such as alcohol use status and treatment patterns. Further study is underway. 

**SPONSORSHIP:** AstraZeneca.

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**C03 Platinum Rechallenge in Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck**

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**BACKGROUND:** Real-world management of recurrent/metastatic squamous cell carcinoma of the head and neck (SCCHN) is not well known. Platinum-based chemotherapy is generally recommended in the first-line (1L) setting. The optimal sequencing of regimens beyond 1L remains unclear, with no current standard of care for patients who progress following platinum-based treatment.

**OBJECTIVE:** To describe the sequencing of systemic therapy in metastatic SCCHN, specifically the extent to which patients are rechallenged with platinum-based regimens. Healthcare resource utilization (HCRU) among platinum-rechallenged patients is also described.

**METHODS:** This retrospective study used the MarketScan database of commercially insured patients. Patients with recurrent/metastatic SCCHN treated between January 1, 2009 and March 31, 2015 were identified by ICD-9-CM codes. Patients aged ≥ 18 years with primary SCCHN who received systemic therapy and had ≥ 180 days of follow-up were included. Platinum rechallenge was defined as 1L platinum treatment followed by second line (2L) platinum treatment ≥ 45 days later. Outcome measures included selection and sequencing of systemic treatment, HCRU, and associated costs.

**RESULTS:** Of 3,684 patients identified, 1,380 (37%) received systemic therapy. Most patients (87%) were treated with a platinum-based regimen in the 1L setting, of which the majority were either platinum mono-therapy or platinum/taxol doublet. Only 12% (n = 161) of treated patients received subsequent systemic therapy; in this subgroup, 133 patients received 1L platinum treatment, of whom 50% (n = 66) were rechallenged with platinum. Average time from 1L platinum to 2L platinum was 150 days (standard deviation [SD] = 237 days). Platinum-rechallenged patients averaged 14 outpatient visits, with 16% (n = 111) visiting the ER and 19% (n = 13) admitted to the hospital with an average of 1.3 (SD = 0.9) hospital admissions and an average stay of 4.3 days (SD = 3.1). Total annual healthcare cost for platinum-rechallenged patients was $132,028 (SD = $114,506).

**CONCLUSIONS:** With limited treatment options for patients with recurrent/metastatic SCCHN, many patients who go on to receive more than one line of treatment are rechallenged with platinum in the 2L setting. The HCRU and economic burden of these platinum-rechallenged patients was substantial. New treatment options could potentially help ease some of the associated burden with both impatient and outpatient resource use and cost.

**SPONSORSHIP:** Funding provided by Bristol-Myers Squibb.

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**C08 Direct Healthcare Cost of Patients with Pancreatic Cancer Compared to a General Managed Care Population in the United States**

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**BACKGROUND:** Systemic therapy is often perceived as a main driver of cancer costs, but other healthcare costs could contribute more to overall spend for patients with pancreatic cancer (PaCa).

**OBJECTIVE:** To describe differences in direct healthcare costs of patients diagnosed with PaCa compared to non-PaCa patients in a U.S. managed care population.

**METHODS:** In this observational, retrospective study, patients (age ≥ 18) with ≥ 2 PaCa (ICD-9 157.xx) medical claims between 1/1/2007 and 6/30/2015 were identified using claims from the HealthCore Integrated Research Database. PaCa patients were matched to patients without an observable cancer diagnosis between 1/1/2006 and 6/30/2015 but similar in terms of age, gender, region, and plan type (non-PaCa patients). Patients with other cancer diagnoses during 60 days before the index date (first PaCa medical claim) were excluded. Patients were required to have ≥ 12 months of continuous health plan enrollment prior to the index date. Claims through 6/30/2015 or end of patient eligibility were analyzed. Cost was adjusted to 2015 U.S. dollar value. Results were annualized and reported in per patient per year (PPP).

**RESULTS:** 5,826 PaCa patients met the inclusion criteria and were matched (1:3) against 17,478 non-PaCa patients. Median follow up was 7.2 months for PaCa patients and 29.2 months for non-PaCa patients. 41.3% of PaCa patients had a recorded death during follow up (vs. 4.5% in non-PaCa patients). Average annualized (PPP) total healthcare costs (medical and pharmacy) were nearly 16 times higher for PaCa ($235,233 SD ± $371,271) vs. non-PaCa patients ($14,021 ± $63,652, P < 0.0001. More hospitalizations resulted in additional $159,820 mean cost among PaCa patients ($217,776 ± $403,352) over non-PaCa patients ($57,956 ± $179,267, P < 0.0001, while no cost differences were observed pre-index ($23,929 ± $46,340) vs. ($24,827 ± $39,206, P = 0.242. These increased costs were also observed for physician office visits ($74,825 ± $90,159) vs. ($53,947 ± $19,257, P < 0.0001, and outpatient settings ($3,799 ± $3,222 vs. $902 ± $1,400, P < 0.0001). Pharmacy related costs were also significantly higher for PaCa patients ($9,972 ± $17,497) vs. ($2,440 ± $5,421, P < 0.0001.

**CONCLUSIONS:** PaCa significantly increased economic burden compared to non-PaCa patients. Since inpatient hospitalization was the main cost driver, interventions to reduce the risk of hospitalizations may result in significant savings to the healthcare system. Costs incurred in the outpatient setting and pharmacy related costs contributed least to total costs.

**SPONSORSHIP:** Funded by EMD Serono.

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**C10 Initiation and Duration of Systemic Therapies Among a Managed Care Population with Pancreatic Cancer in the United States**

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**BACKGROUND:** The time to initiation and duration of systemic therapy for patients with pancreatic cancer (PaCa) on a national level is not well-documented.

**OBJECTIVE:** To identify treatment patterns including time to initiation and duration for common systemic therapies in PaCa.
METHODS: In this observational, retrospective study, patients (age ≥ 18) with ≥ 2 PaCa (ICD-9 157.xx) medical claims between 1/1/2007 and 6/30/2015 were identified from the HealthCore Integrated Research Database. Patients with other cancer diagnoses during 60 days before the index date (first PaCa medical claim) were excluded. Patients were required to have ≥ 12 months of continuous health plan enrollment prior to the index date. Claims through 6/30/2015 or end of patient eligibility were analyzed. A regimen was defined as ≥ 1 agents administered within a 4-day period. The end of a line of therapy was defined as either a 60-day gap in treatment, or initiation of a new drug after 28 days from the start of therapy. Death was identified using the Social Security Death Index.

RESULTS: 5,826 PaCa patients met the inclusion criteria with median follow up of 7.2 months. 41.3% of had a recorded death during follow-up. Most PaCa patients (n = 3,372 or 58%) received systemic therapy. The average time between date of PaCa diagnosis and initiation of first line therapy was 58.5 ± 133.8 days, median = 30 days. For the most common first line therapies, patients were on gemcitabine for an average (80.6 ± 80.3) days, on FOLFIRINOX for (96.8 ± 95.6) days, and on nab-paclitaxel + gemcitabine (97.0 ± 84.3) days. Nearly quarter (24%) of patients received second line therapy, which was initiated on an average 103.5 ± 167.7 days from the date of initiation of first line therapy. For the most common second line therapies, patients were on gemcitabine for an average (72.9 ± 59.0) days, on gemcitabine + nab-paclitaxel (102.2 ± 103.5) days, and on capicitabine (64.2 ± 79.8) days. 9.6% received third line therapy, which was initiated on an average 103.1 ± 157.8 days from date of initiation of second line therapy. For the most common third line therapies, patients were on gemcitabine for an average of (70.3 ± 56.0) days, on gemcitabine + nab-paclitaxel (85.9 ± 80.6) days, and on FOLFOX (85.6 ± 86.14) days.

CONCLUSIONS: The average time patients took to progress from first to second line, and from second to third line therapies were similar, however, the variance was wide. The long duration between PaCa diagnosis and initiation of systemic therapy for some patients may indicate non-optimal care for preventing progression.

SPONSORSHIP: Funded by EMD Serono.

C11 Burden of Brain Metastases in Non-Small Cell Lung Cancer Patients Treated with Epidermal Growth Factor Receptor Gene Mutation-Specific Tyrosine Kinase Inhibitor

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BACKGROUND: Brain metastases (BM) affect 9%-17% of patients with lung cancer. There is a need to understand symptomatology and economic burden associated with BM in non-small cell lung cancer (NSCLC), specifically in patients receiving epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) treatment.

OBJECTIVE: To describe the symptoms and economic burden associated with BM compared with other metastases (OM) or no metastases (NM) among patients with NSCLC receiving EGFR TKI treatment.

METHODS: This retrospective study identified patients aged ≥ 18 years with ≥ 2 ICD-9 diagnosis codes for lung cancer (first diagnosis date = index date) within 90 days of each other, and ≥ 1 administrations of TKI between 5/1/2012 and 3/31/2015 from the HealthCore Integrated Research Environment. A treatment-based algorithm excluded patients with small cell lung cancer. Patients were assigned to BM, OM, or NM cohorts based on ICD-9 diagnosis codes for site of metastasis. Patients were divided into 2 mutually exclusive groups based on first observed date for metastasis code; cancer diagnosed before metastasis (CancerBeforeMet, CBM) or cancer diagnosed on the same date as the metastasis (CancerOnMet, COM). There was a 12-month pre-index enrollment requirement. Follow-up time was variable. Outcomes included select neurologic/physical symptoms, measured by ICD-9 diagnosis codes, and total healthcare cost. CBM and COM patients were analyzed separately. Cost analyses were conducted using a generalized linear model (gamma with log link), controlled for age and reported in per-patient-per-month (PPPm) values.

RESULTS: There were 15 BM, 49 OM, and 85 NM CBM patients and 24 BM and 23 OM COM patients. Mean age was 69 years and 57% were women. CBM: BM patients suffered more fatigue, nausea/vomiting, headaches, pain/numbness, altered mental status, and seizures versus OM and more headaches and pain/numbness versus OM during follow-up. Both BM ($10,631) and OM ($9,350) patients had significantly higher PPPM all-cause costs than NM ($6,369) during the post-index period (P ≤ 0.05). Costs for BM ($17,064) after metastases diagnosis were higher than for OM ($13,004), but the difference was not statistically significant. COM: BM patients had more fatigue and nausea/vomiting vs. OM. Post-index costs were significantly higher for BM patients ($20,578) than for OM ($10,861; P ≤ 0.05).

CONCLUSIONS: Patients in this study who developed BM after their NSCLC diagnosis experienced more symptoms and higher economic burden than those with NM. For patients diagnosed with metastasis at the time of their NSCLC diagnosis, costs were almost double for BM versus OM. Novel agents that can treat BM along with TKI therapy may reduce this burden.

SPONSORSHIP: AstraZeneca.

C12 Costs Associated with Diagnostic and Postprogression Biopsy Among Patients with Non-Small Cell Lung Cancer in the United States

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BACKGROUND: Management of patients with advanced non-small cell lung cancer (NSCLC) is increasingly driven by the underlying molecular mutation. Per label, use of approved drugs (e.g., osimertinib, crizotinib) will require information on patients' mutation status obtained via biopsy.

OBJECTIVE: To evaluate initial diagnostic and post-progression biopsy costs among patients with NSCLC.

METHODS: A retrospective observational study was conducted using the HealthCore Integrated Research Database (2006-2014) and included adult (≥ 18 years) patients with diagnosis of NSCLC. Patients with continuous health plan enrollment ≥ 12 months prior and ≥ 3 months post index date (first observed) of NSCLC diagnosis were included and followed until health plan disenrollment, study end, or death, whichever occurred first. Costs (2015 USD) associated with a diagnostic or post-progression biopsy were calculated for the day of the biopsy procedure and 7 and 30 days post biopsy procedure. Costs were further stratified by patients with and without biopsy-related complications (e.g., pneumothorax) on or within 30 days of the biopsy procedure. All analyses were descriptive in nature.

RESULTS: Study included 13,718 NSCLC patients (median age: 69 years; female: 50%; health plan PPO: 73%; Midwest region: 35%) with ≥ 1 complication versus those without a complication, the average diagnostic and post-progression biopsy costs were higher on the day of biopsy ($12,030 vs. $6,508), 7 ($13,657 vs. $7,765), and 30 days ($24,968 vs. $12,030 vs. $6,508).
Predictors of Guideline-Recommended Initiation of First-Line Systemic Therapy for Patients with Metastatic Non-Small Cell Lung Cancer

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BACKGROUND: Previous studies of guideline adherent treatment for non-small cell lung cancer (NSCLC) have either lacked performance status (PS) or are limited geographically. This study advances our understanding of factors associated with adherence to guidelines at initiation of therapy by using a national, mostly Medicare population and includes a validated claims-based algorithm to predict PS.

OBJECTIVE: To determine factors associated with guideline recommended initiators (GRI) in a metastatic non-small cell lung cancer (mNSCLC) cohort.

METHODS: mNSCLC patients were identified from Humana claims and treatment authorizations for infusion therapy initiated in 2013-2014. PS was approximated using a claims-based algorithm from procedures, diagnoses and durable medical equipment codes. PS ranges from 0-4 (higher values indicate more functional limitations), and was defined as high (3-4), medium (2) and low (0, 1). GRI had >1 cycle from 0-4 (higher values indicate more functional limitations), and was associated with a 6.2% (0.938 (0.918-0.957), P=0.0277) lower risk of death. Baseline demographic and clinical features, including age, sex, cancer type, and prior therapies were described for all GRI initiators. Patients with at least 6-months of continuous plan enrollment prior to index date were included to assess indications of PD1 use. Only fully insured patients were included in analyses of post-index utilization and outcomes. Patients were followed-up until the earlier of death, disenrollment, or discontinuation, which was defined as a gap in therapy of the index drug by at least 45 days without evidence of death or disenrollment during this 45-day window.

RESULTS: A total of 1,133 patients started therapy with a PD1 agent through 3/31/16; 135 (12%) started pembrolizumab and 998 (88%) started nivolumab. The number of patients starting therapy with PD1s has increased every quarter; 33% of all PD1 initiators were in Q2 2015, the most recent full quarter analyzed. Males comprised 61% of PD1 initiators, mean (SD) age was 69 (10) years. 14% of patients initiated therapy prior to 1/1/16 have discontinued. The percent of patients with a claim for melanoma, lung, or kidney cancer in the 6-month pre-index period prior to starting nivolumab was 13%, 82%, and 10%, respectively. The percent of patients with a claim for melanoma or lung cancer in the 6-month pre-index period prior to starting pembrolizumab was 87% and 24%, respectively. Evidence of metastasis prior to starting a PD1 was seen in 84% of patients.

CONCLUSIONS: Uptake of PD1s increased quarterly. The two PD1s appear to be used differently for the treatment of melanoma and lung cancer with pembrolizumab more commonly used for the treatment of melanoma, and nivolumab more frequently used for the treatment of lung cancer. This pattern of use is most likely due to differences in FDA-labeling between pembrolizumab and nivolumab regarding PD-L1 expression testing for lung cancer. Continued review of prescribing trends is essential to ensure proper use of PD1s.

SPONSORSHIP: Humana.
C15 Initiation of Guideline-Recommended First-Line Systemic Therapy and Clinical Outcomes for Patients with Metastatic Non-Small Cell Lung Cancer

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1Comprehensive Health Insights; 2Genentech

BACKGROUND: Guideline-recommended initiation of therapy (GRI) has been advocated to encourage consensus evidence-based treatment. Previous studies considered the impact of guideline adherence treatment on survival in metastatic non-small cell lung cancer (mNSCLC) patients. There is a gap in information regarding GRI influence on other outcomes.

OBJECTIVE: To determine the impact of GRI for mNSCLC patients on outcomes, including hospice initiation, survival, and hospitalization or infusion 30 days prior to death.

METHODS: mNSCLC patients were identified from Humana medical claims and treatment authorizations for infusion therapy in 2013-2014. Performance status (PS) was approximated using an algorithm based on procedure, diagnosis and durable medical equipment codes. GRI was defined as a claim for >1 cycle of a National Comprehensive Cancer Network recommended therapy based on age and predicted PS for systemic therapy and targeted therapy regardless of age and PS. The index date was the date of the first infusion. Mortality outcomes were restricted to Medicare patients. End-of-life care quality indicators (EOLC) for Medicare patients included hospital admission and oncology infusions 30 days prior to death. A Cox proportional hazards model, adjusted for age, gender, comorbidity burden and treatment regimen characteristics, assessed the impact of GRI on mortality. Results were reported as hazard ratios.

RESULTS: Of 1,458 patients, 347 (23.8%) received non-GRI therapy at initiation. Non-GRI patients were older (71.9 ± 7.4 vs. 70.0 ± 7.5 years, \(P < 0.0001\)), more often dually eligible for Medicare/Medicaid (23.1% vs. 10.5%, \(P < 0.0001\)), and had a Part D low-income subsidy (30.3% vs. 16.7%, \(P < 0.0001\)). Among the 46.6% of the patients who died ≤12 months post-index, a greater percentage were non-GRI (55.0% vs. 43.9%, \(P = 0.0005\)). There was no difference in hospice use within 12 months of index by GRI. In risk-adjusted models, PS, but not GRI was predictive of mortality. Compared to PS = 0.1, patients with a PS = 3.4 had a 1.5 times greater hazard of death (\(P = 0.005\)). Overall, 54.0% of patients were hospitalized and 23.6% had an oncology-related infusion ≤30 days of death, with no differences by GRI.

CONCLUSIONS: Differences observed in mortality by GRI were no longer present in risk adjusted models among patients with mNSCLC. A PS indicative of greater functional limitations was associated with mortality. No differences were found in hospice use or EOLC by GRI. Future studies should examine how adherence to guideline recommended treatment, beyond initiation, influences patient outcomes.

SPONSORSHIP: This project was sponsored by Genentech.
of validity (agreement, positive predictive value (PPV), negative predictive value (NPV), sensitivity, and specificity) were used to compare clinical information between data sources. Observations without available data for a given data point were excluded from the analysis for which data was missing.

RESULTS: All 300 BC records reviewed were confirmed BC, while 197 of the LC records and 197 of the CRC records were confirmed (PPV = 0.99 for each). The agreement of disease stage was 85% for BC, 90% for LC, and 94% for CRC. The agreement of LC histology (small cell vs. non-small cell) was 97%. Agreement of progesterone receptor, estrogen receptor, and HER2 status in BC was 92%, 97%, and 92%, respectively. EGFR and ALK agreement in LC was 97% and 92%, respectively; and agreement of KRAS status in CRC was 98%. Measures of PPV, NPV, sensitivity and specificity showed similarly strong evidence of validity.

CONCLUSIONS: The high agreement between the HIRe- oncology data and medical records support the validity of these data for research. Currently ongoing and future research will utilize the data obtained from the CCQP, which can enhance claims-based studies by providing real-world clinical data that is not otherwise available to researchers on a national level.

SPONSORSHIP: This research was sponsored by HealthCore.

C21 Prevention of Stomatitis Using a Dexamethasone-Based Mouthwash in Postmenopausal Women with Hormone Receptor-Positive Metastatic Breast Cancer Treated with Everolimus + Exemestane: SWISH Trial

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BACKGROUND: Stomatitis is one of the most common adverse events (AEs) associated with mTOR inhibitors in BOLERO-2, patients receiving everolimus + exemestane (EVE + EXE) reported all grade (Gr) stomatitis of 67%; 33% had Gr ≥ 2 and 8% Gr 3. The median time to ≥ Gr 2 onset was 15.5 days, the incidence of new stomatitis (Gr ≥ 2) plateaued at 6 weeks. In a meta-analysis, 89% of first stomatitis events occurred within 8 weeks. Topical steroids are used to treat aphthous ulcers; anecdotal use as prophylaxis has been reported. AEs may have a negative impact on treatment adherence and clinical outcomes. Interventions that may prevent AEs therefore are highly relevant.

OBJECTIVE: To evaluate prophylactic use of dexamethasone (DEX) mouthwash (MW) in preventing stomatitis in postmenopausal (PM) women with hormone receptor-positive (HR+) metastatic breast cancer (MBC) receiving EVE + EXE.

METHODS: Eligible patients with HR+ MBC were prescribed with EVE 10 mg + EXE 25 mg QD and 10 mL of commercially available alcohol-free DEX 0.5 mg/5 mL oral solution to swish × 2 min, and spit QID for 8 weeks, starting day 1. Patients completed a daily adherence log, including an oral pain (range 0-10) and normalcy of diet score. The primary endpoint was to compare the incidence of Gr ≥ 2 stomatitis at 8 weeks with BOLERO-2 results. Secondary endpoints were MW use by average times/day, EVE + EXE dose intensity, incidence of all Gr stomatitis and time to resolution to Gr ≤ 1.

RESULTS: Of 92 patients enrolled, 86 were evaluable for efficacy. Median age was 61 years (range 34-87). >35% were treated with EVE + EXE in the 2nd/later-line setting. Median dose intensity was 10 mg (range 3-10) for EVE and 25 mg (range 8-25) for EXE. 95% of patients used the MW 3-4 times/day (median MW use/day = 3.95, range 1.9-4). The incidence of Gr ≥ 2 stomatitis at 8 weeks was 2.4% (2 patients) vs. 33% in BOLERO-2. The incidence of all-grade stomatitis at 8 weeks was 21.2% (n = 18) vs. 67% in BOLERO-2. The rate of Gr 1 stomatitis was 18.8%. Of 75 patients with complete ECOG scores, 88% maintained/improved ECOG status. Mean pain scale score was <1 at all visits; 88% of patients reported a normal diet at 8 weeks. 13% discontinued EVE + EXE due to treatment-related AEs (most common: rash [2%], hyperglycemia [2%], stomatitis [2%] and pneumonitis [1%]).

CONCLUSIONS: Prophylactic use of 0.5 mg/5 mL DEX oral solution markedly decreased the incidence and severity of stomatitis in patients receiving EVE + EXE for MBC and should be considered a new standard of oral care in this setting.

SPONSORSHIP: This study was sponsored by Novartis (NCT02069093).

C22 Healthcare Costs Among Metastatic Breast Cancer Patients Initiating Nab-Paclitaxel or Eribulin as a Second-Line Chemotherapy

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BACKGROUND: The goals of treatment for patients with metastatic breast cancer (MBC) are to prolong patient survival and minimize cancer-related disease symptoms. Limited data are available on the comparative effectiveness of nanoparticle albumin-bound paclitaxel (nab-P) vs. eribulin for second-line (2L) treatment of MBC in a real-world setting.

OBJECTIVE: To compare total cost of care in patients with MBC treated with 2L chemotherapy including nab-P or eribulin in a large insured U.S. population.

METHODS: This retrospective cohort study selected adult women from the Truven Health MarketScan Research Databases (commercial and Medicare insurance) with ≥ 1 medical claim for secondary malignant neoplasm diagnoses, ≥ 2 medical claims with a breast cancer diagnosis, and who initiated nab-paclitaxel or eribulin as a 2L chemotherapy during January 1, 2010 and January 31, 2015. Patients were required to be continuously enrolled in their health plans for ≥ 12 months prior to and 6 months following the initiation of 2L treatment. A generalized linear model (GLM) with gamma distribution to control for baseline clinical characteristics and adjunctive treatment was used to compare total healthcare costs and MBC-related treatment costs for nab-paclitaxel and eribulin patients per patient per month during 2L.

RESULTS: There were 479 eligible MBC patients that met selection criteria of which 324 initiated 2L treated with nab-paclitaxel (mean ± standard deviation [SD] age 59.0 ± 10.9) and 155 with eribulin (mean ± SD age 58.5 ± 10.1). The total all-cause unadjusted healthcare costs in the nab-paclitaxel cohort had a mean of $23,081 (SD $44,613) compared with $26,229 (SD $49,073) for the eribulin cohort. The lower unadjusted total healthcare costs for nab-paclitaxel were driven primarily by lower outpatient office visits costs (mean ± SD $411 ± $659 vs. $606 ± $2,960), outpatient pharmacy costs (mean ± SD $570 ± $1,689 vs. $778 ± $1,810), MBC treatment standard care costs (mean ± SD $9,921 ± $12,116 vs. $10,949 ± $22,489) and MBC supportive care costs (mean ± SD $3,693 ± $5,306 vs. $4,005 ± $6,284).
Consistent with unadjusted results the nab-paclitaxel cohort incurred lower costs (versus eribulin) for both total all-cause and MBC treatment (standard care and supportive care) following adjustment for baseline covariates, although this difference was not statistically significant ($P = 0.98$ and $P = 0.50$, respectively).

**CONCLUSIONS:** The results from this analysis suggest that the per patient per month total cost of care is similar between patients receiving 2L nab-Paclitaxel and 2L eribulin for the treatment of metastatic breast cancer.

**SPONSORSHIP:** Celgene Corporation.

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**C26 A Cost-Effectiveness Analysis of Enzalutamide Versus Abiraterone Acetate Plus Prednisone for the Treatment of Metastatic Castration-Resistant Prostate Cancer: A U.S. Perspective**

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**BACKGROUND:** Enzalutamide (ENZA) and abiraterone acetate plus prednisone (ABI) are oral treatments for patients with metastatic castration-resistant prostate cancer (mCRPC). Despite its low prevalence, mCRPC carries a high economic burden, and therefore the ability to assess the cost-effectiveness of oral oncolytics to treat mCRPC is an important benchmark. In 2016, after evaluating a global cost-effectiveness model, the UK’s National Institute for Health and Care Excellence issued the following guidance: “Enzalutamide is recommended, within its marketing authorisation, as an option for treating metastatic hormone-relapsed prostate cancer in people who have no or mild symptoms after androgen deprivation therapy has failed, before chemotherapy is indicated, and only when the company provides it with the discount agreed in the patient access scheme.” Therefore, the global economic model was adapted to the U.S. setting.

**OBJECTIVE:** To evaluate the cost-effectiveness of ENZA versus ABI for chemotherapy-naive patients with mCRPC in the U.S. setting.

**METHODS:** The model was developed utilizing a Markov approach with 3 health states to execute a cost-utility analysis. Clinical safety and efficacy inputs were obtained from the pivotal clinical trials PREVAIL (ENZA) and COU-AA-302 (ABI). However, because of the absence of a common comparator arm, a naïve comparison of progression and survival curves was performed. All model inputs, including treatment sequences, health-resource utilization, and clinical practice patterns, were adapted to the U.S. setting. Costs were obtained from the Red Book, Centers for Medicare and Medicaid Services physician and clinical laboratory fee schedules, and Healthcare Cost and Utilization Project (HCUPnet), and were supplemented with the scientific, peer-reviewed literature.

**RESULTS:** The total lifetime costs for the ENZA and ABI arms were $287,638 and $274,430, total quality-adjusted life-years (QALYs) were 2.275 and 2.169. The incremental cost-effectiveness ratio was estimated to be $119,580 per QALY. Probabilistic sensitivity analysis revealed that ENZA was cost effective in $61% of cases at the willingness-to-pay threshold of $150,000.

**CONCLUSIONS:** From a U.S. perspective, ENZA is a cost-effective option for the treatment of chemotherapy-naive patients with mCRPC, a result consistent with the 2016 NICE appraisal.

**SPONSORSHIP:** Sponsored by Medivation and Astellas Pharma.
METHODS: A cross-sectional study was conducted using healthcare claims from the Truven Health MarketScan Research Databases. Study population included adult patients with ≥1 claim for AA, ENZ, or DOC between 09/01/2012 and 07/31/2014 (date of first claim served as index date), with ≥1 prostate cancer (PC) diagnosis, and no claim for the treatment of interest during the 6-month baseline period. Use of co-administration medications (i.e., glucocorticoids [GCs]) and potential DDIs with any of the three mCRPC treatments prior to the initiation of AA, ENZ, or DOC. Specifically, during the baseline period, 22 (0.7%), 583 (17.3%), and 242 (7.2%) patients received medications with potential DDIs with AA, ENZ, and DOC, respectively. A total of 187 (5.6%) patients were eventually initiated on an mCRPC treatment for which the use of medications with potential DDIs to that treatment were found in the baseline period, including 13, 135, and 39 patients initiated on AA, ENZ and DOC, respectively.

RESULTS: Of the total 3,367 eligible PC patients, 2,050 (61%), 668 (20%), and 649 (19%) were initiated on AA, ENZ, and DOC, respectively. Mean age of the overall population was 72.8 years and mean Charlson Comorbidity Index was 2.7. Approximately 74% of overall population used GCs and 23% received medications with potential DDIs at baseline, suggesting a need for greater awareness of the potential for DDIs when prescribing mCRPC medications. It should be noted that AA is approved for use in combination with prednisone for the treatment of mCRPC. The data provided for the current study is limited to only AA.

CONCLUSIONS: GC use was common before initiation of AA, ENZ or DOC. About a fifth of patients initiated on AA, ENZ or DOC used medications with potential DDIs at baseline, suggesting a need for greater awareness of the potential for DDIs when prescribing mCRPC medications. It should be noted that AA is approved for use in combination with prednisone for the treatment of mCRPC. The data provided for the current study is limited to only AA.

SPONSORSHIP: Supported by Janssen Scientific Affairs.
and, docetaxel (22.1%; 32.1%; 42.6%; 48.6%). The two-year survival rate was 57.1% (25th percentile: 250 days, 50th percentile: 541 days) and the average monthly total healthcare costs were $10,379 in Medicare and $14,025 in commercial patients.

CONCLUSIONS: Majority of treated patients (57.6%) had at least two separate LOT and almost half (49.3%) are treated with combination of agents. A majority of treated patients (57.1%) survived 2 years after the start of treatment.

SPONSORSHIP: Funded by Bayer Healthcare Pharmaceuticals.

C31 Treatment Patterns and Costs Associated with Axitinib and Everolimus as Subsequent Treatment for Renal Cell Carcinoma in the United States

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BACKGROUND: Real-world data may inform treatment decisions for metastatic renal cell carcinoma (mRCC).

OBJECTIVE: To compare treatment patterns and healthcare costs for mRCC patients initiating axitinib or everolimus as 2nd-line (2L) or later (3L+) therapy.

METHODS: This retrospective cohort study used Truven Health Marketscan Commercial and Medicare Supplemental (including coordination of benefits) claims databases to identify patients age ≥ 20 years with mRCC newly initiating (index) axitinib or everolimus between 5/1/2012-12/31/2014. Patients had continuous enrollment ≥12 months before and ≥6 months post-index and ≥1 prior line of mRCC therapy using all available claims history. We compared demographics, clinical characteristics and treatment patterns using chi-square, Student t-test, and log-rank test (α=0.05). Overall and daily index medication (while persistent) costs during 180 days post-index were compared using generalized linear modeling to adjust for demographic, clinical, and treatment variables.

RESULTS: Among 408 patients (199 receiving axitinib), cohorts were not significantly (NS) different in demographics or Charlson Comorbidity Index score. Axitinib patients had higher mean [SD] days from earliest RCC diagnosis observed to index (745 [358] vs. 663 [354], P<0.0205) and from earliest metastatic diagnosis observed to index (605 [351] vs. 513 [313], P=0.0055), and higher mean [SD] prior lines of therapy (1.50 [0.79] vs. 1.18 [0.45], P<0.0001). More axitinib patients were persistent (49.8% vs. 36.8%, P<0.01), and fewer switched (21.1% vs. 36.4%, P<0.001) over six months. Median persistence (days) was longer for axitinib compared to everolimus (157 vs. 112, P<0.01). Adjusted mean (95% CI) RCC-related costs ($72,401 [$61,091-$85,805] vs. $67,792 [$56,233-$81,727], P=0.3049), all-cause total costs ($82,538 [$68,897-$98,879] vs. $81,187 [$66,498-$99,122], P=0.8113) and daily index medication costs ($319 [$282-$362] vs. $306 [$268-$351]) were NS different for axitinib and everolimus, respectively. All-cause and RCC-related costs models included interaction terms of treatment group by age category and by line of therapy which were NS indicating consistency of response across age category and line of therapy.

CONCLUSIONS: Although axitinib patients had more time from diagnosis to index and more prior lines of therapy, more axitinib patients were persistent over 6 months and treatment persistence was longer. Adjusted overall and daily index medication costs were NS different between treatment groups.

SPONSORSHIP: Pfizer.

C32 Budget Impact of Everolimus for the Treatment of Well-Differentiated, Nonfunctional Neuroendocrine Tumors of Gastrointestinal or Lung Origin That Are Advanced or Metastatic

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BACKGROUND: Advanced neuroendocrine tumors (NETs) are a rare malignancy, with considerable unmet need for effective therapies. Afinitor (everolimus) is an mTOR inhibitor approved by both FDA and EMA in 2016 for treatment of adults with progressive, well-differentiated, non-functional NETs of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic.

OBJECTIVE: To assess 3-year budget impact for a typical U.S. health plan following availability of everolimus for treatment of GI and lung NETs.

METHODS: An Excel model was developed to calculate expected costs associated with introduction of everolimus for treatment of lung and GI NETs (pancreatic NET not included). Two scenarios considered costs with or without everolimus from the pharmacy perspective or that of the entire health plan (including costs for hospitalizations, physician visits, monitoring, and adverse events [AE]). As there are very few FDA-approved agents in this disease area (only Afinitor is FDA-approved in lung NET, and only Afinitor and Somatuline are FDA-approved in GI NET), this model includes treatment classes based on NCCN guidelines. Guideline-recommended drug therapies for GI NETs included somatostatin analogues (SSA) and cytotoxic chemotherapy, while drug therapies for lung NETs included these agents and a targeted therapy. Drug costs were estimated based on mean daily doses and wholesale acquisition cost. AE rates and costs are based on product labels and published literature.

RESULTS: In a U.S. health plan with 1 million members, the model estimates that 66 patients with GI NETs and 20 with lung NETs are treated each year. The total estimated budget impact for GI NETs is $0.0568 per member per month (PMPM) in the first year after FDA approval, $0.1005 in the second year, and $0.1443 in the third. The estimated pharmacy budget impact for GI NETs is $0.0606, $0.1072, $0.1538 PMPM in the first, second, and third year, respectively. The total estimated budget impact for lung NETs is $0.0181 PMPM in the first year, $0.0253 in the second, and $0.0355 in the third. The estimated pharmacy budget impact for lung NETs is $0.0204, $0.0285, and $0.0396 in the first, second, and third year, respectively. Total budget impact was shown to be lower than pharmacy budget impact because it includes cost offsets from administration and AE management for Afinitor compared with alternative therapies (e.g., chemotherapy, etc.).

CONCLUSIONS: The budget impact for everolimus has been shown to be minimal in this high unmet need disease area, due largely to low prevalence for this rare disease.

SPONSORSHIP: Novartis.

C33 Carcinoid Syndrome: Economic Analysis of Dose Escalation with Somatostatin Analogues

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BACKGROUND: Somatostatin analogues (SSA) are commonly used to treat carcinoid syndrome (CS), but dose escalation is often required.

OBJECTIVE: To identify dose escalation among patients with CS and compare their economic outcomes before and after dose escalation.
METHODS: Using administrative claims, adult commercial and Medicare Advantage health plan enrollees were included if they had 1+ claims with a CS diagnosis code (ICD-9-CM: 259.2x) between 1/1/2007-6/30/2013. Subjects were required to have 60+ claims for octreotide long-acting release (LAR) and to be continuously enrolled for 3+ months before and after dose escalation. SSA dose escalation was defined as the earliest of: (1) the first of 2 octreotide LAR dose amounts beyond label (> 30 mg); (2) the first of 2 octreotide LAR dosing intervals shorter than 22 days apart; or, (3) the last octreotide LAR claim before switching to lanreotide or an infusion pump. Economic outcomes included all-cause and CS-related health care utilization and costs before and after dose escalation. Per-patient-per-month (PPPM) costs were computed to account for variable follow-up.

RESULTS: 358 patients met the inclusion criteria, with mean (SD) age 61 (12) years and 50% female. The mean observation periods before and after dose escalation were 2.2 and 2.3 years, respectively. Mean total PPPM all-cause costs were higher after dose escalation than before ($4,116 vs. $8,305, P < 0.001), and 77% and 86% of costs before and after dose escalation were for CS-related care ($3,156 and $7,101, respectively). Ambulatory care represented the largest proportion of total costs and highest increase from before to after dose escalation for all-cause ($2,601 vs. $5,595, P < 0.001) and CS-related costs ($2,005 vs. $4,869, P < 0.001).

CONCLUSIONS: All-cause health care costs doubled in patients with CS who required octreotide LAR dose escalation, driven by ambulatory visits and mostly attributable to CS-related care. These findings suggest continuing challenges in the management of carcinoid syndrome and complications after dose escalation. Understanding the reasons for dose escalation and finding alternative solutions should be further explored to improve patient outcomes and contain costs.

SPONSORSHIP: This study was sponsored by Lexicon Pharmaceuticals.

A Literature Review of Trends in Incidence of Gastrointestinal and Lung Neuroendocrine Tumors in the United States

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BACKGROUND: Neuroendocrine tumors (NETs) is a rare and diverse group of tumors, predominately develop in digestive and bronchial tracts. Few studies have provided literature reviews on recent epidemiology of lung and gastrointestinal (GI) NETs in the U.S.

OBJECTIVE: To review the literature on the epidemiology of GI and lung NETs.

METHODS: Studies published from 1996 to August 2015 were identified from the MEDLINE, EMBASE, and Cochrane databases. We searched studies in English language only, with three sets of search terms included: disease (4 terms), epidemiology (4 terms), and observational studies (15 terms).

RESULTS: Fourteen studies (3 for both GI and Lung, and 11 for GI only) met inclusion criteria. The SEER database was the most commonly used source among the included studies (12 of 14 studies). Lung NET had an incidence of 13.5 per million persons per year (PMPY) in year 2000-2004, highest among all NET origins. When observed from 1993-1997 to 2000-2004, the incidence increased by 31% and 52% in Whites and Blacks, respectively. Lung NET incidence was higher in Whites than in Blacks (14.2 vs. 12.0, P < 0.001), and seemed higher in older age group (0.06 for 0-29 years old, and 1.35 for mean age 62 years old). GI-NETs accounted for 71% of all NETs, with a prevalence of 216 PMPY in 2009 and an annual percentage change (APC) of 4.4% during 1970-2010. Over the last four decades, incidence of rectal and stomach NETs have increased substantially compared to other GI sites, with respective APC of 7.8% and 7.0%. Based on SEER 9 (2003-2007), the incidence rates (PMPY) of specific GI site tumors are: stomach: 3.3, small intestine: 10.8; colon: 6.0, rectum: 10.5, and appendix: 2.0. Female predominance was observed for stomach, appendix and cecum and male predominance was seen for duodenum, jejunum/ileum and rectum. The highest incidence rate was reported in Blaks for all GI sites except appendix.

CONCLUSIONS: There is very few epidemiology data currently available in literature for lung NET in the U.S. Assessments mostly using SEER data have shown that the incidence of GI and lung NETs appear to vary by age, gender, race, and sites of origin, but both appear to increase greatly in the past few decades. It is unclear if the escalating incidence of GI and Lung NET is due to more new cases, or the existence of advancing diagnosis technology to detect these cases, or increased awareness of NET among clinicians and pathologists. The results summarized in this review warrant health plans to consider carefully how to appropriately manage this increased patient population using clinically effective and safe treatments.

SPONSORSHIP: Novartis Pharmaceutical Corporation.

Real-World Adherence and Its Determinants in Patients with Newly Diagnosed Multiple Myeloma Treated with Oral or Intravenous Regimens

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BACKGROUND: Adherence to newly diagnosed multiple myeloma (ndMM) treatment regimens may impact clinical outcomes. Real-world evidence regarding adherence in ndMM is sparse, and there are no published assessments of adherence to oral compared to intravenous (IV) therapy in this setting.

OBJECTIVE: To assess adherence and its determinants in patients with ndMM treated with regimens containing the oral agent lenalidomide (R) + dexamethasone (d) or the IV agent bortezomib (V) + dexamethasone (d).

METHODS: U.S. claims data from PharMetrics Plus was linked to socioeconomic data and used to identify patients with ≥ 2 MM diagnoses (ICD-9 203.0x) and a claim for Rd or Vd (index date), between 1/1/2009 and 3/31/2014. Regimens were defined as all MM treatment observed within 60 days of index. Non-persistence was defined as a >45-day gap in therapy (prior to any treatment progression). Given the lack of standardization in methods of measuring adherence, three medication possession ratio (MPR) measures of adherence were used: MPR1 = (days’ supply in the patient-specific persistent period)/(days in the same period); MPR2 = (days’ supply in the median persistent period for each regimen)/(days in the same period); MPR3 = (days’ supply in a 12 cycle period prior to treatment progression)/(days in the same period). Each 21-units of dispensed R was assigned a 28-day supply (the label recommended dosing for a 28-day cycle), and each V administration was assumed to have a days’ supply of 5.25 (based on standard clinical dosing of 4 administrations in a 21-day cycle). Multivariate regression models were used to identify determinants of MPR for Rd and Vd separately.

RESULTS: Of 774 identified patients, 419 (54.1%) received Rd, 355 (45.9%) received Vd, mean (SD) age was 61.2 (9.0) years and 56.9% of the sample was male. Mean (SD) MPR1 was 0.94 (0.09) for Rd patients, 0.83 (0.17) for Vd patients (P < 0.0001). The median number of persistent months was 6.4 for Rd patients, 4.0 for Vd patients (P < 0.0001). Mean (SD)
MPR2 during the 6- and 4-month periods for Rd and Vd, respectively, was 0.77 (0.26) for Rd, 0.70 (0.23) for Vd. MPR3 was 0.77 and 0.57 for the 245 and 170 patients remaining on initial Rd and Vd treatment after 12 cycles, respectively. Determinants of MPR varied by regimen type.

CONCLUSIONS: This analysis of adherence measures in ndMM found high adherence to Rd and Vd in the initial persistent period. Patients taking oral therapies seem to be more adherent to treatment recommendations; however, factors affecting adherence to oral and IV therapy were different between these two groups.

SPONSORSHIP: Study funding was provided by Celgene.

C38 Cost-Effectiveness of Pomalidomide, Carfilzomib, and Daratumumab for the Treatment of Patients with Relapsed-Refractory Multiple Myeloma in the United States

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BACKGROUND: Pomalidomide plus low-dose dexamethasone (POM-d), carfilzomib (CARF) monotherapy, and daratumumab (DARA) mono-therapy have been approved by the U.S. FDA for the treatment of patients with relapsed-refractory multiple myeloma (RRMM). The comparative cost-effectiveness of these treatments in heavily treated patients has not been investigated to date.

OBJECTIVE: To evaluate the cost-effectiveness of POM-d vs. CARF and DARA in heavily treated RRMM patients from a U.S. payer perspective.

METHODS: An economic model with 3 health states (progression-free [PF], post-progression [PP], and death), was developed to estimate incremental costs, PF life years (PFLYs), and life years (LYs) between POM-d and its comparators over a 3-year time horizon. Results from a matching-adjusted indirect comparison, which assessed the relative PF survival (PPS) of POM-d vs. CARF (HR=0.833, P=0.24) and vs. DARA (HR=0.945, P=0.75; i.e., both favoring POM-d) by adjusting for differences in baseline patient characteristics between trials, informed the model. All patients received treatment until disease progression, death, premature discontinuation, or 3 years, whichever occurred first. A common PP survival was assumed for all treatment following death, premature discontinuation, or 3 years, whichever occurred first.

RESULTS: Over 3 years, POM-d yielded slightly more LYs than both CARF and DARA (1.43 vs. 1.36 and 1.41, respectively), with most of the difference occurring in the PF state (PFLYs 0.58 vs. 0.48 and 0.55, respectively). Duration of initial-line treatment (DoT) was nearly identical for all treatment (range: 0.47-0.49 years); however, POM-d incurred a slightly lower total cost relative to CARF and DARA ($130,808 vs. $131,025 and $137,830, respectively). Differences in cost were mostly due to higher acquisition and administration costs for CARF and DARA over the DoT. In the equal efficacy scenario, incremental costs for POM-d were $12,619 vs. CARF and -$9,814 vs. DARA per patient. In the PSA, POM-d was cost-effective vs. CARF and DARA at a threshold of $50,000 per LY in 83% and 98% of replicates, respectively.

CONCLUSIONS: POM-d may provide a convenient therapeutic option that is cost-effective relative to CARF and DARA in appropriately selected MM patients.

SPONSORSHIP: Celgene.

C39 Comparison of Treatment Outcomes and Costs in Patients Receiving Lenalidomide or Bortezomib in Newly Diagnosed Multiple Myeloma: A Retrospective Administrative Claims-Based Analysis

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BACKGROUND: First line treatment of MM frequently includes lenalidomide(R) and/or bortezomib(V) based regimens. Real-world evidence describing health outcomes and costs in newly diagnosed multiple myeloma (ndMM) patients without any evidence of a stem cell transplant is limited.

OBJECTIVE: To evaluate time to next treatment (TTNT), time to treatment discontinuation (TTTD) and associated costs in patients initiating R+ dexamethasone (Rd) or Vd.

METHODS: Patients in the Truven Health MarketScan databases from January 2008-May 2015 (study period) with a claim of Rd or Vd (defined as index date), and ≥ 2 claims of MM diagnosis (ICD-9: 203.0x) 12 months pre and 3 months post-index were included. Patients were continuously enrolled in the health plan for at least 12 months pre- and post-index, with no evidence of MM diagnosis, MM treatment (during pre-index) and stem cell transplant (during entire study period) and had ≥ 1 full cycle of Rd or Vd. Regimens were defined as all MM treatments observed within 60 days of index and Patients were followed to progression or end of database eligibility. TTD was defined as time from treatment initiation to discontinuation with a permitted gap of < 180 days. TTNT, a progression proxy, was defined as addition of a new treatment > 60 days from index, or treatment restart following a > 180 day treatment gap unless the restart was maintenance therapy. TTNT and TTTD were determined using Kaplan-Meir and Cox proportional hazard models. Adjusted differences (Δ) in healthcare costs, measured over 12-month follow up, were calculated from generalized linear regression models.

RESULTS: A total of 1,767 patients met the inclusion criteria (814 Rd, 953 Vd); mean age was 69.2 years. Vd initiators had a higher mean comorbidity burden (CCI: 5.1 vs. 4.3; P<0.001) than Rd at baseline. Median 1st line duration was significantly longer in Rd compared with Vd patients (12.0 vs. 5.9 months; P<0.001). Rd initiators demonstrated significantly longer median TTTD (13.0 vs. 5.9 months, HR = 0.64, P<0.001) compared to Vd. Rd patients had higher 12-month adjusted total healthcare costs (Δ = $14,964; P = 0.001) and pharmacy costs (Δ = $65,419; P<0.001), but significantly lower adjusted outpatient physician (Δ = -$9,434; P<0.001) and MM treatment (IV) & chemotherapy-related visits costs (Δ = -$44,592; P<0.001), compared to Vd.

CONCLUSIONS: Over a 12-month period Rd was associated with slightly higher ($14,964) total healthcare cost. However, Rd demonstrated significantly longer median TTTD (7 months) and significantly longer median TTNT (12.3 months), compared with Vd, suggesting a good value for money with Rd treatment.

SPONSORSHIP: Celgene.

D01 Evaluation of Value-Based Pricing Models for Cancer Drugs in a Clinical Setting

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**BACKGROUND:** Spending on cancer drugs has risen ten-fold and costs are often passed on to patients. Profits at each supply chain level limit the incentives of each decision maker to decrease costs, and patient copays can be unaffordable. Incremental cost-effectiveness ratios (ICER) are the “gold standard” for assigning comparative value to drugs but require time and expertise. Organizations are developing shorter value frameworks, but there is no universal guideline for selecting and using these frameworks.

**OBJECTIVE:** To (a) determine availability of cost-effectiveness study ICERs for 11 new cancer medications; (b) evaluate the utility of value frameworks to a managed care setting; and (c) construct a decision model of supply chain movement incorporating value, cost-effectiveness, and patient-centeredness.

**METHODS:** The Medication Outcomes Center (MOC) at UCSF is evaluating value based frameworks to assess the value of cancer drugs and help facilitate patient physician decision-making. We performed a literature search to identify all cost-effectiveness studies evaluating MOC’s 11 newest cancer drugs and all cancer value frameworks. Six UCSF clinicians completed the best value frameworks that also had a CEA study to test validity and applicability clinically. Finally, we built a model that incorporates value assessment into the UCSF healthcare system.

**RESULTS:** We reviewed the quality of three frameworks: ASCO’s original and updated framework, NCCN’s Evidence Blocks, and a Memorial Sloan Kettering’s Drug Abacus. ASCO’s framework was the most developed and patient-centered; therefore, it was used in our validity assessment. Scores for evaluation of nivolumab/Ipilimumab combination therapy were compared to either drug recommended, with the greatest variation in toxicity, which ranged from -20 to 20; also, the framework scores did not specify a comparator. The ICER for this study concluded that the combination therapy was more cost effective only against ipilimumab. Ten of 11 cancer drugs had at least one CEA study published, showing good availability. We suggested formation of a high-cost oncology subcommittee to begin collecting value-based data and assessing patterns.

**CONCLUSIONS:** Although the ASCO framework was the best framework for clinical use, it does not provide reliable scores across clinicians and needs more guidelines based on assessment of scoring patterns across drugs. ICER scores are available as an accurate value framework and can be a validity check on shorter frameworks. System-wide changes to the hospital infrastructure must be implemented to incorporate value.

**SPONSORSHIP:** None.

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**D06 Value Frameworks for the Patient-Provider Interaction: A Comparison of the ASCO Value Framework Versus NCCN Evidence Blocks in Determining Value in Oncology**

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**BACKGROUND:** To address the rising concern about oncology drug costs, the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have recently developed tools to help providers and patients make informed decisions about the value of an oncology regimen. Currently, there is a gap in the literature discussing a head-to-head review of ASCO versus NCCN frameworks when comparing oncology regimens.

**OBJECTIVE:** To compare the characteristics of ASCO versus NCCN frameworks by applying each tool to the same clinical scenarios.

**METHODS:** ASCO’s Value Framework (AVF) allows users to generate a net health benefit (NHB) score along with drug acquisition costs for two regimens that have been compared in a prospective randomized clinical trial. The AVF generates scores for clinical benefit, toxicity, and bonus points that range from zero to 180. In contrast, the NCCN Evidence Blocks (NEB) visually depict consensus values from an expert panel in a 5 × 5 matrix representing treatment efficacy, safety, quality and consistency of evidence, and affordability. Scores for NEB range from 1-5, with 1 as the least favorable and 5 as the most favorable based on clinical trials from guidelines and expert panel assessment. We used two regimens as examples for comparing the AVF and NEB scores: enzalutamide for treatment of metastatic castration-resistant prostate cancer (MCRPC) as well as nivolumab vs. docetaxel in treatment of advanced non-squamous non-small-cell lung cancer (NSCLC).
RESULTS: The AVF for enzalutamide generated a total NHB score of 70.8 (high score; range 0-180) with a monthly cost of $8,494.91, while the NEB scored it a 4 (very effective) for efficacy, 4 (occasionally toxic) for safety, and 2 (expensive) for affordability in the non-visceral metastases block and a score of 3 (moderately effective) for efficacy, 4 for safety, and 2 for affordability in the visceral metastases block. Nivolumab scored a 3.4 (medium score) out of 180 with a monthly cost of $7,009.86 in AVF and was given a score of 4 for efficacy and safety and 1 (very expensive) for affordability in NEB.

CONCLUSIONS: Both AVF and NEB are novel tools that present oncology treatment values differently. An understanding of the characteristics and methodology of each tool is necessary for users to make a value decision on a given anticancer regimen.

SPONSORSHIP: None.

D07 Anemia Prevalence and Treatment Rates in Stage 3-5 Nondialysis-Dependent Chronic Kidney Disease Patients

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BACKGROUND: Nondialysis-dependent chronic kidney disease (NDD-CKD) patients are at risk of anemia. Little is known about contemporary prevalence of anemia and its treatment patterns in this population.

OBJECTIVE: To estimate anemia prevalence and characterize anemia treatment using the Truven Marketscan database.

METHODS: We used the MarketScan database, containing inpatient and outpatient health care claims, and medications, to identify stage 3-5 NDD-CPK patients aged 18-64 years. We defined comorbidities and anemia by diagnosis codes, and characterized anemia treatment patterns from October 1, 2011 to September 30, 2012.

RESULTS: A total of 56,188 stage 3-5 NDD-CPK patients were identified. Anemia prevalence was 28.0% and increased by CKD stage (22.4% in stage 3, 41.3% in stage 4, and 53.9% in stage 5). Anemia increased by age and was significantly higher in women across all ages and CKD stages. Anemia prevalence was highest among patients with a diagnosis of liver disease (52.2%) and congestive heart failure (47.9%) during the study period. Treatment with any use of erythropoiesis-stimulating agents (ESAs), transfusions, and intravenous (IV) iron were generally low, and varied by CKD stage and age. Among NDD-CPK patients at stages 3, 4, and 5 with a diagnosis of anemia, 3.9%, 11.4%, and 13.5% received treatment with ESAs, respectively. Transfusion rates also increased by stage: 5.2%, 5.9%, and 7.1%, respectively. IV iron was used less often, ranging from 3.2%–6.4%. A smaller percentage of patients received more than one anemia treatment modality.

CONCLUSIONS: Anemia prevalence increased by CKD stage and age, and women were more likely to be anemic. Anemia treatment rates were generally low.

SPONSORSHIP: AstraZeneca.

D08 Anemia Is Associated with Higher Healthcare Utilization and Costs in Nondialysis-Dependent Chronic Kidney Disease Patients

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BACKGROUND: Anemia is common among patients with chronic kidney disease (CKD). Information on the current prevalence of anemia and the burden on healthcare utilization (HCU) and costs in stage 3-5 nondialysis-dependent (NDD)-CKD patients is in need of updating.

OBJECTIVE: To examine prevalence of anemia and associated HCU and costs in stage 3-5 NDD-CKD patients.

METHODS: The study population consisted of stage 3-5 NDD-CKD patients aged <65 years using 2011-2013 MarketScan data. A 1-year baseline period was used to define CKD, anemia, and comorbidities from diagnosis codes. A 1-year follow-up period was used to define HCU and costs. HCU was collected for patient visits to inpatient hospital, emergency department (ED), outpatient, and physician/specialist visits, respectively. Unadjusted HCU was calculated by dividing the total number of claims during follow-up by total follow-up years and expressed as total number of claims per patient-year (PPY). All-cause healthcare costs included payment for hospital inpatient services, outpatient services, physician, and outpatient medication. Unadjusted cost was calculated by dividing the total payments during follow-up by total follow-up years and expressed as SPY.

RESULTS: A total of 56,188 stage 3-5 NDD-CKD patients were identified, and 28% (n = 15,716) had anemia. Claims with HCU were more frequent among patients with anemia compared with those without anemia (0.6 vs. 0.3 PPY for inpatient visits, 0.6 vs. 0.3 PPY for emergency department visits, and 32.0 vs. 20.6 PPY for outpatient visits). Numbers of physician/specialty visits were higher for patients with anemia than for patients without anemia: 1.6 times higher for nephrologists, 1.4 for cardiologists, 4.0 for hematologists, 1.2 for endocrinologists, and 1.3 for primary care physicians. Total cost (including medication) for patients with anemia was 2.2 times higher ($38,096 PPY for patients with anemia vs. $17,739 PPY for patients without anemia); inpatient cost was 2.8 times higher ($15,704 PPY for patients with anemia vs. $5,602 PPY for patients without anemia).

CONCLUSIONS: Stage 3-5 NDD-CKD patients with anemia use more healthcare resources, and therefore, these patients incur more costs compared with NDD-CKD patients without anemia. Further investigation evaluating adjusted association of CKD anemia with HCU and costs will be conducted.

SPONSORSHIP: AstraZeneca.

D09 Anemia Prevalence and Treatment Patterns in Nondialysis-Dependent Chronic Kidney Disease Patients Before and After Revised FDA Label and Anemia Guidelines for Erythropoiesis-Stimulating Agents

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BACKGROUND: In June 2011, the U.S. Food and Drug Administration (FDA) added additional boxed warnings to erythropoiesis-stimulating agent (ESA) labels. In 2012, the Kidney Disease: Improving Global Outcomes (KDIGO) released new anemia treatment guidelines for chronic kidney disease (CKD) patients.

OBJECTIVE: To examine anemia prevalence and treatment patterns before and after the boxed warnings in stage 3-5 nondialysis-dependent (NDD)-CKD patients.

METHODS: Stage 3-5 NDD-CKD patients with anemia (defined by diagnosis codes) were identified from commercially insured patients aged 18-63 years in the MarketScan database. Two study cohorts
Results: The 2008 and 2012 cohorts included 6,425 and 15,716 stage 3–5 NDD-CKD patients with anemia, respectively. Anemia prevalence was 29% in 2008 cohort and 28% in 2012 cohort. Compared with ESA treatment rates in 2008, ESA treatment declined by 61% in 2012 (28.4% in 2008 to 10.8% in 2012). IV iron use increased from 7.6% to 9.4%, and RBC transfusions increased from 10.1% to 11.7% in the same timeframe in CKD-NDD patients with anemia. In 2008, 77% of stage 3–5 CKD-NDD patients received consistent ESA treatment, declining to 2.6% in 2012. Median time to treatment initiation from anemia diagnosis nearly tripled for ESAs (8 to 21 days), increased by 10 days for IV iron (34 to 44 days), and decreased by 4 days for RBC transfusions (37 to 33 days).

Conclusions: Anemia prevalence remained stable in 2008 and 2012 cohorts. ESA use decreased by 61% from 2008 to 2012, whereas use of IV iron and RBC transfusion increased by 24% and 16%, respectively. This is the first study to report on the impact of FDA and KDIGO action on anemia treatment patterns in commercially insured stage 3–5 NDD-CKD patients.

Sponsorship: AstraZeneca.

D13 Comparison of Real-World Prophylactic Dosing of Recombinant Coagulation Factor IX to Prescribing Information-Recommended Doses

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Background: Recombinant coagulation Factor IX therapies are used prophylactically among hemophilia B patients to prevent bleeding episodes and joint damage, and to ease the burden of disease. For prophylactic treatment, eftrenonacog alfa (Alprolix) is recommended at a weekly dose of 50 IU/kg or 100 IU/kg every 10 days and nonacog alfa (BeneFIX) is recommended at 40 IU/kg every 3–4 days. However, few studies have examined real-world dosing of these therapies.

Objective: To examine real-world prophylactic dosing of nonacog alfa and eftrenonacog alfa as compared to prescribing information (PI)-recommended doses.

Methods: A retrospective study was conducted using data on prescriptions shipped to patients from specialty pharmaceutical and service providers from 1/2012-3/2016. Patients aged ≥3 years with non-missing weight data who received ≥2 prophylactic shipments of eftrenonacog alfa or nonacog alfa (but not both or any other Factor IX infusion) were included. Daily doses were calculated for the first period of continuous use (until a gap in shipment >60 days) by summing total volume shipped (IU) and dividing by duration of therapy and patient weight (kg). Daily doses were aggregated into weekly doses. Median (interquartile range [IQR]) dose was compared to PI-recommended doses using the non-parametric sign test to account for non-normality of data. The cumulative distribution function of annual consumption (weekly dose multiplied by 52) was plotted. A sensitivity analysis removed the highest 2% of weekly dose values to assess the robustness of results to outliers.

Results: Median (IQR) weekly doses for eftrenonacog alfa (N=61) and nonacog alfa (N=234) were 70.4 IU/kg (50.9, 109.7) and 141.3 IU/kg (93.8, 207.0), respectively. Mean ± standard deviation weekly doses were 85.2 ± 48.8 IU/kg for eftrenonacog alfa and 167.4 ± 119.7 IU/kg for nonacog alfa. The median weekly eftrenonacog alfa dose was higher and significantly different than the PI-recommended lower dose (50 IU/kg), and for nonacog alfa was higher and significantly different than both upper and lower PI-recommended doses (all P<0.001). Approximately 77% of eftrenonacog alfa and 86% of nonacog alfa patients were dosed above the lower weekly recommended levels. Results were robust to the exclusion of outliers.
CONCLUSIONS: Real-world prophylaxis dosing for eftrenonacog alfa and nonacog alfa, the most common recombinant factor IX therapies, are greater than PI-recommended doses, indicating that actual treatment costs to payers and patients may be higher than expected costs based on PI.

SPONSORSHIP: Supported by CSL Behring.

D14 Healthcare Costs Among Treated Patients with Hemophilia A in the United States
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BACKGROUND: There is limited information in recent literature examining healthcare costs for patients with hemophilia A with inhibitors treated with bypassing therapy in the United States (U.S.).

OBJECTIVE: To assess costs for patients treated with bypassing agents versus patients treated only with factor VIII (FVIII) replacement in a real-world setting.

METHODS: This retrospective analysis used claims data from a large U.S. health plan to identify treated patients with hemophilia A. Inclusion required ≥1 medical claim with a diagnosis code for hemophilia A (ICD-9-CM 286.0) and ≥1 medical or pharmacy claim for bypassing therapy and/or FVIII replacement during 01/01/2007-08/31/2014. The bypassing therapy cohort comprised patients with ≥1 claim for bypassing therapy; all others were assigned to the FVIII replacement cohort. The index date was the first claim for therapy. Patients with ≥1 claim for bypassing therapy during baseline (12 months pre-index) or any time post-index date were excluded from the FVIII replacement cohort. At least 30 days post-index date (including index date) were required. Post-index hemophilia-related costs were computed as the sum of all medical claims with hemophilia A diagnosis code or hemophilia therapy procedure code (bypassing therapy, FVIII replacement therapy, desmopressin, antifibrinolytic therapy) plus outpatient pharmacy costs for hemophilia therapy on a per-patient-per-month (PPPM) basis. Cost differences between cohorts were assessed by independent sample t-tests.

RESULTS: The study sample represented 589 patients: 50 (8.5%) in the bypassing therapy cohort (mean age: 38.5 years; mean post-index period: 2.1 years) and 539 (91.5%) in the FVIII replacement cohort (mean age: 29.4 years; mean post-index period: 2.7 years). Compared with the FVIII replacement cohort, mean total PPPM hemophilia-related costs were 4.8-fold greater in the bypassing therapy cohort ($77,575 vs. $11,993, P<0.001), representing 4.4-fold higher medical costs ($53,911 vs. $10,471, P<0.001) and 7.8-fold higher outpatient pharmacy costs ($11,846 vs. $1,521, P<0.022).

CONCLUSIONS: Patients with hemophilia A treated with bypassing agents incur considerably higher hemophilia-related medical and pharmacy costs than patients treated only with FVIII replacement.

SPONSORSHIP: Study funding was provided by Genentech.

D18 Budget Impact Analysis of Ibrutinib for Patients with First-Line Chronic Lymphocytic Leukemia
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BACKGROUND: In the U.S. in 2016, there will be an estimated 18,960 incident cases and 4,660 deaths due to chronic lymphocytic leukemia (CLL). As new targeted therapies have recently been approved in CLL and the treatment armamentarium has expanded, payers are interested in the potential budget impact of these therapies. Ibrutinib received FDA approval in March 2016 for first-line treatment of CLL based on data from the Phase 3 RESONATE-2 study.

OBJECTIVE: To examine the estimated budget impact of ibrutinib in a hypothetical 1-million member U.S. health plan over 1 year for first-line CLL.

METHODS: An Excel-based budget impact model was developed. Comparators included FDA-approved and Category 2A or higher NCCN-recommended regimens for first-line CLL. Dosing, administration, mean duration of therapy (DOT), and adverse event (AE) rates were assessed.

CONCLUSIONS: In a hemophilia population, outpatient costs exceeded inpatient costs in a commercially insured population while inpatient costs outweighed outpatient costs in the Medicaid population. Different opportunities may exist to improve hemophilia care and the associated costs depending on the type of payer.

SPONSORSHIP: Funded by Biogen.
were based on package inserts for approved drugs and published literature for NCCN-recommended regimens. Drug and administration costs were based on Red Book and CMS Physician Fee Schedule, respectively. Adverse event costs were based on AHRQ H-CUP data and published literature. The estimated treatment-eligible population was based on epidemiologic data and a Truven claims database analysis. The market share was estimated for each treatment in scenarios with and without utilization of ibritinib. The incremental per-treated-member-per-month (PTMPM) cost and incremental per-member-per-month (PMPM) cost were calculated. One-way sensitivity analysis was performed.

**RESULTS:** The model estimated a treatment-eligible population of 23 first-line CLL patients for a 1-million member health plan. Prior to utilization of ibritinib, the baseline 1-year treatment costs for treating first-line CLL patients was $4,654 PTMPM and $0.107 PMPM. The 1-year incremental budget impact of adopting ibritinib for first-line CLL patients was $243 PTMPM, or $0.006 PMPM. The model results were most sensitive to ibritinib DOT, followed by ibritinib market share, and percent of treated population ≥65 years of age.

**CONCLUSIONS:** The model results indicate that the budget impact of ibritinib is estimated to be modest from a U.S. health plan perspective. This is important for healthcare decision-making considering the efficacy and safety benefits for ibritinib in this orphan disease with high unmet need.

**SPONSORSHIP:** Funded by Janssen Scientific Affairs.

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**D19 Characteristics and Treatment Patterns of Von Willebrand Disease in the United States**

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**BACKGROUND:** The CHOICE Project was conducted in partnership between the U.S. Centers for Disease Control and Prevention and Hemophilia Federation of America, a non-profit, community-based advocacy organization, to survey persons with bleeding disorders, including those with von Willebrand disease (VWD). A better understanding of the VWD population and disease burden in the U.S. may help payers support access and improve care and treatment for this patient population.

**OBJECTIVE:** To examine real-world Hizentra-to-IVIG dose ratios in the U.S. after PI patients switch from IVIG to Hizentra.

**METHODS:** A retrospective longitudinal study was conducted using shipment data on prescriptions dispensed from specialty pharmaceutical and service providers from 2011-2016. PI patients who switched from IVIG (≥1 dispensing prior to switch) to Hizentra (≥2 dispensings, with the date of first dispensing defined as the switch date and ≥1 dispensing in the 6 months post-switch), were ≥2 years of age at 6 months pre-switch, and without claims for IVIG during the 6 months post-switch were included. Monthly Hizentra doses were calculated for each 2-month interval post-switch by aggregating daily doses estimated from dispensed volume and time between dispensings. Mean monthly IVIG dose was calculated from the total volume dispensed prior to switch. Hizentra-to-IVIG dose ratios were calculated for each patient by dividing monthly Hizentra dose by monthly IVIG dose during each 2-month interval. Median dose ratios were reported to minimize the impact of outliers. Dose ratios at months 2-4, 4-6, and 6-8 were compared to the dose ratio at months 0-2 with the Wilcoxon signed rank test. A sensitivity analysis excluded pediatric patients (younger than age 8) to reduce effects of patient weight changes on dose.

**RESULTS:** 278 patients met the inclusion criteria for the study. The initial median Hizentra-to-IVIG dose ratio was 1.14:1 at months 0-2 post-switch, which declined to 1.09:1 at months 2-4, 1.05:1 at months 4-6, and 1.05:1 at months 6-8 post-switch. The median dose ratios at months 2-4, 4-6, and 6-8 were statistically significantly lower than the median dose ratio at months 0-2 post-switch (all P<0.001). Results were robust to the exclusion of pediatric patients.

**CONCLUSIONS:** Real-world data show that patients switching to Hizentra from IVIG started at dosing ratios lower than current U.S. prescribing information, and close to the 1:1 dosing ratio used in the EU. Stabilization of the dose ratio at 1.05:1 over months 4-6 and 6-8 from the initial dose ratio of 1:1:4:1 at months 0-2 is consistent with management of PI in clinical practice.

**SPONSORSHIP:** Supported by CSL Behring.
U.S. Costs of Intravenous and Subcutaneous Therapy for the Treatment of Primary Immunodeficiency Disease in the United States from 2012-2015

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BACKGROUND: Primary Immune Deficiency Disorder (PIDD) is a rare, chronic, genetic disease of the immune system that leaves patients highly susceptible to infections. As a result, PIDD patients more frequently utilize medical services leading to higher healthcare costs. Immunoglobulins (Ig), the current standard of care for PIDD patients, include nurse-infused intravenous (IV) or self-administered subcutaneous (SC) products. While past literature often depicts SC-based Ig as the lower cost alternative, no current research has investigated if treatment costs have changed over time.

OBJECTIVE: To evaluate the extent of change in real-world PIDD-related costs from 2012 to 2015 in PIDD patients treated with SC- and IV-based immunoglobulin therapy in a U.S. payer database.

METHODS: Using the Pharmetrics Plus dataset from 2012-15, we identified PIDD patients (ICD-9 code 279.XX) with at least two claims > 90 days apart for PIDD who were receiving either SC- or IV-based Ig therapy. Only months where patients received Ig therapy were included in the analysis and patients were not excluded for switching therapies. Mean costs per treated member per treated month (PTMPTM) for a SC product (Hizentra) and the mean of the three most commonly used IV products (Gammagard, Gamunex-C, Privigen) were calculated for each year from 2012-2015. Cost categories included drug, administration, and total (drug + administration) costs for each Ig route.

RESULTS: 7,316 and 4,854 PIDD patients met all inclusion/exclusion criteria for 2012 and 2015, respectively. Of the PIDD patients, 81% (5,907) in 2012 and 78% (3,802) in 2015 were receiving IV therapy. Within each group, average months on treatment per patient were consistent from 2012 to 2015. Total costs PTMPTM from 2012 to 2015 increased by 8% for IV patients ($4,328 to $4,678) and by 21% for SC patients ($4,020 to $4,863). Administration costs PTMPTM were relatively consistent for each Ig route during the same time frame, changing from $224 to $229 for IV and $124 to $106 for SC. However, Ig drug costs PTMPTM changed from $4,104 to $4,449 for IV and from $3,895 to $4,757 for SC (2012 to 2015, respectively).

CONCLUSIONS: The current study gathered insight into the changing cost landscape of IV and SC Ig in the treatment of PIDD. From 2012-2015, total costs for SC-based Ig therapy appear to have increased at a rate of 2.5 times that of IV-based Ig therapy, outweighing the cost offset of IV Ig administration. Future research should elucidate on these findings to determine how these rising costs impact patient preferences and treatment.

SPONSORSHIP: Grifols SSNA.

Insulin Degludec in Clinical Practice: A Systematic Review of Japanese Real-World Data

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BACKGROUND: Randomised controlled trials (RCTs) are the gold standard for comparing the safety and efficacy of new treatments with current practice; however the external validity is limited by study design and inclusion/exclusion criteria.

OBJECTIVE: To evaluate the real-world clinical effectiveness of switching to insulin degludec (IDeg) in Japanese patients.

To evaluate the extent of change in real-world PIDD-related costs from 2012 to 2015, we identified PIDD patients (ICD-9 code 279.XX) with at least two claims > 90 days apart for PIDD who were treatment naïve for ≥ 1 year prior to the index period. Patients switching administration routes were excluded, with the exception that SC patients could receive up to 2-IV loading infusions per treatment guidelines. To adjust for physician treatment preferences and large base population characteristic differences, the two cohorts were matched on age, gender, and all 31 Elixhauser index criteria using propensity score matching. Median pharmacy, administration, and total (pharmacy + administration) costs between the combined 3 most commonly used IV products (Privigen, Gamunex-C, Gammagard) were compared to a SC product (Hizentra) using Wilcoxon Rank-Sum tests.

RESULTS: Before matching, 1,639 PIDD patients (986 IV and 653 SC) met all inclusion/exclusion criteria. SC patients were significantly younger (40 vs. 49 years), with a greater proportion female (63% vs. 58%) and had lower Charlson Comorbidity Index Scores (1.7 vs. 3.0; P < 0.05 for all). After matching, 553 patients in each group had no significant demographic differences. IV median total ($19,195) and pharmacy costs ($18,449) were significantly lower than SC ($23,097 and $21,773, respectively; P<0.05), while IV median administration costs ($581) were $281 higher than SC ($300; P<0.05). Median pharmacy costs accounted for 96% ($18,449) and 94% ($21,773) of median total costs for IV and SC. 

CONCLUSIONS: While subcutaneous use of immunoglobulins appears to reduce administration costs, this real world U.S. retrospective study reveals that PIDD patients, similar in age, gender, and comorbidities, who were treated with intravenous immunoglobulins had significantly lower median total and pharmacy costs when compared to their subcutaneous counterparts.

SPONSORSHIP: Grifols SSNA.
METHODS: Studies were identified from Japanese Diabetes Society (JDS) abstracts (2014-2015) and PubMed (2012 onwards). Inclusion criteria were: Japanese population, >15 participants and only studies switching patients from basal or basal–bolus insulin regimens to IDeg.RCTs and case reports were excluded. Weighted mean changes in safety and effectiveness endpoints were calculated using the number of patients in each study. The threshold for statistical significance was P≤0.05.

RESULTS: A total of 81 JDS abstracts and 5 manuscripts met the search criteria (21 type 1 diabetes [T1D], 15 type 2 diabetes [T2D], 50 diabetes type not specified), representing 4,238 patients (1,028 T1D, 602 T2D, 2,608 not specified). Hba1c was reported in 93% of studies and was improved in 84% (51% significant, 33% numerical), unchanged in 12% and worse in 4% (3% numerical, 1% significant). Across all studies the weighted mean actual change in Hba1c was -0.25% (-2.7 mmol/mol). Basal insulin dose was reported in 57.6% of studies and was lower in 60% (30% significant, 30% numerical), numerically unchanged in 26% and higher in 14% (2% significant, 12% numerical). The weighted mean change in basal insulin dose was -4.81% and -3.72% for all studies and for significant-only studies, respectively. The weighted mean change in basal dose based on all studies was -8.9%, -5.9% and -2.9% for T1D, T2D and unspecified populations, respectively. Hypoglycemia was recorded in 28.1% of the studies. After switching, 54.8% of studies reported decreased hypoglycemia, 29.0% no change and 16.1% an increase. Quality of life (QoL) was measured in 11.1% of studies. 81.8% reported improved QoL after switching, 18.2% reported no change in QoL. No studies reported a worsening in QoL.

CONCLUSIONS: Real-world evidence from Japanese clinical practice demonstrate that switching from a conventional basal insulin to IDeg has the potential to improve Hba1c with a lower insulin dose. Switching to IDeg may also provide a reduced risk of hypoglycemia and the potential for improvement in QoL.

SPONSORSHIP: This study was sponsored by Novo Nordisk A/S.

E06 Patient and Provider Factors Impacting Clinical Inertia in Patients with Type 2 Diabetes on Metformin Monotherapy

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BACKGROUND: Nearly 48% of patients with type 2 diabetes (T2D) do not achieve the recommended hemoglobin A1c (A1c) goal of <7%. Clinical inertia (CI) or the delay of treatment intensification is a major cause of inadequate glycemic control in T2D patients and exists in over 50% of T2D patients. Understanding factors impacting CI is necessary to plan strategies to reduce CI. Previous studies in this area have limitations such as older data, restricted patient populations, and non-examination of provider factors impacting CI.

OBJECTIVE: To determine the impact of patient and provider factors on CI in T2D patients on metformin monotherapy (MM) at a large, integrated healthcare system in the U.S.

METHODS: This retrospective cohort study used data from Carolinas HealthCare System’s electronic medical records. The study cohort included T2D patients aged 18-85 years, on MM between January 2009 and September 2013, who experienced MM failure (had an uncontrolled A1c reading ≥8%) after at least 3 months of MM. A cutoff of A1c <8% was used for T2D control based on medical guidelines that consider factors such as age and comorbidities (primary cohort). However, secondary analyses were performed using A1c <7% as the cut-off (secondary cohort). CI was defined as absence of treatment intensification with an add-on therapy within 180 days after the date of MM failure (index date). The impact of patient and provider factors on CI was determined using generalized estimating equations.

RESULTS: The primary cohort consisted of 996 patients, 58% male and 59% Caucasian, with a mean age of 53 (±11.8) years. CI was observed in 49.8% of the patients. Lower A1c at index date (odds ratio [OR] = 0.88, 95% CI = 0.88, 0.88) and presence of renal disease were associated with CI. The secondary cohort consisted of 967 patients, 53% male and 64% Caucasian, with a mean age of 56 (±11.8) years. CI was 49.1% in this cohort.
67.9%. Greater patient age (OR=1.01, P=0.01), lower A1c at index date (OR=0.72, P<0.001), greater provider age (OR=1.01, P=0.02) and being a primary care physician (PCP, OR=1.85, P=0.01) were associated with CI.

CONCLUSIONS: CI was more likely in patients with lower A1c, patients without liver disease, those without renal diseases, older patients, older providers, and PCPs. These findings could guide planning of interventions to reduce CI in T2D patients.

SPONSORSHIP: Study funding was provided by Merck & Co.

E07 Impact of Various Clinical Strategies on the CMR Completion Rate for CMS Star Ratings

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BACKGROUND: As the United States healthcare system rapidly transitions away from fee-for-service models, the majority of health insurers are placing an increased emphasis on quality of care. To assist Excellus BlueCross BlueShield in improving the quality of care delivered to their beneficiaries, Magellan Rx Management has collaborated on the development and implementation of a clinical program designed to specifically address the CMS Star Rating measure D15-MTM Program Completion Rate for CMR, which is defined as the percent of Medication Therapy Management (MTM) program enrollees who received a Comprehensive Medication Review (CMR) during the measurement year.

OBJECTIVE: To measure the impact of various methods of patient engagement on the CMR completion rate.

METHODS: A clinical program was implemented to improve the CMR completion rate through various methods of patient engagement, including an interactive voice response (IVR) system, member care management (MCM) services, help desk interactions (SafeRx), patient mailings (Medication List), direct patient outreach (Adherence, Historical, Quality Incentive Program [QIP]), and caregiver outreach at long-term care (LTC) facilities. The IVR, MCM, and SafeRx groups have a transfer component, where a member is immediately transferred to a live pharmacist upon request. Adherence patients were those who also qualified for one or more CMS Star Adherence measures, QIP patients were those with comorbid heart failure and diabetes, and historical patients were those who were also MTM eligible during the previous measurement year.

RESULTS: Between January and June of 2016, a total of 4,528 CMRs were completed. The CMR completion rates were: IVR (57.9%), MCM (74.5%), SafeRx (50.2%), Medication List (51%), Adherence (24.4%), Historical (39.0%), QIP (27.7%), and LTC (59.5%). Additionally, the inclusion of a live transfer component in the IVR group had a substantial positive impact on the CMR completion rate. Additional results will be available during the fourth quarter of 2016.

CONCLUSIONS: Patient engagement is critical in improving the CMR completion rate for Star ratings. Leveraging multiple sources of patient engagement helps improve reach rates in a clinically synergistic manner. It has been estimated that a cumulative 1-star improvement across all measurements (from 3 to 4) is worth $50 per member per month. Such results support the efficacy and viability of a clinical program that incorporates care coordination and customized outreach.

SPONSORSHIP: Conducted by Excellus BlueCross BlueShield and Magellan Rx Management without external funding.
adverse outcomes) by skipping or reducing their insulin dose, and hypoglycemia.

**OBJECTIVE:** To evaluate hypoglycemia risk and clinical outcomes in patients with T2D who were previously treated with basal insulin and switched to the recently marketed insulin glargine 300 units/mL (Gla-300) in a retrospective observational medical chart review.

**METHODS:** Data were obtained from pre-existing medical charts for patients with T2D. A total of 184 patients who switched to Gla-300 and had been on insulin treatment ≥ 30 days were included in this analysis. The pre-switching (baseline) period was defined as the 6 months prior to Gla-300 initiation. The post-switching period was defined as the duration of ≥ 30 days of Gla-300 treatment (range: 30-329 days). Collected data included demographics, medical history, glycated hemoglobin A1c (AIC), and hypoglycemia event rates. Generalized linear mixed-effect models adjusting for patient demographics and clinical characteristics were used to examine the differences in pre- vs. post-switching clinical outcomes.

**RESULTS:** During baseline, mean (SD) patient age was 56.2 (10.5) years, 58.2% were male, mean (SD) body mass index was 33.7 (6.6) kg/m²; the mean (SD) duration of prior basal insulin therapy was 61.1 (53.0) months. Post-switching to Gla-300, the mean (SD) duration of Gla-300 treatment was 4.0 (2.3) months. Mean AIC was significantly decreased (least square mean: 8.57% pre-switch vs. 7.61% post-switch; relative risk: 0.23 [95% CI 0.16 to 0.32]; p < 0.0001). The annualized mean number of hypoglycemic events per patient-year was also significantly lower following a switch to Gla-300 (LSM: 0.75 pre-switch vs. 0.17 post-switch; relative risk: 0.23 [95% CI 0.16 to 0.32]; p < 0.0001).

**CONCLUSIONS:** In this real-world study of patients with T2D, switching to Gla-300 was associated with a significant reduction in AIC and a significantly lower hypoglycemia rate compared with prior basal insulin treatments. Therefore, this real-world study is in line with the findings of the EDITION clinical trial program, but also suggests that, in a real-life setting, Gla-300 provides an advantage in terms of glycemic control and hypoglycemia event rates.

**SPONSORSHIP:** Study funding and editorial support provided by Sanofi U.S.

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**E15 Clinical and Economic Outcomes in Patients with Type 2 Diabetes Switching from Basal Insulin Plus Rapid-Acting Insulin to Basal Insulin Plus Glucagon-Like Peptide-1: A Real-World Observational Study**

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**BACKGROUND:** In patients with type 2 diabetes (T2D) the addition of a glucagon-like peptide-1 receptor agonist (GLP-1 RA) to basal insulin (BI) may be associated with improved patient outcomes when compared with BI plus a rapid-acting insulin (RAI).

**OBJECTIVE:** To evaluate characteristics, clinical outcomes, and health care utilization in patients switching from treatment with BI plus RAI to BI plus GLP-1 RA.

**METHODS:** Data were extracted retrospectively from the U.S. CDM dataset for the period January 2007-September 2015. Adult patients with T2D who continued on BI plus RAI (continuers) and patients who switched from BI plus RAI to BI plus GLP-1 RA (switchers) were included. Propensity score matching (PSM) was used to control for differences in baseline demographics between continuer and switcher groups. Clinical outcomes included hypoglycemia events and economic outcomes (including all-cause and diabetes-related health care utilization and costs) during a 6-month follow-up.

**RESULTS:** After hard-matching for age and gender there were 7,270 continuers and 727 switchers (mean age: 57.2 years; 48.0% male). Before PSM, many baseline characteristics (including the Charlson Comorbidity Index; 3.68 for both) were similar for the two groups; ordinary least squares comparisons were made between the two cohorts; ordinary least squares models and logistic regression were used to adjust for confounders in AIC change and hypoglycemia, respectively.

**RESULTS:** Of a total of 28,123 adults receiving dual OAD therapy and with evidence of AIC≥7.0%, 3,900 (14.2%) underwent TI. Patients in the TI cohort were younger than patients in the NTI cohort (58.3 vs. 61.3 years; P < 0.001); the proportion of men was higher in the TI cohort (59.0% vs. 57.2%; P = 0.033). Index AIC was higher in the TI cohort (8.8% vs. 8.0%; P < 0.001). In a multivariate analysis, TI patients showed greater AIC reductions than NTI patients (-0.59% vs. -0.25%; P < 0.001). The hypoglycemia rate was higher in the TI cohort (odds ratio: 1.68, P < 0.001). Only 31.2% of TI patients met glycemic targets at follow-up.

**CONCLUSIONS:** These real-world data show that clinical inertia is still widespread despite the availability of multiple treatment options for T2D. TI was effective in achieving glycemic control but was associated with a higher hypoglycemia rate. In addition, less than one-third of patients reached recommended AIC targets at 12 months. Our data indicate a need for new agents that effectively manage glycemia and lower hypoglycemia risk.

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

E16 Predictors and Clinical Outcomes of Treatment Intensification in Type 2 Diabetes Patients Uncontrolled on 2 or More Oral Antidiabetic Agents in a Real-World Setting

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BACKGROUND: Clinical inertia is an ongoing barrier in diabetes care.

OBJECTIVE: To understand the risk factors associated with clinical inertia as well as to assess whether treatment intensification leads to improved HbA1c (Alc) levels in patients with uncontrolled type 2 diabetes (T2D) using data from a U.S. cloud-based electronic health records (EHR) platform.

METHODS: Insulin-naive T2D patients prescribed ≥2 types of oral antidiabetic agents (OAD), with the most recent OAD in the 6 months prior to an uncontrolled Alc level (Alc≥7.0%), were identified from 2011 to 2015 in the Practice Fusion EHR database. The most recent uncontrolled Alc date following the prescription of a 2nd OAD marked the index date. The baseline (BL) period was defined as the 6 months prior to the index date. Patients were categorized into intensifier (INT) and non-intensifier (N-I) cohorts based on whether or not they used an additional OAD, a basal insulin (INS), or a glucagon-like peptide-1 receptor agonist (GLP-1). The observation period was defined as the 12 months following intensification, where intensification date for N-I was defined as a post-index day randomly generated from a gamma distribution among INT. BL demographic, clinical, and physician characteristics were used in multivariable logistic regression to predict treatment intensification. Change in Alc and achievement of Alc≤7% were assessed with respect to intensification status, adjusting for age, physician specialty, BMI, Alc, BL OADs, and comorbidities.

RESULTS: Of the 25,365 patients, 71.7% patients did not intensify their treatment regimens. BL Alc, and BMI were significantly different between cohorts (P<0.001). Controlling for BL characteristics, patients of endocrinologists had 1.6 times (OR 1.59, 95% CI 1.39-1.81, P<0.0001) the odds of intensifying their diabetes treatment compared to patients of another physician specialty and this was significant across INS (OR 2.3), GLP-1 (OR 2.4), and OAD (OR 1.4) intensifier groups (P<0.0001). Adjusting for BL characteristics, compared to N-I, INT had a larger decrease in Alc (β -0.22, P<0.0001) and had 1.3 times (OR 1.33, 95% CI 1.21-1.45, P<0.0001) the odds of achieving Alc≤7% at 12-months post-intensification.

CONCLUSIONS: In this EHR analysis, the majority of patients on ≥2 OADs with uncontrolled Alc levels did not intensify their treatment regimens. Patients who went to endocrinologists were more likely to intensify their regimens, and treatment intensification was associated with improved Alc levels. Findings from this study will help physicians better manage care for patients with T2D.

E17 Predictors of Adherence to Initial Oral Antidiabetic Medications in Veterans with Diabetes

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BACKGROUND: Medication nonadherence remains a significant public health issue and negatively influences health outcomes, particularly among patients with diabetes. Considering the prevalence of diabetes among American veterans, it is of paramount importance to understand the profiles of patients who may be more likely to be less adherent to prescribed treatment and placed at increased risk for detrimental outcomes.

OBJECTIVE: To assess oral antidiabetic medication (OAD) use among veterans during the first year following diagnosis for patient characteristics related to lower levels of adherence.

METHODS: The VA Corporate Data Warehouse was used to identify the first diagnosis for uncomplicated diabetes and the presence of disease was confirmed by an accompanying first prescription for an OAD during 2002-2014. Use of OADs was assessed by proportion of days covered (PDC) for one year from the first filled prescription following diagnosis using outpatient VA pharmacy records. The odds of being adherent to therapy over the course of the year (PDC≥80%) was analyzed by logistic regression, controlling for baseline sociodemographic and clinical characteristics.

RESULTS: A total of 177,444 veterans were analyzed. The average age at treatment initiation was 62 (SD: 11.0), mean hemoglobin Alc was 7.4 (SD: 1.3), and a majority of patients lacked significant comorbidities. Median adherence over the first year for all patients was 91.2% and average adherence was lowest among younger veterans (<34 years) and minorities while it tended to slightly increase with higher baseline hemoglobin Alc values (r=0.09, P<0.001). Over the first year, 62% attained a PDC>80%, however, 20% were less than 50%. When controlling for baseline characteristics, African Americans (OR: 1.64; CI: 1.59-1.68), Native Americans (OR: 1.43; CI: 1.30-1.58), and veterans who reported being single (OR: 1.13; CI: 1.08-1.17) or divorced (OR: 1.17; CI: 1.14-1.20) had a higher odds of being nonadherent. Additionally, the odds of being nonadherent were lower for veterans from the Midwest (OR: 0.87; CI: 0.84-0.90) and tended to decrease with age- those aged 55-64 had the lowest odds of being nonadherent (OR: 0.36; CI: 0.32-0.40).

CONCLUSIONS: Nonadherence to OAD agents in the first year of therapy is a prevalent issue for veterans with diabetes and is especially prominent among minorities and the unmarried; measures to improve medication use behaviors in these populations should be considered in the first year of therapy.

SPONSORSHIP: Funding for this research was provided by a KL2 award from the UT Institute for Research, Innovation, Synergy, and Health Equity.
E20 Real-Life Data Demonstrate Significant Reductions in HbA1c in T2DM Patients Switching From Other Insulins to Insulin Degludec

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BACKGROUND: Insulin degludec (IDeg) is an ultra-long acting basal insulin analogue whose safety and efficacy, while reaching similar HbA1c to insulin glargine, has been established in randomized control trials.

OBJECTIVE: To describe the clinical effectiveness of IDeg in insulin treated patients with type 2 DM (T2DM) switching from other insulins to IDeg in a real world setting.

METHODS: Included in this retrospective cohort study were T2DM patients from Maccabi Health Services (MHS) in Israel, mainly treated by basal insulin with or without bolus prior to IDeg initiation for at least one year. HbA1c and weight were measured at baseline (less than or equal to 180 days pre-switch) and at 6 months of IDeg therapy (±90 days).

RESULTS: A total of 211 eligible patients were identified, 57% were males, mean age was 62.2 years (SD = 12.1), mean pre-switch basal insulin dose was 34.5 units (SD = 21.23) and all patients had diabetes duration of >10 years. Prior to IDeg initiation patients were mainly treated with basal bolus (55.2%) and basal only (37.1%) therapy. Switch to IDeg led to a mean decrease in HbA1c of 0.58% (95% CI: 0.44 to 0.71, P < 0.001) from a mean baseline of 8.0% (SD = 1.5). Baseline HbA1c of >8.5% and daily insulin dose of ≥50 units were associated with a greater reduction in HbA1c (1.00% [95% CI: 0.79 to 1.21, P < 0.001] and 1.24% [95% CI: 0.78 to 1.70, P < 0.001], respectively). The mean daily IDeg dose was 39.0 (SD = 16.41) units during the first 90 days after switch. The mean daily IDeg dose from day 91 to 180 after switch was 5.1 units lower (SD = 14.59, P < 0.001) from a mean baseline of 8.8% (SD = 1.5). Baseline HbA1c of >8.5% and daily insulin dose of ≥50 units were associated with a greater reduction in HbA1c (1.00% [95% CI: 0.79 to 1.21, P < 0.001] and 1.24% [95% CI: 0.78 to 1.70, P < 0.001], respectively). The mean daily IDeg dose was 39.0 (SD = 16.41) units during the first 90 days after switch. The mean daily IDeg dose from day 91 to 180 after switch was 5.1 units lower (SD = 14.59, P < 0.001) from a mean baseline of 8.8% (SD = 1.5). Baseline HbA1c of >8.5% and daily insulin dose of ≥50 units were associated with a greater reduction in HbA1c (1.00% [95% CI: 0.79 to 1.21, P < 0.001] and 1.24% [95% CI: 0.78 to 1.70, P < 0.001], respectively). The mean daily IDeg dose was 39.0 (SD = 16.41) units during the first 90 days after switch. The mean daily IDeg dose from day 91 to 180 after switch was 5.1 units lower (SD = 14.59, P < 0.001) from a mean baseline of 8.8% (SD = 1.5). Baseline HbA1c of >8.5% and daily insulin dose of ≥50 units were associated with a greater reduction in HbA1c (1.00% [95% CI: 0.79 to 1.21, P < 0.001] and 1.24% [95% CI: 0.78 to 1.70, P < 0.001], respectively).

CONCLUSIONS: In a real life setting, switching from another insulin (mainly basal bolus and basal only therapy) to IDeg in Type 2 DM patients significantly improved glycaemic control without weight gain. Initially a minor dose increase was observed but basal insulin doses returned to pre-switch levels after 3 months treatment.

SPONSORSHIP: Data analysis sponsored by Novo Nordisk A/S.

E23 Divergence in Definitions of Control Among Patients with T2DM, Clinicians, and Payers

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BACKGROUND: Perspectives of what it means for patients to be “in” and “out of control” are not well understood.

OBJECTIVE: To understand how patients with T2DM on basal insulin, clinicians, and payers in the U.S. perceive of and define “control” as it relates to T2DM.

METHODS: The qualitative portion of the study consisted of 6 patient focus groups (total respondents in study: n = 7 with AIC < 7%, n = 14 with AIC > 7%), 8 clinician focus groups (total respondents in study: n = 8 endocrinologists, n = 13 primary care physicians, n = 4 nurse practitioners/physician assistants), and 20 one-on-one payer interviews (managed care organizations (n = 9), pharmacy benefit managers (n = 4), and integrated delivery networks (n = 7). Discussions were conducted by trained interviewers using a semi-structured discussion guide, were video recorded, and subsequently transcribed. The analysis of the qualitative data was based in grounded theory. Dedoose software was used to analyze transcript passages with the aim of quantifying emerging concepts on how patients, clinicians, and payers define T2DM control.

RESULTS: Patients, clinicians, and payers in the U.S. had differing perspectives of what it meant for a patient to be in and out of control. Patients most frequently defined control as being adherent to lifestyle changes and/or treatment regimens (44 mentions), whereas clinicians most frequently defined control as being based on daily blood glucose levels (33 mentions). Payers, in turn, most frequently defined control as being based on AIC (18 mentions). Both patients and clinicians most frequently defined being out of control by the presence of diabetes-related symptoms (36 and 46 mentions, respectively) while payers most frequently defined control as the presence of diabetes-related comorbidities and complications (11 mentions).

CONCLUSIONS: Patients, clinicians, and payers in the U.S. have differing views on the definition of being “in control” of type 2 diabetes. Obtaining a better understanding of what each party means when they discuss control can aid communication throughout the healthcare system, with the potential to improve patient adherence to therapy and, ultimately, patient outcomes.

SPONSORSHIP: Novo Nordisk.

E24 Factors Associated with Multiple Daily Injection Therapy and Achieving Glycemic Control in Adults with Type 2 Diabetes

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BACKGROUND: Multiple daily injection (MDI) therapy is needed for people with type 2 diabetes mellitus (T2DM) to achieve glycemic control when the disease has progressed, and oral therapies are no longer effective. Few studies have assessed predictors of control in T2DM adults on MDI.

OBJECTIVE: To examine this question, we used a real-world cohort with disease and comorbidity characteristics in T2DM patients to identify variables predictive of glycemic control.

METHODS: An online survey for people with diabetes was fielded in 2016 with the dQ&A Patient Panel. Type of insulin treatment, years using insulin, age at diagnosis, other diabetes medications taken, comorbidities, use of glucose monitoring, self-reported adherence, insurance and patient sociodemographics were collected. Multivariate and descriptive statistics were used to describe patients achieving Hemoglobin Alc (HbA1c) < 7% and for those with HbA1c above 9.1%.

RESULTS: Adults with T2DM, using MDI and reporting HbA1c (n = 454) had a mean age of 63.70 (9.87) years, 59.70% were female and the mean duration of insulin was 10.46 years. Fewer than 35% (n = 157) reported achieving HbA1c < 7% and 12% (n = 53) reported HbA1c > 9.1%. Participants reaching target were older (62.45 vs. 58.11, P = 0.031) and less likely to take an oral (52.90% vs. 69.80%; P = 0.01) and less likely to have comorbid depression (20.40% vs. 34.00%; P = 0.03). A backward stepwise multivariate model predicting HbA1c control (< 7% vs. > 7.1%) found men (OR 1.55; P = 0.03) were more likely to achieve HbA1c control while those with a higher body mass index (OR 0.982; P < 0.01) were less likely to achieve HbA1c control. A second model predicting
being out of control (> 9.1% vs. < 7%) found that taking orals (OR 5.14; P < 0.01) and having a family income of $25-49k (OR 2.76; P = 0.01) were predictive of being out of control with HbA1c > 9.1% and years on insulin (OR 0.94; P = 0.03), age at diagnosis (OR 0.98; P < 0.01) and reporting being adherent (OR 0.33; P = 0.03) were predictive of being in control with HbA1c < 7%.

CONCLUSIONS: This study identifies factors predicting levels of glycemic control in T2DM adults on MDI therapy. Understanding these factors may provide direction on best practices to help patients improve and achieve treatment goals.

SPONSORSHIP: CeQur.

E26 Novel Predictive Modeling Identifies and Quantifies Factors That Predict the Risk of Hypoglycemia in Patients with Type 2 Diabetes

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BACKGROUND: Patients on certain antidiabetic therapies may encounter hypoglycemic events and complications. Identifying patients at risk of hypoglycemia and taking action to reduce the risk can improve outcomes and lower healthcare costs.

OBJECTIVE: To identify risk factors for hypoglycemia in adults with type 2 diabetes (T2D) treated with antidiabetic medications and quantify hypoglycemia risk based on the totality of risk factors identified.

METHODS: This retrospective cohort study used data collected between January 2008 and December 2013 from the Truven Health MarketScan Commercial, Medicare Supplemental, and Laboratory databases. Patients with a first observed pharmacy claim for an antidiabetic medication (index date) who had continuous enrollment for 6 months pre- and 12 months post-index were eligible. Baseline characteristics were collected during the pre-index period, and all patients were required to have ≥ 12 months of follow-up. Any hypoglycemia was identified from claims. We applied GNS Healthcare’s REFS (Reverse Engineering and Forward Simulation) machine learning platform to create an ensemble of 128 prediction models for hypoglycemia using baseline characteristics. The best performing model (lowest Bayesian information criterion score) was used to create hypoglycemia risk values and validated with an independent dataset.

RESULTS: 558,963 patients (mean age 55 years; 48.4% female; mean [SD] Charlson Comorbidity Index score 1.90 [1.16], 4.4% using basal insulin) met eligibility criteria; 11,999 (2.1% overall) had a hypoglycemic event with a median of 2.9 years’ follow-up. In the best model, the risk factors predictive of hypoglycemia included pre-index hypoglycemia, oldest vs. youngest age (≥ 75 vs. < 35 years), insulin use, sulfonylurea use, mood disorder, female gender, baseline healthcare utilization and costs. Patients were classified into incremental risk strata (0-2%, 2-4%, 4-6%, 6-8%, and > 8%) for incidence of hypoglycemia, and the corresponding mean risk estimates from the validation were 1.3%, 2.7%, 4.7%, 6.8%, and 9.0%, respectively.

CONCLUSIONS: The current analysis presents a systematic procedure to quantify the risk for hypoglycemia following the first observable antidiabetic treatment. The increasing risk across the risk strata demonstrates an incremental risk for hypoglycemic events via independent validation. Prevention and early identification of hypoglycemia in diabetes patients is necessary to reduce the clinical and economic burden in this population.

SPONSORSHIP: Sanofi U.S.
**RESULTS:** There were 8,108 T2D patients (mean age 57 years, 48% female) receiving DAPA identified in the EMR data. More than half of the patients (63%) had a treatment duration of more than 180 days (mean duration 372 days). Among patients with a treatment duration > 180 days, mean change in AIC was 0.8% (9.0% during baseline vs. 8.2% during follow-up, P < 0.01). Mean weight change was -2.6 kg (105.2 kg during baseline vs. 102.6 kg during follow-up, P < 0.01). Mean SBP change was -2.3 mmHg (130.5 mmHg during baseline vs. 128.2 mmHg during follow-up, P < 0.01). Mean change in DBP was -1.7 mmHg (78.2 mmHg during baseline vs. 76.5 mmHg during follow-up, P < 0.01).

**CONCLUSIONS:** The results demonstrate that in a real-world setting, treatment with DAPA is associated with significant reductions in AIC, weight, SBP, and DBP. These results support the findings from dapagliflozin clinical trials.

**SPONSORSHIP:** AstraZeneca.

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**METHODS:** Adult T2D patients previously untreated with a SGLT2i who received DAPA between January 1, 2014, and November 30, 2015, were identified in a U.S. EMR database. The date of their first DAPA prescription was defined as the index date. Patients were followed from 12-months before their index date (baseline period) until their last day on DAPA or November 30, 2015, whichever came first. Baseline AIC was required to be at least 7%. Patients who met all inclusion and exclusion criteria were included in the final population. Outcomes included change in AIC since their last recorded value, changes in weight, as well as systolic and diastolic blood pressure (SBP and DBP). Paired t-tests were conducted to test for a difference between the AIC, weight, SBP, and DBP values at baseline and during follow-up.

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**CONCLUSIONS:** The results demonstrate that in a real-world setting, treatment with DAPA is associated with significant reductions in AIC, weight, SBP and DBP. These results support the findings from dapagliflozin clinical trials.

**SPONSORSHIP:** AstraZeneca.
**E33** Disproportionately High Direct Economic Burden of Comorbid Cardiovascular Disease in Patients with Type 2 Diabetes Mellitus

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**BACKGROUND:** Patients with type 2 diabetes mellitus (T2DM) are at an increased risk of complications including cardiovascular disease (CVD). However, the extent to which CVD contributes to the overall economic burden of T2DM is not well understood.

**OBJECTIVE:** To describe the direct economic burden of CVD in patients with T2DM.

**METHODS:** A descriptive, cross-sectional study was conducted using integrated healthcare claims data from a commercially insured population in the U.S. Continuously enrolled patients aged ≥18 years with a diagnosis for T2DM were identified during the index year (2014) and study cohorts with and without CVD were identified during the pre-index year (2013). Demographic and clinical characteristics, and all-cause, CVD-, nephropathy-, neuropathy-, and retinopathy-related healthcare costs were measured during the index year and compared between CVD and non-CVD cohorts using t-tests and chi-square tests.

**RESULTS:** A total of 778,344 patients with T2DM were included, 17.8% had comorbid CVD but contributed to 37.7% of the $92 billion total all-cause costs of care for patients with T2DM in year 2014. On average, CVD patients were older (65.0 vs. 56.4), male (65.1% vs. 52.9%), had a higher Charlson Comorbidity Index score (0.97 vs. 0.36), and more likely to have hypertension, dyslipidemia and obesity (all comparisons P < 0.001). The mean ± SD all-cause cost for a T2DM patient was $11,829 ± 32,327, 32.7% ($3,865) of which was associated with treating T2DM and related complications including CVD. Of the $3,865, 28.3% were attributed to treating CVD. On average, comorbid CVD patients incurred $16,149 higher mean total all-cause costs ($25,107 vs. $8,958, P < 0.001) compared to those without comorbid CVD, primarily due to higher inpatient ($8,330 vs. $1,347, P < 0.001) and outpatient ($11,992 vs. $4,494, P < 0.001) costs.

**CONCLUSIONS:** About 1 in 5 T2DM patients had comorbid CVD but contributed approximately 38% to the total all-cause costs of patients with T2DM in 2014.

**SPONSORSHIP:** Boehringer Ingelheim.

**E34** The Cost of Patients with Type 2 Diabetes Mellitus Hospitalized for Heart Failure

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**BACKGROUND:** Heart failure (HF) is common among patients with type 2 diabetes mellitus (T2DM), however, the immediate and long term cost of a HF hospitalization in patients with T2DM is not well quantified.

**OBJECTIVE:** To determine the direct cost of HF hospitalization and incremental costs following hospitalization among patients with T2DM.

**METHODS:** A U.S. integrated healthcare claims database was used to identify adults with a diagnosis of T2DM. T2DM patients with a hospital claim for HF between 07/2011 and 06/2014 were matched to those without an HF hospitalization. The year preceding the HF hospitalization admission date was considered the pre-index period for HF cohort and the year prior to the index date for the non-HF cohort. The presence or absence of a cardiovascular (CV) hospitalization in the pre-index period was used to define high and low risk patients in both cohorts. T2DM patients with and without an HF hospitalization were propensity score (PS) matched 1:1 separately for high and low risk strata using age, gender, geographic region, plan type, index year, CV condition or hospitalization, CV risk factors, chronic obstructive pulmonary disease, and cancer. Patients were followed for a variable period, until health plan disenrollment or end of available data, whichever came first. All-cause healthcare costs were computed separately for the index hospitalization and per patient per month (PPPM) following discharge, and compared between the PS-matched cohorts using McNemar’s chi-square tests and paired t-tests.

**RESULTS:** A total of 10,256 low and 602 high risk patients were included in our PS-matched cohorts. The mean costs of an HF hospitalization were $20,619 and $21,410 in the low and high risk patients, respectively. Post-index mean PPPM all-cause costs were 3.4 ($5,494 vs. $1,601, P < 0.001) and 4.9 times ($10,599 vs. $2,143, P < 0.001) higher in the HF cohort compared to the non-HF cohort among low and high risk patients, respectively. HF patients had mean PPPM medical costs 3.9 and 5.7 times greater than non-HF patients (low: $5,125 vs. $1,306, P < 0.001 and high: $10,192 vs. $1,789, P < 0.001), including inpatient costs which accounted for the largest difference (low: $3,126 vs. $581, P < 0.001 and high: $7,602 vs. $967, P < 0.001).

**CONCLUSIONS:** In this T2DM patient population, the cost of an HF hospitalization was approximately $20,000 and incremental costs following discharge were $4,000-$8,500 PPPM.

**SPONSORSHIP:** Boehringer Ingelheim.

**E35** The Direct Cost of Cardiovascular Disease-Related Death in Patients with Type 2 Diabetes Mellitus in a Commercially Insured Population in the United States

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**BACKGROUND:** Patients with type 2 diabetes mellitus (T2DM) are at an increased risk of death from cardiovascular disease (CVD); however, the direct cost of CVD-related death among patients with T2DM is largely unknown.

**OBJECTIVE:** To determine the incremental direct economic burden of CVD-related death in patients with T2DM, in the 3-, 6-, and 12-months prior to their death.

**METHODS:** The study employed a retrospective, matched-cohort design using claims data from a commercially insured U.S. population. Patients aged ≥18 years with a diagnosis for T2DM from 07/01/2010 to 06/30/2015 were identified. T2DM patients who died of a CVD-related cause (cases) were matched 1:1 to those with no evidence of death (controls), during the period 07/01/2012-04/30/2015, on age at index ± 2 years, gender, geographic region, plan type, and index year. The index date was defined as the date of death for cases or date of last medical claim with a primary diagnosis of T2DM for controls. The 2 years preceding the index date were divided into an outcomes period (0 to 12 months prior to the index date) and a baseline period (13 to 24 months prior to the index date). All-cause costs were assessed and reported for 3, 6, and 12 months prior to the index date and compared between the matched cases and controls using McNemar’s chi-square tests and paired t-tests.
RESULTS: A total of 7,648 cases were matched to 7,648 controls. Average age of patients was 67.2 years, 63.8% of whom were male. Cases had a higher mean ± SD Charlson Comorbidity Index score than controls (1.99 ± 2.2 vs. 0.99 ± 1.5; P < 0.001). The mean total direct costs for cases were $7,149 ± 6,472 and $11,898 ± 9,381, respectively; all P < 0.001). Medical costs for cases were 6.4, 5.2, and 4.2 times as much as controls during the 3 timeframes (all P < 0.001), and included hospitalization costs 9.6, 7.9, and 6.5 times higher than controls ($26,683 vs. $2,785; $32,892 vs. $4,172; $40,869 vs. $6,327, respectively; all P < 0.001) and emergency department costs 6.2, 4.9, and 3.9 times those of controls ($1,829 vs. $294; $2,296 vs. $472; $3,001 vs. $766; all P < 0.001).

CONCLUSIONS: The direct cost of CVD-related death in this T2DM population was significantly higher in the year leading up to their death.

SPONSORSHIP: Boehringer Ingelheim.

CONCLUSIONS: Obesity impacts work impairment and indirect costs across all industries. In addition, industry may differentially affect this association. For example, the construction/installation industry, despite mid-ranked obesity prevalence, had the highest work impairment and indirect costs.

SPONSORSHIP: Sponsored by Novo Nordisk.

E40 Burden of Illness in School-Aged Patients with Cystic Fibrosis in the United States

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BACKGROUND: Cystic fibrosis (CF) is a rare, progressive genetic disease affecting patients from birth. The CF disease burden in school-aged children is not well understood.

OBJECTIVE: To describe the burden of CF in patients aged 6-17 years by comparing their healthcare resource utilization (HCRU) to that of demographically similar controls without CF.

METHODS: This retrospective study used administrative claims from the Truven MarketScan Commercial (COMM) and Medicaid Multi-State (CAID) databases. Patients with CF aged 6-17 years were identified as having ≥1 inpatient (IP) or ≥2 outpatient (OP) medical claims ≥30 days apart with primary diagnosis of CF (ICD-9-CM: 277.0x) between 2010 and 2014. Other inclusion criteria were ≥12 months of continuous medical and pharmacy coverage and ≥1 healthcare encounter due to CF during the most recent year of data. Patients were matched (1:3) to non-CF controls by age, gender, geographic region (COMM cohort), race (CAID cohort), enrollment (calendar year) and insurance plan type. The most recent year of data was used to assess outcomes, which included IP admissions, OP visits and medication use. Bivariate statistics were used to compare outcomes between patients and matched controls, overall and by age group (6-11 and 12-17 years) using chi-square tests for categorical variables and t-tests and ANOVA for continuous variables.

RESULTS: In total, 2,400 patients with CF were included in the COMM cohort and 1,264 in the CAID cohort, all were matched 1:3 to controls (n = 7,200 and n = 3,792, respectively); mean [SD] age of patients and controls: COMM, 11.9 [3.5]; CAID, 11.4 [3.5]. Annual hospitalization rates were ≥22-fold higher in the CF cohorts vs. matched controls (COMM, 0.64 vs. 0.02; CAID, 0.87 vs. 0.04) with longer lengths of stay per hospitalization (COMM, 8.4 vs. 4.5 days; CAID, 10.1 vs. 6.8). Higher annual rates of OP visits were evident in the CF cohorts vs. controls (COMM, 9.9 vs. 2.8; CAID, 9.9 vs. 3.2). Patients filled 5 times as many unique medications (COMM, 11.6 vs. 2.0; CAID, 15.8 vs. 3.2) and 10 times as many total prescriptions per year than controls (COMM, 39.8 vs. 3.6; CAID, 67.3 vs. 7.2). P values were <0.001 for all comparisons (CF patients vs. controls). While patients aged 12-17 years generally had higher HCRU than those aged 6-11, trends and magnitude difference vs. controls within each age group were similar.

CONCLUSIONS: Patients with CF aged 6-17 years have greater HCRU than demographically similar non-CF controls, illustrating significant disease burden and a need for better treatment options in this school-age population.

SPONSORSHIP: Sponsored by Vertex Pharmaceuticals.

E39 The Association Between Body Mass Index, Work Productivity Impairment, and Indirect Costs Across Different Employment Industries in the United States

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BACKGROUND: Body mass index (BMI) can affect work productivity.

OBJECTIVE: To quantify the relationship between workers’ BMI and work productivity within various industries.

METHODS: Data from 2 administrations (2014/2015) of the United States (U.S.) National Health and Wellness Survey, an Internet-based survey administered to a demographically representative adult sample of the U.S. adults (≥18 years) population, were used for this study. Participants (n = 59,772) that supplied socioeconomic status, medical history, behavior, and occupation data were included. Body mass index (BMI) category was calculated based on self-reported height and weight and divided into 5 groups; normal weight (BMI ≥ 18.5 to <25), overweight (BMI≥25 to <30), obesity class I (BMI ≥ 30 to <35), obesity class II (BMI≥35 to <40), and obesity class III (BMI≥40). Occupation was categorized into the 23 classifications based on the U.S. Department of Labor’s 2010 Standard Occupational Classification and Coding Structure, then merged into 12 industries. Outcomes included self-reported work productivity impairment (Work Productivity and Activity Impairment), and estimated annual indirect costs (lost work productivity and wages; indirect costs; U.S. Department of Labor). Separate generalized linear models (GLMs), controlling for sociodemographics and medical history covariates, were conducted for each industry.

RESULTS: Protective services (n = 1,176; 39.20%) had the largest percentage of obese respondents and science/engineering had the lowest (n = 1,949; 20.99%). For all 12 industries there was a significant difference (P < 0.05) in work productivity impairment and indirect costs between normal weight and at least one obesity class. Construction/Installation industry (n = 2,221) had the 6th highest number of obese individuals (n = 2,221; 29.18%), but had the highest level of work impairment (11.66 [normal weight] to 19.42 [obesity III]), whereas the legal industry (n = 738) had the 2nd lowest level of obese individuals (23.71%) and lowest level of work impairment (11.66 [normal weight] to 19.42 [obesity III]). The construction industry also had the highest indirect costs ($7,070.70 [normal weight] to $12,336.75 [obesity III]) while manufacturing/production (n = 2,350; 5th highest number of obese individuals) had the lowest ($23.70 [normal weight] to $1,097.40 [obesity III]).

CONCLUSIONS: Obesity impacts work impairment and indirect costs across all industries. In addition, industry may differentially affect this association. For example, the construction/installation industry, despite mid-ranked obesity prevalence, had the highest work impairment and indirect costs.

SPONSORSHIP: Supported by Vertex Pharmaceuticals.

S42 Journal of Managed Care & Specialty Pharmacy
E41 Clinical and Economic Impact of Hyperkalemia in Patients with Chronic Kidney Disease and Heart Failure
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1Magellan Rx Management; 2Relypsa

BACKGROUND: Hyperkalemia (HK) is a concern for patients with chronic kidney disease (CKD), heart failure (HF) and those who receive medications inhibiting the renin-angiotensin-aldosterone system (RAASi). Among hospitalized patients, HK may affect 20-40% of those with CKD and almost 20% of those with HF. This study evaluates the impact of HK on resource utilization in patients with CKD and HF.

OBJECTIVE: To evaluate the prevalence of HK in patients with CKD and/or HF and its impact on healthcare utilization and costs in a diverse cohort of commercially insured patients.

METHODS: This retrospective cohort study was conducted using medical and pharmacy claims from multiple regional health plans. Qualifying patients were ≥18 years old, continuously enrolled for 6 months prior and throughout study period (January 1, 2014 to December 31, 2015), and had a ICD diagnosis code of CKD and/or HF. Outcomes of health care utilization, including hospital length of stay, and associated costs were assessed by subgroups—patients with CKD only, with HF only, and with both conditions. Medians were used as summary measures due to skewed data distribution.

RESULTS: In this study of 17,462 patients, those with HK had higher median medical costs and lengths of stay than those without HK. Patients with both CKD and HF, treated with RAASi therapy, and diagnosed with HK were the most costly patients studied, with a median expenditure of $27,670 annually and an average LOS of 11 days. These patients cost $17,674 more than those without HK and remained hospitalized 4 days longer. Patients with HF and HK on RAASi therapy had a median cost of $23,237 and a median LOS of 6 days; $16,028 more and one day longer LOS than the median for patients without HK. Patients with CKD and HK cost $7,591 more than those without HK and had a LOS half a day longer. Those with CKD, HK and also on RAASi therapy had a LOS 2.5 days longer than those without HK that were also receiving RAASi therapy. For patients with CKD, including those currently receiving RAASi therapy, the medication sample had a positive effect on PDC for 90 days, with treatment patients having 72.8% adherent days and 35.1% for controls. At 180 days, PDC adherence was 57.1% for treatment patients vs. 35.4% for controls, and 43.6% vs. 33.9% for the 365-day period. PDC80 was significantly better among the treatment patients at 90 days, (53.5% vs. 31.2%, respectively), 180 days (38.4% vs. 29.1%), but not significant at 365 days (23.7% vs. 23.7%). Costs were reduced by $395 for the treatment group.

CONCLUSIONS: Patients were more likely to fill and adhere to prescriptions when given a free medication sample. This program can impact healthcare costs, as evidenced by lower costs for the treatment group.

SPONSORSHIP: This project was funded by MedVantx.

E42 Evaluating the Impact of Sample Medication on Subsequent Patient Adherence
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BACKGROUND: Medication nonadherence is problematic throughout healthcare practice. Efforts to improve adherence have been implemented, but new strategies are needed to ensure that patients fill medications and adhere to their prescribed use.

OBJECTIVE: To investigate if providing patients a free 30-day generic sample of their prescribed medication dispersed via a kiosk at the point-of-care had a measurable impact on patient adherence and healthcare costs.

METHODS: The population includes diverse patients with existing or new prescriptions for medications to treat diabetes, hypertension, and dyslipidemia drawn from the electronic health records of a large healthcare provider. The treatment group included patients who received a free 30-day sample of their prescribed medication and were compared against a control group matched on a number of criteria. The study outcome was Primary Medication Nonadherence (PMN), defined as whether a patient filled a new prescription within 90, 180 or 365 days of prescribing. Secondary Medication Adherence (SMA), measured as Proportion of Days Covered (PDC) and Proportion of Days Covered >80% (PDC80), was also examined. Propensity score methods and multivariate regression models were used to examine the outcomes and group differences. Cost data was represented using healthcare claims during the 365 days prior to and following the delivery of the sample or initial prescription. Key informant interviews of clinicians regarding the use of the sample kiosks were conducted and thematic analysis performed.

RESULTS: Patients who received a 30-day generic medication sample had a higher probability of filling a first prescription within 90 days (72.2% for treatment patients vs. 37.6% for controls), 180 days (79.1% vs. 43.3%, respectively) and 365 days (85.5% vs. 48.6%, respectively). The medication sample had a positive effect on PDC for 90 days, with treatment patients having 72.8% adherent days and 35.1% for controls. At 180 days, PDC adherence was 57.1% for treatment patients vs. 35.4% for controls, and 43.6% vs. 33.9% for the 365-day period. PDC80 was significantly better among the treatment patients at 90 days, (53.5% vs. 31.2%, respectively), 180 days (38.4% vs. 29.1%), but not significant at 365 days (23.7% vs. 23.7%). Costs were reduced by $395 for the treatment group. Interviews with clinicians indicated a positive view of the program.

CONCLUSIONS: Patients were more likely to fill and adhere to prescriptions when given a free medication sample. This program can impact healthcare costs, as evidenced by lower costs for the treatment group.

SPONSORSHIP: Research funded by Relypsa.

E43 Evaluation of Prior Authorization Requests for Alirocumab and Evolocumab at a PPO Health Plan
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Blue Cross Blue Shield of Michigan

BACKGROUND: Alirocumab and evolocumab were FDA-approved in summer 2015 as adjunct treatment of familial hypercholesterolemia (FH) and clinical atherosclerotic cardiovascular disease (ASCVD), based on their ability to significantly reduce low density lipoprotein cholesterol (LDL-C). Studies to support cardiovascular risk reduction are in progress. Guidelines recommend statins as first line therapy in FH and ASCVD since cardiovascular risk reduction is well documented, with ezetimibe and bile acid sequestrants (BAS) as options for adjunct therapy. While statins have been the mainstay, intolerance is highly reported in the community. Alirocumab and evolocumab could significantly impact health plans financially, despite lack of cardiovascular risk reduction data.

OBJECTIVE: To examine baseline treatment of members requesting prior authorization (PA) of alirocumab and evolocumab and effects on LDL-C among those approved for therapy.

METHODS: Retrospective review of commercially insured members with Blue Cross Blue Shield of Michigan pharmacy benefit requesting alirocumab and evolocumab from July 24, 2015 to June 30, 2016 was conducted. Member demographics, diagnoses, current medications and intolerances, lifestyle modifications, LDL-C, and PA approval status were analyzed using pharmacy claims data and PA requests.
submitted by prescriber offices. Approved PAAs were reviewed for repeat LDL-C after two to three months of therapy.

RESULTS: A total of 284 PA requests were received, with 272 (95.8%) being denied initially. Ninety-six cases were appealed, with 63 (65.6%) denied. After a denied appeal, one case was escalated for external review, and the denial was upheld. Diagnoses included clinical ASCVD (55.6%), heterozygous FH (3.9%), and homozygous FH (0.4%). Off-label use was requested among 40.1% of cases. Baseline therapy included maximal dose of high-intensity statin (10.6%), ezetimibe (22.9%), and BAS (6.7%). Intolerances to statins (75.7%), ezetimibe (22.5%), and BAS (9.5%) were reported. Ninety-one members (32.0%) had documented lifestyle modifications. Forty-five members (15.8%) were initiated on therapy with samples. Average LDL-C was 160.5 mg/dL (range 38-357 mg/dL) among patients with a submitted LDL-C (n=228). A total of 25 approved cases had repeat LDL-C available (average 73.1 mg/dL, range 12-191.3 mg/dL), representing average LDL-C reduction of 60% (range 32.6-90.0%).

CONCLUSIONS: Guideline recommendations were not consistently followed among members requesting alirocumab and evolocumab. Documented LDL-C reductions were in accordance with packaging labeling.

SPONSORSHIP: Blue Cross Blue Shield of Michigan.

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The Economic Burden of Calcium Kidney Stones in the United States

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BACKGROUND: Kidney stones are a highly prevalent metabolic disease, approximately 80% of patients form calcium-based stones and have limited therapeutic treatments. Current prevalence and cost estimates have not traditionally reflected the intermittent, yet recurrent, nature of the disease.

OBJECTIVE: To better understand the epidemiology and medical costs associated with calcium kidney stones in the U.S., and to identify patient sub-segments for emerging treatments in clinical development.

METHODS: We developed a Markov Model to estimate and project the U.S. calcium kidney stone incidence, prevalence, and associated direct medical costs. Model parameters were derived from published literature, national procedure databases and fee schedules, Optum Claims, and clinician interviews. Literature-based incidence and prevalence estimates were used to establish a 20-year baseline patient population (from 1995-2015) which was then forecasted to 2035 with population growth rates and published disease incidence growth rates. Interviews with stone disease KOLs, nephrologists and urologists were used to segment patients by rate of occurrence and likelihood to form kidney stones in an “episodic year.” Using a best-fit model approach, fast-recurring patients were defined as having at least three episodes per episodic year and a 30% chance of annual recurrence. Treatment paradigms informed weighted-average cost attribution to estimate the direct medical costs per patient in each patient segment. The average cost was multiplied by annual episode frequency to calculate the total annual direct medical costs to the U.S. healthcare system. Model outputs were validated against published reports of U.S. stone incidence and prevalence, and sensitivity analyses were conducted to assess the impact of selected variables on model outcomes.

RESULTS: We estimated that 17.8 million patients were affected by calcium kidney stones in 2016, with 3.1 million experiencing stone episodes. While fast-recurring patients account for approximately 5% of patients, they account for 10% of associated healthcare costs. Average direct medical costs per episode in the year treated were estimated at $6,900, with 42% of costs attributed to complications from treatment. In total, the 2016 direct medical cost of calcium kidney stones in the U.S. was estimated to be approximately $23.3 billion, and is expected to grow to $70 billion by 2035.

CONCLUSIONS: Calcium kidney stones represent a significant and growing cost burden to the U.S. healthcare system. There is a high unmet need for effective prophylactic treatments.

SPONSORSHIP: Allena Pharmaceuticals.

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Budget Impact Analysis of Eliglustat for Treatment of Gaucher Disease Type 1 in the United States

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BACKGROUND: Current therapeutic options for Gaucher Disease Type 1 (GD1) include intravenous enzyme replacement therapy (ERT) with imiglucerase, velaglucerase alfa, or taliglucerase alfa or oral substrate reduction therapy with eliglustat or miglustat. Transfer of patients from ERT to eliglustat may present an opportunity for cost savings.

OBJECTIVE: To evaluate the budget impact associated with increased utilization of eliglustat for the treatment of adults with GD1.

METHODS: A budget impact model reflecting the U.S. payer perspective calculated the change in pharmaceutical and administration costs resulting from increasing eliglustat market share from 12% (current) to 44% (hypothetical). Eliglustat market share was drawn equally from existing shares of imiglucerase (40%) and velaglucerase alfa (40%) and assumed to be static over the analysis period. Unit costs were obtained from Redbook (WAC), 2016: Eliglustat and miglustat costs were $850/day and $894/day respectively with annual costs calculated assuming 92.3% adherence. ERT WAC costs were adjusted to account for site of care-based markup and the proportion of patients receiving infusions in each site of care: home, 36%; physician office, 32%; hospital outpatient, 32%, with 20%, 25% and 100% markup respectively based on a typical large regional health plan. Derived costs to a payer were $2,334.59/400 U vial for imiglucerase, $2,026.94/400 U vial for velaglucerase and $1,478.35/200 U vial for taliglucerase alfa. Annual ERT costs were calculated assuming a dose of 474 U/Kg, a 72 kg patient, and 24 infusions/year. Administration costs were obtained from analysis of claims (DataMart Multiplan). All costs expressed in 2016 USD.

RESULTS: In a plan with 5 million members and 25 treated patients with GD1, increased utilization of eliglustat resulted in total 3-year savings of $4.5M (13.6%) to the plan. The corresponding per member per month (PMPM) savings were $0.025. Assuming eliglustat uptake is drawn exclusively from the hospital outpatient setting with pharmaceutical costs reweighted based on the revised proportions in each site of care, total savings increased to $5.17M (15.3%) and PMPM savings increased to $0.029. Results were sensitive to proportion of patients receiving infusions at each site of care.

CONCLUSIONS: Based on these analyses, increased utilization of eliglustat resulted in meaningful cost savings to a payer’s overall budget. Cost savings are highest among patients switching from ERT administered in a hospital outpatient setting.

SPONSORSHIP: This study was sponsored by Sanofi Genzyme.
F02  Real-World Evidence: Buprenorphine Adherence Predictive of Reduced Risk of Opioid Relapse

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BACKGROUND: Adherence to buprenorphine medication assisted therapy (BMAT) has been associated with reduced relapse in opioid use disorder (OUD) patients, but few studies have assessed the impact of low, intermediate, and high adherence on relapse outcomes.

OBJECTIVE: To examine the impact of BMAT adherence on relapse after BMAT initiation in a real-world sample of OUD patients.

METHODS: OUD patients initiating a new BMAT episode between 2008-2014 were identified in the MarketScan Commercial and Medicaid claims databases (earliest BMAT claim = index date). Patients were followed for 6 months post-index and at least 12 months post-index. Adherence was measured over 12 months post-index using proportion of days covered (PDC) and was grouped into categories: <20%, 20-39%, 40-59%, 60-79%, and ≥80%. Relapse and time to relapse were identified in the 12 months post-index and at any time following index using service-based relapse proxies.

RESULTS: 16,085 Commercial and 5,688 Medicaid patients qualified for the analysis. Commercial patients in each of the lower PDC groups had significantly increased odds of relapse in the 12 months post-BMAT initiation compared to patients with PDC ≥80% (<20%: OR = 2.80, 20-39%: OR = 2.84, 40-59%: OR = 1.88, 60-79%: OR = 1.60; all P < 0.001). Medicaid patients in the lower PDC groups also had significantly increased odds of relapse in the 12 months post-index compared to patients with PDC ≥80% (<20%: OR = 2.27, 20-39%: OR = 1.95, 40-59%: OR = 1.62, 60-79%: OR = 1.66; all P < 0.001). The CPHM model showed that Commercial patients in each of the lower PDC groups had a significantly higher hazard of relapse any time after BMAT initiation than those with PDC ≥80% (<20%: HR = 1.96, 20-39%: HR = 2.02, 40-59%: HR = 1.77, and 60-79%: HR = 1.57, all P < 0.001). Similarly, in the Medicaid sample, the model showed there was a significantly higher hazard of relapse any time after BMAT initiation in the lower PDC groups compared to PDC ≥80% (<20%: HR = 1.45, 20-39%: HR = 1.48, 40-59%: HR = 1.35, and 60-79%: HR = 1.28, all P < 0.05).

CONCLUSIONS: This study assessed relapse risk across the adherence continuum, finding that OUD patients with all lower levels of BMAT adherence had significantly increased risk of relapse compared to adherent patients (PDC ≥80%), providing further evidence that BMAT adherence is associated with better outcomes.

SPONSORSHIP: Research was funded by Indivior.

F03  Addressing the Risk of Opioid Abuse in Medicare Members: The Development, Implementation, and Evaluation of a Pilot Educational Intervention for Providers

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BACKGROUND: A predictive model of opioid abuse was previously developed, validated, and published. It is unknown whether educational interventions using this model to identify members at risk can impact opioid use and associated outcomes.

OBJECTIVE: To evaluate whether a pilot educational intervention for providers of members at risk for opioid abuse had any impact on opioid use and associated outcomes.

METHODS: Humana Medicare members at risk for opioid abuse were identified from 7/1/2012-4/30/2014, based on a published predictive model. Members were linked to their opioid-prescribing providers, and providers were randomly assigned using a factorial design to one of the following mailings: Arm 1: member information; Arm 2: links to educational materials for diagnosis and management of pain; Arm 3: both member information and links to educational materials; and Arm 4: no intervention. Difference-in-difference analyses (91-270 days post-intervention vs. 180 days pre-intervention) compared opioid and pain medications prescribed, morphine-equivalent dosing, uncoordinated opioid use (>3 opioid prescriptions by ≥3 prescribers in any 90-day period), and other utilization and cost measures. Logistic regression examined differences in the diagnosis of opioid abuse between cases and controls post-index.

RESULTS: Mean age in the four arms ranged from 57.3 to 58.7 years (P = 0.1990 between arms). There were no significant differences between arms in gender, race or geographic region (all P > 0.10). 84.7% of members had ≥1 psychiatric diagnoses during pre-index (P = 0.8862 between arms), yet only 9.3% had ≥1 visits with a mental health specialist (P = 0.5326 between arms). The interventional mailings had no statistically significant impact on numbers of opioid or pain medications prescribed, morphine-equivalent dosing, uncoordinated opioid use, ER visits, mental health specialist visits, healthcare costs, or rate of diagnosed opioid abuse. However, a steady decline in number of opioid prescriptions was observed from 10/2013 to 12/2015 for both cases and controls (cases: 3,563 to 2,573, controls: 3,132 to 2,192, P = 0.7130).

CONCLUSIONS: The educational mailings had no significant impact on opioid or pain prescription use, or other utilization and cost measures for cases relative to controls. Despite a decline in opioids prescribed, the rate of diagnosed opioid abuse remained steady, indicating the need for different, more impactful interventions. These future interventions may benefit with a focused approach for both behavioral health and pain management.

SPONSORSHIP: This abstract was sponsored by the Humana-Pfizer Research Collaboration.

F04  Diagnosis-Level Drivers and Trajectory of Excess Costs Prior to and After Diagnosis of Opioid Abuse

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BACKGROUND: Prior research has found that opioid abuse/dependence/poisoning (“abuse”) is associated with substantial excess healthcare costs, with estimates ranging from approximately $10,000 to $20,000 per patient-per-year. Little is known, however, about the specific drivers of these excess costs and their evolution prior to and after an abuse diagnosis.

OBJECTIVE: To evaluate the drivers of the excess costs of opioid abuse among a commercially insured population, as well as to assess the monthly pattern of excess costs in the months before and after an incident diagnosis.

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**METHODS:** Using the de-identified OptumHealth commercial claims database for a large number of employers, we selected patients ages 18-64 whose first observed diagnosis of opioid abuse (ICD-9-CM diagnosis codes: 304.0x, 304.7x, 305.5x, 965.00, 965.02, 965.09) occurred in Q1/2012-Q1/2015. The study period was defined as the 12-month period centered on the first abuse diagnosis and was preceded by a 6-month baseline period. Abusers were matched to Non-abuser controls using propensity score methods. Excess costs were calculated as the mean difference between healthcare costs of abusers and controls, in 1-month and 6-month increments. Primary cost drivers were identified by grouping medical claims at the 3-digit ICD-9-CM level within 6-month increments, overall and by place of service.

**RESULTS:** Excess costs in the abuser cohort began to rise from $254 per-patient-per-month 5 months before the abuse diagnosis to $1,119 in the month prior to the abuse diagnosis. Excess costs peaked in the month of the abuse diagnosis at $6,010. While excess costs decreased in subsequent months, they continued to be elevated in the 6 months post-diagnosis. 47% of excess costs during the 6-months prior to the incident diagnosis were attributable to non-opioid substance and alcohol abuse and dependence. In the 6 months following the index event, treatment specifically for opioid abuse was the leading driver of incremental cost (39%), with a large proportion of costs (32%) still associated with treatment for alcohol and non-opioid drug abuse.

**CONCLUSIONS:** Our findings highlight the complex nature of opioid abuse, which often occurs in the context of other substance abuse. We document a rising trend in excess costs among opioid abusers even prior to the medical event leading to their diagnosis, with a substantial share of those costs associated with non-opioid drug and alcohol abuse treatment.

**SPONSORSHIP:** This study was funded by Purdue Pharma.

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**SM4**

Prevalence and Treatment Patterns in Patients with Alcohol Use Disorder

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**BACKGROUND:** Alcohol use disorders (AUD) comprise alcohol abuse and alcohol dependence and are highly prevalent in the United States.

**OBJECTIVE:** To determine the period prevalence of AUD, describe clinical characteristics and treatments patterns in patients with AUD, and assess characteristics of providers who prescribe medication assisted therapy (MAT).

**METHODS:** De-identified claims data from the HealthCore Integrated Research Database were used in this analysis. Prevalence was defined based on ≥ 1 claim(s) with a diagnosis code for AUD (ICD-9-CM codes 303.xx and 305.xx) during January 1, 2006 to December 31, 2014 (study period). Patients were required to have ≥ 2 days of medical and pharmacy enrollment to be included in the prevalence estimation. The earliest period of an AUD diagnosis during the study period was set as the index date, and patients who were continuously enrolled for a period of ≥ 12 months prior to the index date and ≥ 6 months post-index date and after the first claim for MAT (naltrexone, disulfiram, or acamprosate; follow-up) were included in the treatment pattern analysis.

**RESULTS:** Annual period prevalence of AUD increased by 52.2%, from 4.81 per 1,000 commercially insured adults in 2006 to 7.32 per 1,000 in 2014. Among 167,976 AUD patients, 63.4% were male, mean (±SD) age was 43 (±17.1) years, Elixhauser Comorbidity Index score was 1.18 (±1.70), and prevalence of alcohol-related conditions was < 1%. Co-morbid psychiatric diagnoses were common. Only 3.6% of AUD patients had ≥ 1 claim for any MAT during 6 months of follow-up, and mean time to the first MAT fill in the follow-up period was 32.6 (±45.0) days. Within 6 months of the first MAT claim, 91.9% discontinued MAT. Adherence to MAT based on medication possession ratio ≥ 80% was highest among patients prescribed naltrexone (10.4% for oral and 10.3% injectable vs. 7.6% disulfiram and 5.0% acamprosate). Among 207,689 (69.7%) providers with available specialty data, the most common physician specialties treating AUD patients were primary care (21.5%) and internal medicine (14.8%), although 32.0% were non-physicians.

**CONCLUSIONS:** The prevalence of AUD increased by more than 50% during the 9-year study period, although rates of MAT use and adherence to MAT remained low among AUD patients. These results suggest that there is room for improvement to increase adherence to MAT as a component of AUD treatment, which may be achieved through education and advocacy.

**SPONSORSHIP:** This study was funded by Alkermes.
**F07 Stocking and Dispensing of Opioids and Related Medications: A Survey of Community Pharmacists in a High-Abuse Region**

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**BACKGROUND:** Opioid misuse and abuse is a health crisis in the United States. In 2015, West Virginia led in deaths from prescription drug overdose—32.4 per 100,000 inhabitants, twice the national average. Pharmacists are in a unique position to affect prescription drug abuse in communities across the country.

**OBJECTIVE:** To determine pharmacist’s real-world stocking and dispensing practices regarding opioid medications prescribed for pain management and/or opioid use disorder in the Appalachian region.

**METHODS:** The current study design was a cross-sectional survey of non-retired, licensed pharmacists working in a community setting. Surveys were distributed at live continuing pharmacy education sessions across the state of West Virginia. Data was imported into SPSS Version 22.0 for analysis. To compare the groups for differences in demographics, stocking, dispensing, and other perceptions by type of pharmacy in which the pharmacist worked, chi-square tests were performed.

**RESULTS:** Of 109 community pharmacist respondents, 56% were male, mean age was 48.8 (SD = 13.0) years, and the median decade of first licensure was 1991-2000. West Virginia was the primary state of employment for 81.7% of the respondents. All represented pharmacies stocked opioids, 74.8% of pharmacists stocked buprenorphine/naloxone, and 53.3% stocked buprenorphine. Pharmacists responded that in the previous week, 29.6% declined to fill an opioid prescription out of concern it was fraudulent and 48.1% declined because they feared it was not for a legitimate medical purpose. When asked about willingness to dispense an opioid prescription written by an out-of-state provider, 37.0% of pharmacists said that they would not dispense. That number increased to 57.1% for pharmacists refusing out-of-state buprenorphine/naloxone or buprenorphine if they stocked those products. The majority of pharmacists (84.4%) agreed that opioids were overprescribed in their county, and 71.5% felt that by declining to fill certain prescriptions they were curbing opioid diversion and/or abuse.

**CONCLUSIONS:** A notable portion of pharmacists in the region are hesitating to dispense opioid medications prescribed for pain management and/or opioid use disorder. This practice may decrease the flow of potentially abused drugs into the community, but may not be a sufficient solution for the opioid epidemic and appropriate treatment of patients with pain or opioid use disorder. As a next step, these results will be demographically weighted to improve generalizability so that it can be used to support statewide education materials.

**SPONSORSHIP:** CareSource.

**F08 Provider Intervention Reduces High-Dose Opioid Prescribing in a Health Plan’s Chronic Pain Population**

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CareSource

**BACKGROUND:** Opioid use, both prescribed and non-prescribed, is a proven potential gateway to substance use disorder (SUD), heroin addiction, and overdose-related death. Given limited evidence to support chronic, non-cancer pain therapy with opioids and the modern escalation of opioid SUD, efforts to reduce quantities of opioid units (any dosage form) in public circulation is a viable public health strategy.

**OBJECTIVE:** Even though high-dose daily opioid use is variably defined, interventions to identify and inform providers on outlier prescribing behaviors may lead to fewer units available for abuse or diversion in the public domain, better quality of life, and decreased mortality.

**METHODS:** CareSource, a health plan with 1.2 million Medicaid members in Ohio, matched the 90th percentile of its members prescribed opioids at or above 200 mg daily morphine equivalent daily dose (MED) to their respective prescribing providers. With data from retail pharmacy dispensing, members were stratified into coordinated and uncoordinated care, depending on the number of prescribing providers for an individual member. A strategy of tiered interventions for high-dose outlier prescribers communicated a de-identified comparison of their practice to other providers. Five possible interventions were offered over 270 days from the date of initial letter, including de-identified comparison information, peer-to-peer discussion, medication therapy management, loss of gold-card status (related to prior authorizations), and a quality improvement intervention. Communications included instructions for safe and effective medication taper.

**RESULTS:** In one-on-one discussions, providers reported that they generally appreciated health plan support in providing guidance, particularly where contentious member feedback opposed a reduction in high-dose prescribing.

**CONCLUSIONS:** 266 physicians represented the 90th percentile by prescribing doses above 200 mg MED during the three months ending in October 31, 2015. Letters and conversations started in November, 2015. For the three months starting January 1, 2016, that group reduced mean daily MED by 50 mg (16% reduction), and represented 1.4 million MED (85,000 dosing units) for the entire group. Health plans play a key role in population health for members with chronic pain or SUD, and can favorably influence opioid risk management for members, providers, and society. Implementing a program to inform providers of their outlier status around opioid prescribing is a persuasive trigger to accomplish improvements supported by tiered interventions.

**SPONSORSHIP:** CareSource.

**F09 Adherence, Persistence, and Inpatient Utilization Among Adult Schizophrenia Patients Using Once-Monthly Versus Twice-Monthly Long-Acting Antipsychotics**

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**BACKGROUND:** The effectiveness of antipsychotics (APs) is associated with achieving and maintaining thresholds of dopamine receptor occupancy in the brain. Receptor occupancy levels decline more slowly with longer apparent half-life. This slower decline is hypothesized to correspond to a delay in clinical deterioration.

**OBJECTIVE:** To compare real-world treatment patterns and inpatient utilization, an indicator of clinical decline, between schizophrenia patients stabilized on treatment with once-monthly (OM) long-acting injectable antipsychotics (LAI) versus twice-monthly (TM) LAI.

**METHODS:** Six states Medicaid data (01/2009-03/2015) were used. Adult schizophrenia patients with ≥2 consecutive claims of OM LAI (paliperidone palmitate or aripiprazole) or TM LAI (risperidone) within 45 days with the same dosage and days supplied were selected. Patients had ≥6 months of eligibility prior to OM or TM LAI initiation and were observed from the second consecutive claim (index date) to the end of data availability. Outcomes were measured for 12 months.
after the index date. Multivariate generalized linear regression models adjusting for cohort differences were used to compare incidence rate ratios (IRR) for inpatient utilization and proportion of days covered (PDC) for adherence. Persistence was defined as the duration on index LAI without gap > 60 days between covered days and was assessed using Kaplan-Meier medians and adjusted hazard ratio (HR). No adjustments were made for multiplicity.

RESULTS: A total of 785 OM and 625 TM patients were selected. OM patients were younger (40 vs. 42 years, \(P = 0.02\)) and were more likely to be males (68% vs. 63%, \(P = 0.04\)) compared to TM patients. In the post-index year, fewer OM patients had ≥ 1 admission (29% vs. 38%, \(P < 0.01\)). After adjustments, OM patients had 27% fewer admissions (adjusted IRR: 0.73, \(P < 0.01\)) and 46% fewer inpatient days (adjusted IRR: 0.54, \(P < 0.01\)). The 12-month adherence was higher for OM versus TM patients (mean PDC 0.56 vs. 0.50, adjusted difference in PDC: 0.06, \(P < 0.01\)). OM patients had a lower hazard of discontinuation (adjusted HR = 0.83, \(P = 0.01\)), and a longer median persistence (7.5 vs. 5.5 months, log-rank test: \(P < 0.01\)) compared to TM patients.

CONCLUSIONS: In the year following stabilization, treatment with OM LAI was associated with greater adherence, higher persistence, and lower inpatient utilization than treatment with TM LAI. Future research is warranted to examine the direct and adherence-mediated relationships between AP pharmacology including frequency of administration and health outcomes.

SPONSORSHIP: Supported by Janssen Scientific Affairs.

F11 Predictive Models to Identify Future High-Cost Schizophrenic Patients Using High Dimensional Administrative Data

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Background: Schizophrenia is a chronic illness that has disproportionately high costs. Identification of potentially high-cost schizophrenic patients can help providers and case managers more effectively allocate resources and appropriately monitor high-risk patients. Various risk-adjustment models like Centers for Medicare and Medicaid Services Hierarchical Condition Categories Risk Adjustment (CMS-HCC) model are available to estimate future cost spend. However, limited work has been conducted to further risk stratify and predict individual patients future cost for the schizophrenic population.

Objective: To develop and evaluate predictive models for the identification of future high cost schizophrenic patients, and assessed the value of different patient characteristics captured in administrative data for cost prediction.

Methods: This study used a payer administrative claims database cohort of 97,862 patients diagnosed with schizophrenia from January 2009 to June 2014. Three models (baseline, intermediate, final) were developed to assess the value of different variable categories for cost prediction (demographics, insurance type, cost, healthcare utilization, antipsychotic medication usage, and clinical conditions). The three models developed on a training cohort (n = 34,510) were assessed in a separate evaluation cohort (n = 30,077) using the regression R², patient classification accuracy (PCA), and cost accuracy (CA). The final model achieved 0.23 R², 43% PCA, and 63% CA, in contrast, the CMS-HCC model achieved 0.09 R², 27% PCA with 45% CA. The final model identified 11% more of total cost compared to CMS-HCC model at the top 10% cost cutoff (33% vs. 22%).

Conclusions: This study showed that, using advanced feature selection and machine learning methods, there was significant improvement in the ability to predict and identify high cost schizophrenic patients than that predicted by the CMS-HCC Risk Adjustment model. We also demonstrated the added prediction power that could be achieved by leveraging detailed clinical and medication utilization features.

Sponsorship: Research was sponsored by ODH.

F12 Quality Measure Attainment Among Adults Diagnosed with Schizophrenia Treated with Paliperidone Palmitate or Oral Atypical Antipsychotics

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Background: The Healthcare Effectiveness Data and Information Set (HEDIS) includes quality measures related to antipsychotic (AP) medication adherence for patients with schizophrenia and timely outpatient follow-up after discharge for a mental health-related (MHR) hospitalization. HEDIS quality measure attainment may differ for patients treated with once-monthly paliperidone palmitate (PP1M) compared to those treated with oral atypical antipsychotics (OAA).

Objective: To compare quality measure attainment between schizophrenia patients initiated on PP1M or OAA.

Methods: Medicaid data from IA, KS, MS, MO, and NJ (09/2008-03/2015) were used to identify adults with schizophrenia initiated on PP1M or OAA (index date) on or after 09/2009. Baseline characteristics, assessed during the 12 months pre-index, were compared between groups using standardized differences. Quality measures, assessed during the 12 months post-index period, included the proportion of patients with the proportion of days covered (PDC) ≥80% by the index medication or by any AP medication, and the rates of MHR rehospitalization and MHR follow-up outpatient visit within 30 days of the first post-index MHR inpatient discharge. Attainment of quality measures was compared using chi-square tests.

Results: Overall, patients initiated on PP1M (N = 2,053) were younger (mean age: 41 vs. 44 years, standardized difference: 19.8%), less likely to be female (39.2% vs. 50.8%, standardized difference: 23.6%), and more likely to have used APs at baseline (87.8% vs. 61.8%, standardized difference: 62.8%) compared to OAA patients (N = 22,247). During the 12 months post-index, PP1M patients were more likely to be adherent to index AP medication (PDC ≥80%: 30.4% vs. 22.7%, \(P < 0.001\)) and to any AP medication (44.8% vs. 37.9%, \(P < 0.001\)) compared to OAA patients. Among patients with ≥1 MHR inpatient visit during the 12 months post-index (PP1M vs. OAA: 35.6% vs. 42.6%, \(P < 0.001\)), fewer PP1M patients had a 30-day MHR rehospitalization (22.6% vs. 26.0%, \(P = 0.040\)) while a higher proportion of PP1M patients received a 30-day MHR follow-up visit following discharge (73.2% vs. 64.0%, \(P < 0.001\)), as compared to OAA patients.

Conclusions: Adults diagnosed with schizophrenia and treated with PP1M showed better quality measure attainment, as they were more likely to be adherent to AP medication, less likely to have a MHR rehospitalization, and more likely have a follow-up outpatient visit after a MHR inpatient stay compared to those treated with OAA.

Sponsorship: Supported by Janssen Scientific Affairs.
F13 Medicaid Spending and Healthcare Resource Use in Patients with Schizophrenia Using Second-Generation Long-Acting Injectable Versus Oral Atypical Antipsychotics

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BACKGROUND: The use of second-generation (atypical) long-acting injectable therapies (SG-LAI) over daily oral atypical antipsychotics (OAA) may reduce healthcare costs and healthcare resource use (HRU) in schizophrenia patients due to less frequent administration and improved adherence.

OBJECTIVE: To compare Medicaid spending and HRU in schizophrenia patients initiating SG-LAI (overall and by type of SG-LAI) versus OAA.

METHODS: Medicaid claims data (2010-2015) from six states were used to identify adult patients with schizophrenia initiated on a SG-LAI or OAA. Adherence (proportion of days covered [PDC] ≥ 80%) to index agent, costs and HRU were measured over a 12-month follow-up. Costs and HRU were compared using ordinary least squares and Poisson regression models, respectively, adjusted for differences in baseline characteristics, and using a non-parametric bootstrap procedure for P value calculation. Costs were expressed in 2015 U.S. dollars and reflect the Medicaid payer’s perspective before any rebate.

RESULTS: Overall, 3,307 and 21,355 patients initiated SG-LAI and OAA, respectively. SG-LAI patients initiated paliperidone palmitate LAI (PPLAI; N = 2,182), risperidone LAI (RLAI, N = 968), aripiprazole LAI (ALAI; N = 108), and olanzapine LAI (OLAI, N = 49). During follow-up, SG-LAI patients were more adherent to the index medication than OAA patients (PDC ≥ 80%: 31% vs. 28%, P < 0.001), which appeared to be driven by PPLAI patients (PDC ≥ 80%: 33% vs. 28%, P < 0.001). Adherence among ALAI and RLAI patients was similar to OAA. Relative to OAA patients, SG-LAI patients had fewer long-term care days (incidence rate ratio [IRR]: 0.75, P < 0.001), and home care visits (IRR: 0.75, P < 0.001). SG-LAI patients had more mental institutional admissions (IRR: 1.16, P < 0.001) and one-day mental institutional admissions (IRR: 1.16, P < 0.001) versus OAA. Moreover, PPLAI was associated with fewer inpatient days (IRR: 0.78, P = 0.004) versus OAA. Overall, SG-LAI patients had lower medical costs (mean monthly cost difference [MMC]: -$168, P < 0.001) than OAA patients, offsetting more than half of the higher pharmacy costs (MMC: $271, P < 0.001). Compared to OAA, PPLAI was associated with significant medical cost savings (MMC: -$22, P < 0.001), whereas costs were similar for RLAI (MMC: -$73, P = 0.269) and ALAI (MMC: $28, P = 0.982) patients.

CONCLUSIONS: Compared to Medicaid beneficiaries with schizophrenia initiating OAA, those initiating SG-LAI, specifically PPLAI had lower medical costs and improved adherence, while no differences were observed for RLAI and ALAI.

SPONSORSHIP: Supported by Janssen Scientific Affairs.

F14 Characteristics and Healthcare Resource Utilization of Medicaid Superutilizers with Schizophrenia

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1Janssen Scientific Affairs; 2Magellan Rx Management

BACKGROUND: Research has shown that a relatively small group of patients account for a disproportionately large share of healthcare resource utilization within a Medicaid plan. The term “superutilizer” has been applied to the set of Medicaid patients with 4 or more hospital admissions per year. In this study we examine superutilizer status among patients with schizophrenia in a Medicaid population.

OBJECTIVE: To describe and compare patient characteristics and healthcare resource utilization between schizophrenia patients meeting superutilizer criteria and those who do not.

METHODS: This retrospective study analyzed data from Magellan Health Services claims database for patients continuously enrolled in a managed Medicaid plan for the study period (10/1/14-9/30/15). Qualifying patients were ≥ 18 years old, had at least 2 paid claims for an antipsychotic medication, and a diagnosis of schizophrenia. Patient demographics, clinical conditions and healthcare resource utilization were compared using chi-square tests and t-tests for categorical and continuous variables, respectively.

RESULTS: Of the 2,273 patients meeting study criteria, 419 (18.4%) were superutilizers. Superutilizers were similar in age to non-superutilizers (~42 years) and predominantly male (64.9% vs. 53.4%, P < 0.001). Superutilizers had a greater medical comorbidity burden, shown by higher inpatient Charlson Comorbidity Index (2.23 vs. 0.60, P < 0.001), and greater substance abuse comorbidity (74.7% vs. 25.6%, P < 0.001). About half (49%) of non-superutilizers had zero inpatient admissions in the study period, while 46.8% of superutilizers had 7 or more hospitalizations with mean length of stay of 5.5 days. Superutilizers accounted for 74% of all inpatient days and averaged (mean [SD]) more hospital days over the 12 month period than non-superutilizers (39.5 [26.9] vs. 8.1 [8.0]). A majority of superutilizers (55.8%) had at least one emergency department visit during the study period versus only 15.9% of non-superutilizers (P = 0.009).

CONCLUSIONS: Medicaid superutilizers with schizophrenia have greater medical and psychiatric comorbidities and consume a disproportionate share of emergency and inpatient healthcare resources. Identification of superutilizers and development of effective interventions may help Medicaid plans achieve improved outcomes for these patients and more effectively manage total treatment costs.

SPONSORSHIP: Research was funded by Janssen Scientific Affairs.

F15 Concomitant Prescribing of Antipsychotics and Antidepressants Among Patients with Schizophrenia Initiating Long-Acting Injectable Antipsychotics: A Medicaid Perspective

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BACKGROUND: Long-acting injectable antipsychotics (LAIs) are indicated as monotherapy for schizophrenia. Despite the lack of clinical justification, anecdotal evidence suggests that physicians often supplement LAI treatment with oral antipsychotics (APs) or antidepressants (ADs).

OBJECTIVE: To examine real-world treatment patterns associated with the use of LAIs, specifically, concurrent use of oral APs (typical and atypical) and ADs during LAI treatment.

METHODS: The MarketScan Multi-State Medicaid databases were used in the analysis. Adults (≥ 18 years) with schizophrenia initiating LAI treatment between 1/1/2013 and 6/30/2015 were identified: aripiprazole (LAI-AZ; n = 2155, 55% male, mean ± SD age 37.7 ± 12.3), risperidone (LAI-AL; n = 3,329, 61% male, age ≥ 42 ± 13.8), or paliperidone palmitate (LAI-PP; n = 9,059, 61% male, age 39.8 ± 12.8). A majority of superutilizers (55.8%) had at least one emergency department visit during the study period versus only 15.9% of non-superutilizers (P = 0.009).
A case-control analysis was conducted using a U.S. nation-
ally representative National Health and Aging Trends Study Database. Approximately 44%, 61% and 51%, of LAI-AZ, LAI-RS and LAI-PP patients respectively, had multiple treatment episodes. At least half of the patients (54%-68%) were prescribed an oral AP concomitantly with the index LAI. Rates of oral AP prescription were also high when examined by individual treatment episodes (48%-60%) and by injections within each episode (37%-51%). Mean ± SD duration of concomitant oral AP prescribing per injection was 8.7±12.2 days for LAI-AZ, 6.6±6.7 days for LAI-RS and 9.5±12.5 days for LAI-PP. Concomitant use of typical APs was low (12%-16% of patients, 10%-12% of episodes, 7%-9% of injections), however, use of atypical APs was substantial: 32%-46% of patients, 27%-36% of episodes, 22%-29% of injections. Antidepressants were co-prescribed in 47%-54% of patients, 40%-49% of episodes and 38%-43% of injections. Concomitant use of either an oral AP or AD was noted in a majority of patients prescribed an LAI (74%-78%) and nearly two-thirds of treatment episodes (66%-72%) and injections (59%-65%).

CONCLUSIONS: The high level of concurrent prescribing of oral APs and ADs with LAIs observed in our study is noteworthy. The reason for and implications of these prescribing patterns warrant further evaluation, and might suggest the need for clinician education in the use of LAIs or might be indicative of suboptimal efficacy of existing LAI treatments.

SPONSORSHIP: Research was funded by Alkermes.

RESULTS: Pain and manifestations of pain, including increased pain medication consumption, was associated with insomnia in older adults in the U.S. Improved strategies to diagnose and manage pain should be explored to reduce and potentially preempt insomnia.

SPONSORSHIP: None.

F19 Clinical Characteristics and Treatment Patterns of Patients with ADHD Initiating Therapy on Quillivant XR: A Retrospective Database Analysis

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BACKGROUND: Quillivant XR, the first extended-release oral suspension of methylphenidate, was approved for the treatment of ADHD in children age six years and older. A long-acting liquid formulation of ADHD medication may provide adherence benefits for younger children.

OBJECTIVE: To evaluate the patient profile of children initiating treatment on Quillivant XR and compare adherence and persistence between patients of varying ages.

METHODS: This analysis used administrative claims data from the Truven MarketScan Early View database. Patients must have met the following criteria: ≥ 1 claim for any long-acting stimulant between 1/1/2013 and 7/31/2014 (first observed medication served as the index; no prescription for the index drug allowed 6 months pre-index), eligibility 6 months pre- (baseline) and 12 months post-follow-up index, age 6-12 at index, and ≥ 1 claim for an ADHD diagnosis (314.XX). Baseline demographic and clinical characteristics were evaluated for all patients on a long-acting stimulant as well as for patients on Quillivant XR. For initiators of Quillivant XR, index treatment discontinuation (gap > 30 days), medication possession ratio (MPR), adherence (MPR≥0.8), and switching to a different long-acting stimulant were evaluated over the follow-up period, stratified by age (6-8 vs. 9-12 years old).

RESULTS: 53,261 patients met study inclusion criteria, 1,606 of which (3.02%) were prescribed Quillivant XR as their index therapy. Quillivant XR patients were slightly younger than the overall cohort (7.9±1.7 vs. 9.0±1.9) and had statistically significantly higher rates of select comorbidities, including delays in development and autism (P<0.01). Younger Quillivant XR patients had a higher average MPR over the follow-up period (age 6-8=0.729, age 9-12=0.684; P=0.009) and a higher proportion adherent (42.4% vs. 34.9%, respectively, P=0.0002) compared to older patients. Compared to children 9-12 years, Quillivant XR patients in the 6-8 age group also were less likely to discontinue therapy (79.9% vs. 84.8%, P=0.018) although a higher proportion switched therapies (26.0% vs. 21.8%, P=0.07).

CONCLUSIONS: Patients initiating Quillivant XR are typically younger than the overall sample of ADHD patients prescribed long-acting stimulant therapy, and the rate of adherence and persistence for Quillivant XR was higher for younger patients compared to older patients. Further analyses that explore the reasons for this age-specific difference in adherence will be important to fully understanding the benefits of Quillivant XR’s novel methylphenidate formulation.

SPONSORSHIP: This research was funded by Pfizer.
**F20** Pharmacist-Run Academic Detailing Behavioral Health Polypharmacy Program Delivers Positive Outcomes Within a Medicaid Population

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**BACKGROUND:** Psychiatric polypharmacy has developed into a widespread clinical practice for many psychiatric conditions. It is estimated that up to one-third of all patients visiting outpatient psychiatry departments are prescribed 3 or more psychotropic drugs. In addition, it is estimated that polypharmacy is responsible for 28% of hospital admissions and is the fifth leading cause of death in the U.S. Individuals with Behavioral Health (BH) disorders can experience poorer health outcomes, if their physical and behavioral conditions are not treated effectively, with poor outcomes being exacerbated when taking multiple medications. A pharmacist run academic detailing program was created to identify patients taking 4 or more BH medications within the last 30 days. Interventions were conducted with prescribers of identified patients, with the goal of these interventions being to reduce the number of prescribed BH medications.

**OBJECTIVE:** To evaluate the clinical and economic outcomes of a prescriber focused outreach program

**METHODS:** Targeted prescribers were identified based on pharmacy claims that showed patients taking 4 or more BH medications within a 30-day period. Medications include antipsychotics, antidepressants, ADHD medications, mood stabilizers, benzodiazepines, sedatives and hypnotics. Intervention methods for consultations included face-to-face visits, telephone, mail and e-mail. During consultations conducted between January and October of 2015, prescribers were asked to validate that each prescription was intended, assess regimen safety, and adherence, and optimize dosage. We performed a 6-month cross-sectional analysis where the intervention date served as the index date. The eligible sample was pooled from 2 independent Medicaid populations to increase statistical power. Significance was calculated using the Wilcoxon signed rank test with a significance threshold of P<0.05.

**RESULTS:** A total of 415 prescribers and 2,784 patients met the inclusion criteria for intervention. We observed a statistically significant 12% reduction in the pharmacy spend specific to BH medications (P<0.05) and a 6% reduction in utilization among BH drugs (P<0.05). At 6 months post-intervention we observed a 28% reduction in the number of members that were prescribed 4 or more BH medications and the per member per month (PMPM) BH claim count decreased from 6.2 to 5.9. Lastly, we observed an 11% reduction in ER utilization.

**CONCLUSIONS:** Academic detailing targeted at prescribers can have a positive impact on BH polypharmacy.

**SPONSORSHIP:** Magellan Rx Management.

**G00-G99** Diseases of the Nervous System

**G02** Development of a Claims-Based Algorithm for Spinal Muscular Atrophy Patients: Methods and Initial Findings

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**BACKGROUND:** Spinal muscular atrophy (SMA) is a rare and debilitating autosomal recessive neuromuscular disorder characterized by degeneration of spinal motor neurons, resulting in severe and progressive muscular atrophy and weakness. SMA is the most common genetic cause of infant mortality. In healthcare claims databases, ICD-9 diagnosis codes have been shown to misclassify diseases.

**OBJECTIVE:** To develop a multi-variate algorithm to identify and characterize patients with high resource utilization associated with SMA using statistical analysis methods in a large claims dataset.

**METHODS:** SMA-diagnosed patients were identified in Truven MarketScan healthcare claims as those reporting ICD-9 codes 333.0x or 335.1x between 2010 and June 2015. Given the severity of SMA and a corresponding limited observation window, a minimum continuous enrollment was not required. Patients were excluded from the data if they experienced >1 inpatient claim for amyotrophic lateral sclerosis or muscular dystrophy. An initial descriptive analysis of these patients was performed. A cluster analysis was then conducted to identify SMA patient subgroups that appeared to more closely resemble the clinical presentation. Finally, a discriminant analysis was performed to create the algorithm.

**RESULTS:** The cluster analysis separated patients on healthcare resource utilization patterns and identified those likely to have SMA as having claims for ≥4 symptoms related to SMA, ≥2 claims for durable medical equipment, ≥1 procedures common to patients with SMA and ≥1 inpatient claim and ≥2 outpatient SMA claims. The discriminant analysis identified age at first observed SMA claim, utilization of occupational/physical therapy and respiratory ailments as the top variables that differentiate SMA patients.

**CONCLUSIONS:** The analysis was limited to 5 years of data, the date of SMA diagnosis is unclear, and diagnosis codes cannot distinguish between different types of SMA. This is the first study to explore the development of an algorithm to identify SMA patients in a claims database. Validation of findings and additional analyses for a more accurate assessment of disease burden, healthcare utilization and clinical outcomes is warranted. This claims-based algorithm may also aid in identifying cases that are potentially misclassified for further review, rather than relying on ICD codes alone.

**SPONSORSHIP:** Biogen sponsored this research.

**G03** Increased Risk for New Onset Mental Disorders Among Patients with Primary Restless Legs Syndrome Receiving De Novo Dopamine Agonists: A Large-Scale Retrospective Claims Matched Cohort Analysis

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**BACKGROUND:** FDA-approved treatments for primary (idiopathic) Restless Legs Syndrome (P-RLS), a sensorimotor neurological disorder, include a calcium channel α2-δ ligand (gabapentin enacarbil) and dopamine agonists (DAs; pramipexole, ropinirole, and rotigotine). Research documents increased risk of mental disorders for patients receiving DAs for Parkinson’s disease. Whether this risk extends to patients with P-RLS receiving DAs, but at lower recommended doses, remains unknown.

**OBJECTIVE:** To compare the likelihood of developing new onset mental disorders between patients initiating versus not initiating DAs among patients with newly diagnosed P-RLS, no mental disorder history, and naive to DAs.

**METHODS:** Selected from 5-year (7/1/2008-6/30/2013) MarketScan Commercial and Medicare Supplemental claims databases were adults (age ≥18 years) with ≥1 RLS claim (ICD-9 333.94) and ≥2 years of data before and after their 1st (index) RLS diagnosis. Excluded were...
those with ≥1 mental disorder diagnosis (ICD-9 290-319) or ≥1 DA (per NDC) pharmacy fill in the 2-year pre-index period; and patients ever diagnosed with Parkinson’s (ICD-9 332), kidney disease (ICD-9 403-4, 584.5, 669.3, 996.81, V42.0; CPT 90951-70; HCPCS A4690, A4653, E1510, E1530-40, E1570-E1632, G0420-21, J2150, S2065), iron deficiency (ICD-9 280), or pregnancy (ICD-9 630-79). Patients were classified into 2 groups: those receiving (DA +) versus not receiving (DA-) ≥1 DA fill in the 2-year post-index period. Each DA+ patient was matched 1:1 to a DA- patient on sex, age at index diagnosis, geographical region, employment and comorbid burden (Charlson Comorbidity Index). Parallel follow-up periods were determined for each matched pair. McNemar’s test examined group differences in % of patients receiving mental disorder diagnoses. If significant (≤ 0.05), logistic regression examined odds ratios (OR) and 95% confidence intervals (CI).

RESULTS: From 4,293 patients, 835 matched pairs were identified. Compared to DA- matched controls, DA+ patients were 1.4 times more likely (OR 1.35, 95% CI 1.01-1.81, P = 0.05) to receive diagnoses at follow-up of Neurotic, Personalty and Other Nonpsychotic Mental Disorders, and 10 times more likely (OR 10.00, 95% CI 1.28-78.00, P = 0.03) to receive diagnoses of Psychoactive Substance Disorders. On average, these appeared within 15 months (SD 9 months) of DA initiation.

CONCLUSIONS: Compared to patients with P-RLS who did not receive DAs, those who did were at significantly increased risk of subsequently developing psychoactive substance and neurotic, personality and other nonpsychotic mental disorders.

SPONSORSHIP: Funding provided by Xenonport.

G04 Postmarketing Adverse Events Associated with Tetrabenazine: Findings Using FDA’s Adverse Event Reporting System
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BACKGROUND: In clinical trials of patients with Huntington disease (HD), treatment with tetrabenazine (TBZ) resulted in more neuropsychiatric adverse events (AEs) compared to placebo, including somnolence, anxiety, depression, and agitation. OBJECTIVE: To summarize post-marketing reports of AEs associated with TBZ by analyzing case reports from the FDA Adverse Event Reporting System (FAERS).

METHODS: FAERS data for branded TBZ (Xenazine) included case reports meeting minimal key identification field criteria: individual safety report number, patient number, drug sequence identification, and MedDRA AE term. RxFilter was used for standardization of case report data and was applied to TBZ data to analyze AEs with relevant regulatory interest. Primary suspect counts of AEs in which TBZ is suspected as the causative agent and calculation of disproportional reporting rates were performed to identify potential safety signals.

RESULTS: Post-marketing safety data for TBZ included many of the most frequent AEs as reported in the pivotal trial, including depression, somnolence, fatigue, fall and insomnia, indicating a consistency between these two sources. Of the AEs that were common between clinical trial and post-marketing observations, depression was most frequently reported in the post-marketing data. In clinical trials, depression was the fourth most commonly reported AE and was preceded by sedation/somnolence, insomnia and fatigue. A disproportionality analysis identified high reporting odds ratios (> 2) for some neuropsychiatric AEs, indicating that there is a higher-than-expected reporting rate.

CONCLUSIONS: Although post-marketing AE reporting is voluntary and thus a potentially more conservative estimate of safety signals compared with clinical trials, there was consistency between TBZ-associated AEs reported in the clinical trial setting and spontaneous post-marketing AE reporting. The real-world spontaneous AE reporting could be a useful data source to guide informed patient care decisions.

SPONSORSHIP: Sponsored by Teva Pharmaceutical Industries.

G06 Incidence, Prevalence, and Treatment Patterns of Alzheimer’s Disease and Cognitive Impairment-Related Conditions Among 4.5 Million Members of a U.S. Health Plan
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BACKGROUND: Numerous symptomatic, disease-modifying, and/or preventative Alzheimer’s disease (AD) therapies are in Phase II/III clinical trials. As these agents come to market and alter current treatment standards, an understanding of the epidemiology of AD, including prodromal stages, is necessary.

OBJECTIVE: To characterize the incidence, prevalence, and treatment patterns associated with AD and other cognitive impairment (CI)-related conditions among Humana’s membership.

METHODS: Patients aged 22-89 years with AD or related CI (identified via medical claims) or AD-related therapies were identified from January 1, 2012 to December 31, 2014. For each calendar year of analysis, patients were categorized by their most severe condition based on a published diagnostic pathway algorithm: AD, dementia with suspected etiology (DSE), dementia with no known cause (DNKC), cognitive disturbance not demented (CDND) or AD-therapy but no conditions of interest. Once assigned a specific condition, a patient was counted as having that condition in all subsequent years if enrolled and did not progress in condition severity. Incidence and prevalence were reported by calendar year for each condition of interest. Treatment patterns were assessed for 2014 incident populations.

RESULTS: The 2014 incidences [prevalences] were: AD, 0.50% [1.08%]; DSE, 0.06% [0.10%]; DNKC, 0.47% [0.85%]; CDND, 2.06% [4.08%]; and, AD-therapy but no conditions of interest, 0.28% [0.52%]. Overall incidence and prevalence rates were consistent for all conditions across the three calendar years of measure. Rates for all conditions increased dramatically, as expected, with age. Of 2014 incident AD cases, treatment with acetylcholinesterase inhibitors (AChEIs) only, N-methyl-D-aspartate receptor antagonists (NMDAs) only, and dual therapy with AChEIs and NMDAs occurred in 33.0%, 7.9%, and 20.2% of members, respectively; 39.0% had no current therapy. Of those treated with AChEIs, donepezil was predominantly utilized (85.0%). AD-related treatments were utilized in 39.3%, 36.7%, and 11.1% of the DSE, DNKC, and CDND groups, respectively.

CONCLUSIONS: While annual incidence and prevalence of AD was consistent year-over-year from 2012-2014, a sub-group with no evidence of recent treatment was found. Modest utilization of AD therapies was found in non-AD forms of dementia and CI. Although underdiagnosis is known to exist, these data suggest that there is an opportunity to improve the care of patients with prodromal disease and symptomatic AD with pharmacologic treatment.

SPONSORSHIP: Sponsored by Teva Pharmaceutical Industries.
Background: Alzheimer’s Disease (AD) is a type of dementia that causes decline in memory, thinking and behavior. AD can have a profound impact on a person’s ability to function and carry out normal daily activities. This analysis explored whether AD has a compounding effect on a person’s ability to manage the other comorbid conditions that become more prevalent in the later years of life.

Objectives: To measure the impact of AD on the cost of Medicare patients with various comorbidities and determine the extent to which AD exacerbates the economic condition.

Methods: A case-control analysis of AD and non-AD patients was conducted using a random 5% sample of Medicare Fee-for-Service beneficiaries that were continuously enrolled from 2010-2013. Cases were AD patients observed reporting ICD-9 code 331.0 between 2010 and 2013, while controls were those with no AD or AD-related dementia reported during the same time period. Cases and controls were 1:1 matched on sex and age group. Comorbidities were based on the diagnostic classification from the Charlson Comorbidity Index. Linear regressions with a gamma distribution and log link function were performed to estimate 2013 annual total patient cost both in the presence and absence of interactions between AD and each comorbidity. Adjusted cost differences between cases and controls were compared among those with and without each comorbidity.

Results: 8,000 cases and 8,000 controls were identified with an average age of 83 and 31% male. 5 (out of 17) comorbidities showed significant (P<0.05) interactions with AD: any malignancy, diabetes without complications, metastatic solid tumor, myocardial infarction (MI) and renal disease. MI had the largest interaction effect with AD, where the difference in case and control patients with MI was $38,996 higher than the difference in case and control patients without MI. Similarly, AD increased the cost of patients with metastatic solid tumor by $20,097, diabetes without complications by $13,663, renal disease by $10,665 and any malignancy by $3,082.

Conclusions: The presence of AD exacerbates the cost of some other comorbid conditions. Declining cognitive ability likely impacts AD patients’ ability to manage their chronic illnesses and cope with serious additional diseases. To avoid the compounding effect of AD, providers supervising these patients should remain hypervigilant when treating and monitoring other comorbidities.

Sponsorship: This research was conducted by Trinity Partners without external funding.

Objective: To determine treatment persistence and reasons for loss of persistence among RRMS patients initiated with injectable DMT therapies in the real world.

Methods: Distinct medical records of RRMS patients (n=300) initiated on injectable DMTs between August 2008-August 2013 were abstracted from 18 U.S. neurology practices. Eligible patients had at least 3 visits: 1 visit prior to iDMT initiation (pre-index visit), 1 visit where iDMT agents were initiated (index visit), and >1 visit within the 24 months following iDMT initiation. All patients were followed for 2 years even if they discontinued iDMT. Baseline demographics and clinical characteristics were collected at the pre-index and index visits. MS-related symptoms, relapse rates, iDMT treatment patterns (i.e., persistence, discontinuation, switching, and restarts), and reasons for non-persistence were tracked in the post-index visits at distinct time windows of 3, 6, 9, 12, 18, and 24 months. Descriptive statistics of iDMT treatment patterns, persistence survival curves, and persistent vs. non-persistent patient comparisons were generated.

Results: Among eligible patients, 74% were female with a mean age of 41.7 years. The iDMT persistence rates were 91.3% at 3 months, 85.3% at 6 months, 75.3% at 12 months, and 61% at 24 months. Over the 2 years of follow-up, 28% of patients on iDMT switched to another MS DMT, 8% discontinued, and 3% re-started the index iDMT. The main identified reasons for switching, discontinuation, and re-starts were moderate/severe adverse events (0-12 months: 5.3%, 0-24 months: 7.3%), perception of lack of efficacy (0-12 months: 5.7%, 0-24 months: 8.7%) and phobia about needles/self-injecting (0-12 months: 2.7%, 0-24 months: 3.7%). Within 24 months post-index, 38% of iDMT patients experienced a relapse and 11% had changes in MRI lesion counts.

Conclusions: In this real-world retrospective chart review, DMT persistence decreased over time. Over 24 months, 61% of patients were persistent on their initial iDMT. Understanding non-persistence and reasons for non-persistence such as tolerability, adverse events, and effectiveness at distinct time points may inform appropriate treatment selection and management.

Sponsorship: This study was sponsored by Novartis.
had an MS diagnosis, were 18-63 years of age at index, and were continuously enrolled in Texas Medicaid during the follow-up period. DMT adherence was defined as the proportion of days covered (PDC) > 0.8. Mann-Whitney U/Kruskal-Wallis and Chi-square tests were used for continuous and categorical variables, respectively. Costs were adjusted to 2013 U.S. dollars.

RESULTS: A total of 617 MS patients met the study criteria; 54.9% were DMT adherent. Compared to their non-adherent counterparts, adherent patients spent significantly (P<0.05) fewer days in the hospital (1.6 vs. 2.5) and had fewer emergency department (ED) visits (0.4 vs. 0.6). In addition, mean annual MS-related medical expenditures (not including DMT costs) were lower for adherent patients ($6,757 vs. $7,214; P<0.05). A greater proportion of patients was adherent to fingolimod (67%) compared to the other DMTs, with the lowest proportion (43%) adherent to interferon beta-1b. Among DMT adherent patients, mean annual MS-related medical expenditures were lowest for those whose index drug was fingolimod ($5,467), followed by subcutaneous interferon beta-1a ($5,717), while highest expenditures were associated with dimethyl fumarate ($8,654).

CONCLUSIONS: In the Texas Medicaid MS population, DMT adherence is associated with lower medical expenditures. To optimize patient health benefits and use of resources, health care providers and decision-makers should be aware of adherence rates associated with DMT products, and actively monitor and encourage DMT adherence among MS patients.

SPONSORSHIP: This research was funded by Novartis.

G12 Disease-Modifying Therapy Access Issues and Their Impact on Multiple Sclerosis Patients: An Online Mixed Methods Study

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BACKGROUND: In the United States, multiple sclerosis (MS) patients often face difficulty accessing disease-modifying therapies (DMT) as a result of insurance, pharmacy or provider policies.

OBJECTIVE: To describe the occurrence of DMT access difficulties and delays, and to understand the clinical, humanistic, and economic impact access barriers may have on MS patients.

METHODS: U.S.-based adult patients self-reporting MS were recruited from an online data-sharing health network, PatientsLikeMe. Patients were invited to complete a web-based survey if they reported a diagnosis of relapsing-remitting MS and were prescribed a DMT for MS. Summary statistics were used to enumerate DMT access difficulties by type and frequency. Follow-up phone interviews were conducted with ten respondents who reported MS relapse(s) during their DMT access issue. Key themes arising from interviews were qualitatively synthesized to supplement survey findings.

RESULTS: Of 947 patients who viewed the invitation, 584 patients participated in the survey (response rate: 62%). Survey completers (n = 507) were female (80%), White (90%), and on average, 49 years old. Nearly half (n = 233) were currently experiencing a DMT access issue or had experienced difficulty accessing a DMT in the past. The most frequently selected reasons for DMT access difficulties were insurance required authorizing documentation (39%) and high out of pocket costs (30%). Other reasons (20%) cited by respondents included administrative coordination problems between insurance companies, pharmacies, and clinician’s offices. About 40% of patients went without MS medication until they could access their prescribed DMT, and 33% reported experiencing at least one MS relapse during their DMT access issue. Of those who experienced past access difficulties, 40% said they were at least partially responsible for resolving their DMT access problem. Some patients felt that the amount of time spent obtaining their DMT led to stress which may have triggered MS relapses. Schematic maps of interviewees’ DMT access experiences were created to illustrate the complexity of the system and to highlight barriers and facilitators of access to DMT medications.

CONCLUSIONS: Access barriers to DMT medications impact MS patients physically and financially; and may worsen medication adherence and quality of life. Patients often serve as their own agents when navigating DMT access difficulties and obtaining MS medication. Healthcare stakeholders should take note of the patient experience with DMT access barriers in order to optimize the delivery of MS treatment and care.

SPONSORSHIP: None.

G13 Real-World Persistence with Fingolimod for the Treatment of Multiple Sclerosis: A Systematic Review and Meta-analysis

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BACKGROUND: Fingolimod (FTY) was the first oral disease-modifying therapy approved for relapsing forms of multiple sclerosis (MS). A recently completed phase 4, randomized, open-label clinical trial found that 81.3% of MS patients remained on fingolimod treatment at 1 year (the PREFERMS trial).

OBJECTIVE: To systematically review reports of fingolimod persistence across data sources and practice settings, and develop a consensus estimate of the 1-year persistence rate in the real world.

METHODS: A systematic literature review was conducted by two reviewers working independently to identify observational studies reporting 1-year fingolimod persistence among adult patients with MS (sample size ≥ 50) published in English. Search terms included MEDLINE, EMBASE, and conference abstracts from major MS, neurology, or health economic conferences between 2013 and 2015. A random-effects meta-analysis was performed to estimate a synthesized 1-year persistence rate and to assess heterogeneity across studies.

RESULTS: Of 527 publications identified, 24 real-world studies reporting 1-year fingolimod persistence rates met the inclusion criteria. These studies included patients from different data sources (e.g., administrative claims, electronic medical records, or registries), used different definitions of persistence (e.g., based on prescriptions refills, patient report, or prescription orders), and spanned multiple geographic regions, primarily in Europe and North America. Reported 1-year fingolimod persistence rates ranged from a low of 69% to a high of 100%, and exhibited statistical evidence of heterogeneity (I^2 = 93% of the variability due to heterogeneity across studies). The consensus estimate of the 1-year persistence rate was 83% (95% confidence interval: 80% to 86%).

CONCLUSIONS: Across heterogeneous study designs and patient populations found in real-world studies, the consensus fingolimod persistence over 1 year exceeded 80%. These findings were consistent with persistence rates identified in the recently completed clinical trial PREFERMS.

SPONSORSHIP: Analyses were supported by Novartis.
**G14 First-Line Selection of Treatment for Multiple Sclerosis in a Medicaid Population**

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**BACKGROUND:** National multiple sclerosis (MS) treatment guidelines do not include treatment recommendations with newer therapies that were introduced beginning in 2010. This study was designed to evaluate what medications are utilized as first-line treatment for MS.

**OBJECTIVE:** To determine what specific disease-modifying medication is used as first-line therapy in treatment-naïve patients with MS.

**METHODS:** Pharmacy and medical claims from 1/1/13-5/31/16 were analyzed to identify members with either a diagnosis (ICD-9 code 340 and/or ICD-10 code G35) of or pharmaceutical therapy for MS. Pharmaceutical treatment included dimethyl fumarate, fingolimod, glatiramer, interferon beta-1a, interferon beta-1b, peginterferon beta-1a, and teriflunomide. Dimethyl fumarate, fingolimod, glatiramer 40 mg, peginterferon beta-1a, and teriflunomide were considered as non-preferred or restricted agents on the preferred drug list (PDL) during the time studied. Patients with disease-modifying therapy for MS in 2013 were excluded as already having treatment. Pharmacy claims of the remaining members were then examined to determine the first-line medication used for treatment of MS.

**RESULTS:** A total of 294 patients with MS who were naïve to treatment as of 1/1/2014 were identified. Glatiramer was the leading first-line medication used in this population at 116 members, followed by interferon beta-1a at 83 members.Even with a non-preferred status, gatifin 40 mg was selected as first-line therapy nearly as often as the preferred glatiramer 20 mg product (57 vs. 59 members, respectively). The primary newer therapy, fingolimod, was the third-leading medication used overall as first-line therapy in this analysis, at 35 members.

**CONCLUSIONS:** The data revealed that the leading medication used as first-line therapy in this study for treatment-naïve patients diagnosed with MS is glatiramer, an older, injectable dosage form. The leading newer oral dosage form, fingolimod, placed third in the overview analysis of first-line treatment selections. Even with the introduction of more convenient oral medications to the market, Medicaid members in this analysis were treated with older, injectable medications as first-line therapy for MS. Older injectable medications still lead the market as the preferred first treatment for MS. Future pharmaceutical considerations include oral treatments that can compete with the injectable formulations for first-line treatment of MS.

**SPONSORSHIP:** This research was funded internally by Xerox State Healthcare.

**G15 The Impact of Step Therapy on Oral Disease-Modifying Treatment Initiation Rates for Patients with Multiple Sclerosis**

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**Kantor Neurology; *Novartis; Comprehensive Health Insights**

**BACKGROUND:** Step therapy and other formulary restrictions are intended to decrease utilization of the targeted medications, promote evidence-based treatment and contain health care cost. However, some stakeholders have criticized these policies for delaying access to treatment. Humana, a nationwide health insurance provider, required multiple sclerosis (MS) patients to have had previous treatment, intolerance to, or a contraindication for, interferon beta-1a/interferon beta-1b and glatiramer acetate injections before oral disease modifying therapies (DMT) were authorized starting 10/7/2010. This double step edit policy was rescinded for all oral DMTs between 1/1/2014 and 2/6/2014.

**OBJECTIVE:** To compare the initiation rates of injectable, oral or any DMT while the double step edit policy was in place (ST), to the period after the policy was rescinded (no-ST), for MS patients with no history of DMT use in the prior 6 months.

**METHODS:** This retrospective cohort study compared DMT initiation rates between the ST and no-ST periods. Humana Medicare beneficiaries and commercially insured members with MS were identified in medical claims during the ST period (10/7/2010-1/1/2014) and no-ST period (2/6/2014-3/31/2015). The index date was the first observation of an MS diagnosis with no claims evidence of MS or any DMT use in the previous 6 months. DMT initiation was assessed in the months post-index. Rates of injectable, oral or any DMT initiation were calculated in the ST and no-ST periods and compared using chi-square tests.

**RESULTS:** Of the qualifying MS patients, 3,829 and 1,670 were identified during the ST and no-ST periods, respectively. Both cohorts were similar in mean age (58.0 ± 14) and the majority were females (72.8%). During the ST period, 22.0% of patients initiated any DMT compared to 27.1% in the no-ST period (P=0.0002). Of those who initiated treatment, 18.8% of patients initiated treatment with injectable DMTs during the ST period and 17.7% during the no-ST period (P=0.3277). Oral DMTs were initiated by significantly fewer patients during the ST period as compared to the no-ST period (7.8% versus 12.8%, P < 0.0001).

**CONCLUSIONS:** After the double step edit policy was rescinded, more MS patients initiated oral DMTs as well as any DMT. However, there was no association between the step edit policies and initiation of injectable DMTs. Future studies should evaluate delays in treatment, potential undertreatment, outcomes, and health care resource utilization associated with step therapy for oral DMTs.

**SPONSORSHIP:** This work was sponsored by Novartis.

**G16 Imaging a World Without Disease-Modifying Therapies: Advancements in Outcomes for Patients with Multiple Sclerosis Between 1993 and 2016**

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**BACKGROUND:** Approximately 340,000 patients in the U.S. have relapsing forms of multiple sclerosis (RMS). Since the first disease-modifying therapy (DMT) was introduced in 1993, continued innovation has provided several new treatment options, which have improved overall quality of life and prognosis for RMS patients.

**OBJECTIVE:** To model the effect that DMTs have had on RMS patient outcomes.

**METHODS:** An epidemiological model was developed for U.S. RMS patients. Baseline DMT efficacy by molecule, relative risks of annual relapse rate (RR) and confirmed disability progression (CDP) were derived via network meta-analysis of randomized controlled trials. Three treatment scenarios were compared against the state of the world prior to 1993 (i.e., no DMT treatment available). These scenarios assumed patients were alternatively treated using treatments newly available between 1993 and 2003 (BRACE DMTs), or treatments newly available between 2004-2016 (non-BRACE DMTs). BRACE DMTs included glatiramer acetate and interferons; and non-BRACE DMTs included alemtuzumab, dimethyl fumarate, fingolimod, natalizumab, and teriflunomide. The third scenario measured annual...
RR and CDP under current treatment patterns based on 2016 IMS market share data. We conducted a sensitivity analysis using various estimates of baseline relapse risk from the literature.

RESULTS: Among all patients with RMS in the U.S., annual RR without DMT-treatment was 1.27. The introduction of BRACE DMTs had the potential to decrease annual relapses by 27.0% relative to no DMT treatment; the introduction of novel non-BRACE DMTs had the potential to decrease annual relapses by 47.8% reduction relative to no DMT treatment. In 2016, 33.0% of RMS patients received no DMT, 39.7% received BRACE DMTs, and 27.3% received non-BRACE DMTs. Expected annual RR under current practice patterns was 23.8% lower than treatment without no DMT treatment. When comparing CDP scenarios in the U.S., DMTs also had the potential to reduce CDP versus no treatment (BRACE 16.3% reduction; non-BRACE, 24.6%; and 2016 current practice, 13.2%).

CONCLUSIONS: Over the 23 years since the first DMT was available, RMS patients and society have reaped the benefits of a world with DMTs including the ability to decrease relapse rates by nearly half and decelerate confirmed disability progression. However, the opportunity exists today for further optimization of treating more RMS patients with approved newer, higher efficacy agents.

SPONSORSHIP: This research was sponsored by Novartis.

G18 Pregnancy Outcomes in Women with Multiple Sclerosis: A U.S. Retrospective Claims Database Analysis

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BACKGROUND: Multiple sclerosis (MS) is three times more common in women, and the clinical onset often occurs during childbearing years. Data from large observational studies can be used to assess outcomes and support decision making in women with MS of childbearing age.

OBJECTIVE: To evaluate pregnancy outcomes of women with MS using a large U.S. healthcare administrative claims database.

METHODS: This was a retrospective analysis of women with MS (ICD-9-CM code: 340.xx) aged 18-65 years with a pregnancy-related claim (diagnosis or procedure code) and 1-year continuous eligibility pre and post-pregnancy claim. Data were from the IMS Health Real World Data Adjudicated Claims U.S. database from 1/1/2006 to 6/30/2015. Pregnancy outcomes evaluated included: indication of a live birth, complications during pregnancy, labor and delivery, and the puerperium period; ectopic/molar pregnancies; and other abortive outcomes.

RESULTS: Of 205,466 women with MS, 10,630 had a pregnancy claim and 5,022 had 1 year of continuous eligibility pre- and postclaim. The mean (standard deviation [SD]) age of women with a pregnancy claim who met the eligibility criteria was 34.3 (8.1) years. Most patients had commercial health insurance (98.1%) and were from the Northeast (32.2%), Midwest (29.9%), or South regions (29.2%) of the U.S. The mean (SD) Charlson Comorbidity Index score was 0.35 (0.89) pre and 0.34 (0.87) post-pregnancy claim. Common comorbidities were: gastrointestinal disorders, 17.6%; depression, 14.4%; thyroid disease, 14.1%; hypertension, 13.5%; anxiety, 12.3%; and hyperlipidemia, 10.5%. Over half of the women had a live birth (n = 2,867, 57.1%). The proportions of women with claims for complications during pregnancy were: diabetes/abnormal glucose test, 12.0%; infection, 8.5%; mental health disorders, 5.0%; hemorrhage, 8.0%; and preeclampsia/eclampsia, 4.2%; and placental problems, 4.0%. The proportions with claims during labor and delivery were: malposition/disproportion, 31.9%; forceps or vacuum, 32.2%; and placental problems, 4.0%. The proportion of pregnancy claims for ectopic/molar pregnancy was 13.0%, and for other pregnancy with abortive outcomes was 14.7%.

CONCLUSIONS: Administrative claims data, although not collected for research purposes, can provide valuable information about pregnancy outcomes among large numbers of women with MS treated in a variety of practice settings.

SPONSORSHIP: EMD Serono.
**G19**

**A U.S. Administrative Claims Database Analysis of the Trends in Pregnancy Rates in Women with Multiple Sclerosis**

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**BACKGROUND:** Multiple sclerosis (MS) is more commonly diagnosed in women of childbearing age than in any other group. Data regarding the rate of pregnancy in women with MS and how pregnancy rates have changed over time are lacking.

**OBJECTIVE:** To evaluate the rate of pregnancy in women with MS from 2006 to 2014, and to determine how these trends varied with age, region, and payer type.

**METHODS:** A retrospective analysis of women with MS (ICD-9-CM code: 340.xx) from the IMS Health Real World Data Adjudicated Claims U.S. database was conducted. Pregnancy rates were assessed by year (2006-2014), age, region, and payer type. Baseline demographic and clinical characteristics were evaluated for women with MS and without a pregnancy-related claim (diagnosis code or procedure) in the dataset for each year of available data.

**RESULTS:** The number of women with MS included in the annual study cohorts from 2006 to 2014 ranged from 39,801 to 59,622. The mean age of women with MS and a pregnancy-related claim ranged from 32.23 to 32.95 years, whereas the mean age of all women with MS ranged from 45.33 to 46.58 years. The proportion of women with MS who had a pregnancy-related claim fluctuated between 2.40% and 2.55% between 2006 and 2011, declined to 2.48% in 2012, and increased to 2.57% in 2014. The proportion of women with MS with a pregnancy-related claim was highest for those aged 25-29 years (range: 11.64-13.62%) and 30-34 years (9.66-11.77%), living in the Northeast (2.41-2.79%), and with Medicaid health insurance (2.64-6.76%).

**CONCLUSIONS:** A numerical increase in pregnancy rates was observed in this U.S. population of women with MS from 2006 to 2014. This is in contrast to pregnancy rates for all women in the U.S., which have steadily declined since 1990. This may reflect a change in perceptions regarding pregnancy risks in this patient population. More women with MS in the Northeast, aged 25-29 and 30-34 years, and with Medicaid health insurance had a pregnancy-related claim.

**SPONSORSHIP:** EMD Serono.

**G20**

**Assessing Patient Satisfaction of a Program Designed to Facilitate Fingolimod Initiation**

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**BACKGROUND:** Fingolimod (GILENYA), an oral disease modifying therapy, is used to treat relapsing forms of multiple sclerosis (MS). Initiation of fingolimod requires a first dose observation (FDO), which includes ≥6 hours observation by a clinician during a patient’s intake of fingolimod to ensure that potential cardiovascular events are monitored and appropriately treated. The GILENYA@Home program was developed to facilitate the initiation of fingolimod (i.e., FDO monitoring and baseline assessment) for commercially covered insurance patients. The GILENYA@Home program was introduced to provide an initiation assessment option at no additional cost to the patient that would allow them to take their first dose of fingolimod in their own homes under the supervision of a medical professional.

**OBJECTIVE:** To assess the patient-reported satisfaction among patients who have completed their FDO as part of the GILENYA@Home program.

**METHODS:** The survey period included in this study was between October 2014 through May 2016. It was administered to all patients at the end of the FDO under the GILENYA@Home program. The survey comprised twelve questions, covering four main areas of patient satisfaction: appointment scheduling, physician & medical assistant @ Home team, personal satisfaction and overall satisfaction. The patients answered the survey using a five-point Likert scale, ranging their experience from “Poor” to “Very Good.”

**RESULTS:** From October 2014 to May 2016, 2,951 patients completed their FDO period using the GILENYA@Home program. Out of 2,951 patients, 1,067 patients returned the survey, accounting for a 37% response rate. The highest patient satisfaction scores were noted with the physicians and medical assistants in the program team (ranging from 86.6%-95.5% across different questions) and personal satisfaction (ranging from 89.2%-92.3% across different questions). The team’s response to patients’ concerns/complaints was ranked the highest among the personal satisfaction category. The lowest satisfaction score was with the ease of scheduling appointments (ranging from 71.3%-77.8%). Overall satisfaction was “Very Good” for 91.4% of patients.

**CONCLUSIONS:** The survey results demonstrate high patient satisfaction with the GILENYA@Home program experience. The at home FDO option provides patients covered by commercial insurance a convenient option to initiate fingolimod under the supervision of a medical professional in their own homes, which would help ease patient burden, especially for patients who are unable to travel to the clinic.

**SPONSORSHIP:** This study was sponsored by Novartis.
and 90 days were 4.6%, 7.3% and 9.4%. Readmissions were highest in 18-44 years age group at 5.8%, 8.7%, and 10.9%, in Native Americans (9.2%, 9.3%, 13.1%) and African-Americans (6.6%, 11.0%, 13.9%) and lowest in the white population. Patients insured by Medicare had patients with higher readmission rates (6.5%, 10.5%, 13.4%) as compared to Medicare (4.2%, 6.7% and 8.8%) and private insurance (3.5%, 5.3%, 6.7%). Case fatality rates were 1.14%, 1.7% and 2.2% at 30, 60 and 90 days.

CONCLUSIONS: Readmission rates for epilepsy after hospitalization for primary diagnosis of epilepsy are highest in 18-44 years age group, Native Americans, and African-Americans. An emphasis on better follow-up care and disease management after hospitalization is needed to reduce the health care disparity in these populations.

SPONSORSHIP: This study was supported by a research grant from A卓da Therapeutics.

G27 The Health Care Cost of Primary Headache and Associated Comorbidities

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BACKGROUND: Primary headache is a common neurological condition. Studies have shown that a variety of additional functional disorders commonly present in patients diagnosed with a primary headache condition. As a result, headache patients utilize a seemingly disproportionate amount of healthcare resource.

OBJECTIVE: To calculate the prevalence and mean annual health care cost of patients diagnosed with primary headache conditions. In addition, we wanted to understand the impact that associated comorbidities have on these costs.

METHODS: Data queries were performed on 20,730,344 adult patients (18-65 years) in the Truven Health MarketScan Commercial and Medicare Supplemental Databases, recorded in the year 2011. The prevalence and total healthcare costs for patients diagnosed with a primary headache condition or one of the following functional disorders; asthma/allergy, psychiatric disorders, gastric motility disorders, tinnitus, sleep disorders and wide-spread chronic pain disorders, were calculated. Furthermore, analysis was conducted to calculate the prevalence and cost of patients diagnosed with headache plus functional comorbidity. The headache cohort was matched to healthy controls without any functional disorders using age, gender, and region.

RESULTS: 905,590 (4.4%) patients have a primary diagnosis of headache. These patients have a significantly higher annual healthcare cost compared to controls ($12,621.73 vs. $2,373.66, P<0.0001). Within these patients, 359,064 (39.6%) have no additional functional disorders diagnosed. A total of 226,514 (25%) patients have at least two or more functional disorders diagnosed alongside their headache, resulting in mean annual healthcare costs of $24,388. Average yearly costs incrementally increased with each additional comorbid functional disorder, with each value being significantly more than matched control groups (P<0.0001).

CONCLUSIONS: This analysis demonstrates the remarkable economic impact attributed to primary headache conditions. Patients with primary headache and associated comorbid functional disorders have significantly higher medical costs than the average patient population. With the additional consideration of lost work days and decreased quality of life, the potential economic impact can be explosive. The results of this analysis further supports the important emphasis for a proper treatment strategy for primary headache and the commonly associated comorbid functional disorders.

SPONSORSHIP: This study was funded by electroCore.

G31 Real-World Analysis of Health Plan Claims Data to Compare Differences in Healthcare Utilization and Cost in Patients Suffering from Cluster Headaches Versus Patients Without Headache-Related Conditions

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Magellan Rx Management

BACKGROUND: According to the WHO, headache disorders are under- appreciated by many health systems and have substantial impact on quality of life. However, the true correlation between headache conditions and increased total health care utilization is not well understood.

OBJECTIVE: To assess differences in healthcare utilization and total cost in patients suffering from cluster headaches (CH) compared with patients without headache-related conditions.

METHODS: Medical and pharmacy claims data from 4 regional health plans was used to evaluate differences in healthcare utilization and cost in patients with a CH diagnosis (chronic, episodic, or unspecified) compared to a control group of patients without a headache-related condition. Qualifying patients were >18 years old and continuously eligible for three consecutive years during the study period (1/1/2009-12/31/2015). The first date with a diagnosis of CH was considered the index date and the subsequent three years of claims data was used for this retrospective analysis. The CH cohort was matched with controls using a 1:1 propensity score match. Differences between cohorts (CH vs. control) were assessed via t-test or Fisher’s Exact Test as appropriate.

RESULTS: A total of 4,174 patients with CH met study criteria and were matched 1:1 with controls (gender: 48% male; mean age: 47, comorbidity index: 0.30). Mean medical costs per patient in the CH cohort for the 3-year measurement period were 155% higher than the control group ($25,805 vs. $10,140, respectively). Unique encounters and cost per patient by medical service type for the CH cohort compared to the control group were as follows: emergency department: 2,151 ($1,986) vs. 962 ($1,268); hospital inpatient: 900 ($7,312) vs. 253 ($8,528); hospital outpatient: 3,422 ($12,459) vs. 2,141 ($7,644); physician office: 4,113 ($7,379) vs. 4,089 ($3,672); home infusion / specialty Rx: 817 ($4,977) vs. 427 ($1,730). Visit counts per patient were significantly higher for cluster headache patients in all categories. Mean pharmacy costs per patient were 111% (P<0.0001) higher in the CH cohort ($9,197 vs. $4,368) with these patients 2.3 times as likely to fill a prescription for an opioid.

CONCLUSIONS: This analysis shows that CH patients utilize health care resources at a significantly higher rate and cost than the healthcare system significantly more than similar patients without headache-related conditions. There is an unmet need for new treatment modalities in this patient population to improve outcomes and contain cost.

SPONSORSHIP: Research was sponsored by electroCore.

G32 A Real-World Claims Analysis of Glioblastoma Treatment Patterns by Lines of Therapy

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BACKGROUND: Glioblastoma (GBM) patients have a poor prognosis and rarely survive longer than 2 years after being diagnosed. Despite continued attempts in drug discovery, few therapies have been successful in demonstrating survival benefit. Real-world treatment of patients with GBM is not well characterized, especially for patients with recurrent disease.

OBJECTIVE: To describe treatment patterns specifically focused on recurrent disease in patients being treated for GBM.
METHODS: This U.S.-based retrospective cohort study used commercial administrative healthcare claims data (Truven Health MarketScan) of patients with GBM. Patients included were ≥18 years; had a diagnosis of malignant brain cancer (ICD-9-CM 191.xx) between January 2010 and September 2015; had brain-related surgery 90 days before or after diagnosis, received temozolomide (TMZ), radiation, or both within 90 days of diagnosis, and were continuously enrolled for 6 months prior to the index date defined as date of diagnosis.

RESULTS: 3,021 patients were identified with an average follow-up time of 490 days. Of those identified, 990 (33%) patients received second-line (2L) therapy. Of those receiving 2L, the mean age was 52 and 60% were male. The majority 859/990 (87%) of patients were treated with TMZ + radiation in the first-line (1L) setting, while a minority 117/990 (12%) of patients were treated with radiation alone, and even fewer 13/990 (1%) with TMZ monotherapy. Overall, the most common treatments in 1L included bevacizumab (BEV) monotherapy (37%), BEV combination (31%), TMZ monotherapy (17%) and chemotherapy (15%). The most commonly used BEV combination was BEV + irino-tecan (25%) followed by BEV + lomustine (14%). The most commonly used chemotherapy regimens included lomustine monotherapy (32%) or combination (17%). Nearly three-quarters of patients who received TMZ + radiation in 1L received BEV (40% monotherapy; 34% BEV combination) in 1L, whereas 37% of patients who received radiation alone in 1L received BEV (24% monotherapy; 13% combination therapy) in 2L. Among patients who received TMZ with or without radiation in 1L, 15% also received TMZ monotherapy in 2L.

CONCLUSIONS: This large real-world evaluation of treatments in patients with GBM demonstrates that few agents are used routinely. TMZ is most often used in 1L, whereas BEV is often used 2L. The limited treatment options and poor outcomes in GBM demonstrate the importance of identifying innovative therapies for this patient population.

SPONSORSHIP: Funding provided by Bristol-Myers Squibb.

RESULTS: A total of 314 CLB-treated patients with probable LGS and a minimum of 12-months follow-up post-CLB initiation were identified. Compared with the 12-month pre-CLB period, patients had significantly fewer seizure-related hospitalizations (P = 0.008), emergency room visits (P < 0.001), and neurologist visits (P = 0.011) in the 12 months post-CLB initiation. Seizure-related total costs increased following CLB initiation ($33,298 pre-CLB vs. $35,083 post-CLB; P = 0.029), but were largely offset by reduced total seizure-related medical costs ($23,740 vs. $19,958; P = 0.004). All-cause total costs also increased following CLB initiation ($73,319 vs. $81,398; P < 0.001), but all-cause total medical costs did not increase significantly ($57,090 vs. $59,292; P = 0.411). Based on pre-CLB initiation cost trends, extrapolated results suggest that greater projected all-cause ($115,667) and seizure-related ($56,625) total costs (reflecting increases of $34,269 and $21,542, respectively) might have been observed had patients not initiated clobazam.

CONCLUSIONS: Among patients with probable LGS, seizure-related HCRU was reduced following CLB initiation compared with an analogous period before CLB initiation. While seizure-related and all-cause total costs increased following CLB initiation, extrapolated data suggest that patients might have accrued greater healthcare costs in the absence of CLB treatment.

SPONSORSHIP: Funded by Lundbeck.

H01 Post-tymanostomy Tube Placement Emergency Department Visits Among Medicaid-Enrolled and Commercially Insured Pediatric Populations

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BACKGROUND: Tymanostomy tube (TT) placement is the most common ambulatory surgery performed on children in the U.S. Tube otorrhea is a common post-surgical sequela requiring physician follow-up. However, it is known that some patients seek care in the emergency department (ED) rather than the physician office, significantly increasing the cost of care.

OBJECTIVE: To evaluate rates of post-TT ED visits among Medicaid-enrolled and commercially insured pediatric populations.

METHODS: Medical and pharmacy insurance claims data from the Truven MarketScan 11-State Medicaid and Commercial Claims and Encounters databases were used. Patients ≤17 years old undergoing TT placement between 1/1/10 and 12/31/13 were selected for inclusion. The main endpoint was ED encounters within 30 days post-TT placement, all-cause and with a primary diagnosis code for otorrhea and other ear-related indications.

RESULTS: 128,472 Medicaid-enrolled and 240,375 commercially insured patients met all study inclusion criteria. Within 30 days following tube placement, the rate of all-cause ED visits was twice as high in the Medicaid-enrolled when compared to the commercially insured population (8.0% vs. 3.9%, P < 0.0001). Otorrhea-related and ear-related ED visits were more than twice as high in Medicaid vs. commercial patients (P < 0.0001).

CONCLUSIONS: The rate of ED visits within 30 days following tube placement was significantly greater among Medicaid-enrolled pediatric patients than those with commercial insurance, regardless of cause for ED admission. Providers should consider these findings when...
considering treatment choices for Medicaid enrollees and educating patients/caregivers on appropriate follow-up care which may help decrease the utilization of ED for non-emergency encounters.

**SPONSORSHIP:** Otonomy.

### H02 Development of an Ear Drop Caregiver Burden Questionnaire for Post-tympanostomy Tube Ear Drop Administration

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**BACKGROUND:** Topical antibiotics are commonly prescribed following tympanostomy tube (TT) placement to treat otorrhea. Administration of ear drops to young children can pose challenges to caregivers such as compliance, administration technique, dose accuracy, and penetration of drops into the middle ear. The Otitis Media-6 (OM-6) survey measures health-related quality of life for children with otitis media but does not address ear drop administration.

**OBJECTIVE:** To develop a questionnaire that assesses caregiver burden of administering post-TT ear drops to young children.

**METHODS:** Eligible participants were adult caregivers of children who received TT for bilateral middle ear effusion within the previous 2-4 weeks and prescribed ear drops. Upon IRB approval, two phases of caregiver interviews were conducted. First, concept elicitation interviews were done to understand the burden of ear drops from caregivers’ perspective. From this, a preliminary item pool for the questionnaire was created. Second, cognitive debriefing interviews using a “think-aloud” format gathered caregivers’ interpretation of each item, importance of each item, and thought process used to develop each response.

**RESULTS:** 16 caregivers participated (concept elicitation n = 5; cognitive debriefing, n = 11). Most were female (81.2%); mean age 32.3 years (range 23-45 years); 50% white; and 37.5% Medicaid enrollees. An 11-item Ear Drop Caregiver Burden Questionnaire was developed and will be further evaluated in an upcoming Phase 3b study. The final 10-item Ear Drop Caregiver Burden Questionnaire was developed and presented.

**CONCLUSIONS:** The results suggest that the ACE I/D polymorphism may contribute to development of hypertension in Saudi population.

**SPONSORSHIP:** None.

### 104 Budget Impact Model for Use of PA32540 (Enteric-Coated Aspirin 325 Mg + Immediate-Release Omeprazole 40 Mg) to Prevent Recurrent Cardiovascular Events

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**BACKGROUND:** Aspirin (acetylsalicylic acid; ASA) is commonly used for secondary prevention of cardiovascular (CV) events but may be associated with gastrointestinal (GI) adverse events (AEs), which can reduce adherence. At doses ≤ 325 mg, enteric-coated (EC) ASA and buffered ASA formulations do not appear to reduce risk of GI toxicity, and the risk of ASA-associated GI AEs is increased regardless of ASA dose. Prescribing and adherence to ASA co-therapy with proton pump inhibitors in patients at risk may be suboptimal. PA32540 is a coordinated-delivery tablet combining EC-ASA 325 mg and immediate-release omeprazole 40 mg. In clinical studies, PA32540 significantly reduced incidences of gastroduodenal ulcers (vs. EC-ASA 325 mg), with fewer upper-GI symptoms and discontinuations due to pre-specified GI AEs (P<0.001 for all).

**OBJECTIVE:** To project financial consequences of introducing PA32540 to prevent recurrent CV events while reducing ASA-associated GI events in U.S. adults, we developed a flexible budget impact model.

**METHODS:** A Markov Model was employed to estimate health state transitions associated with ASA 75-325 mg, ASA 75-325 mg + generic omeprazole 40 mg, PA32540, or clopidogrel 75 mg to prevent recurrent CV events. Health states included ulcer, GI bleeding, CV events, and death. Model inputs included demographics, treatment dosages, the costs of treatments, adverse GI and CV events, and premature death. Peer-reviewed literature and census data enabled appropriate allocation of the cost of treatments (other than PA32540), CV disease prevalence, and GI and CV disease mortality rates. The PA32540 nonadherence rate was conservatively set at 20% (vs. 1.5% observed in phase 3 studies). PA32540 market share was set to 50% of 134,558 plan members at risk for recurrent CV events. Health states included ulcer, GI bleeding, CV events, and death. Model inputs included demographics, treatment dosages, and costs of treatments, adverse GI and CV events, and premature death. Peer-reviewed literature and census data enabled appropriate allocation of the cost of treatments (other than PA32540), CV disease prevalence, and GI and CV disease mortality rates. The PA32540 nonadherence rate was conservatively set at 20% (vs. 1.5% observed in phase 3 studies). PA32540 market share was set to 50% of 134,558 plan members at risk for recurrent CV events.

**RESULTS:** The model projected annual savings of $66.2 million to $159.9 million within 1 to 5 years after PA32540 introduction to the plan. These values translate into savings of $492 (year 1) to $1,188 (year 1) per patient per year and $66 (year 5) to $160 (year 4) per plan member per year. These values were robust to variations in parameters under a deterministic sensitivity analysis.
CONCLUSIONS: In this model, use of PA32540 to prevent recurrent CV events was associated with cost reductions in each year examined. From a health plan perspective, PA32540 is likely to have a net overall effect that is budget saving.

SPONSORSHIP: Funded by Aralez Pharmaceuticals R&D.

105 Cardiac Resynchronization Therapy and Adherence to Heart Failure Regimens  
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BACKGROUND: Guideline-directed therapy for heart failure (HF) with reduced ejection fraction includes angiotensin-converting enzyme inhibitors (ACE-I) or angiotensin receptor blockers (ARB), beta-blockers (BB), and for patients with electrical dyssynchrony (evidenced by wide QRS), cardiac resynchronization therapy alone (CRT-P) or combined with a defibrillator (CRT-D). Adherence to HF medications after CRT implantation has not been described.

OBJECTIVE: To describe CRT patient HF regimen adherence after device implantation.

METHODS: MarketScan administrative claims data from 01/2008 to 12/2014 in patients age <65 years with ≥ 1 claim for CRT were used. The first observed CRT implantation date served as the index date. Patients with cancer diagnoses or continuous use of hypersensitivity myocarditis or other medications in the pre-index period were excluded. Pre- and post-index periods of 6, 12, and 24 months were defined. Adherence to separate medication classes of interest (i.e., diuretic, ACE-I, ARB, BB, aldosterone antagonist, digoxin, and statin) during the pre- and post-index periods were assessed using proportion of days covered (PDC). Comparisons between the two periods were made using the Wilcoxon sign-rank test for continuous PDC and McNemar’s test for dichotomized PDC.

RESULTS: 4,512 patients with CRT and ≥6 months of continuous enrollment pre- and post-index were identified. 2,612 patients had ≥12 months continuous enrollment and 832 had ≥24 months. Mean ± standard deviation of PDC for a regimen of ACE-I/ARB/DRI, Diuretic, and BB increased by 36.4% from 0.41 ± 0.29 in the 12 months before CRT (i.e., pre-index) to 0.55 ± 0.29 in the 12 months after CRT (i.e., post-index; P < 0.001). The compliance increase was 67.1% from 0.30 ± 0.28 in the 24-months before CRT to 0.50 ± 0.30 24 months after (P < 0.001). Patients with PDC ≥80% for the regimen nearly doubled (P < 0.001). The proportion of patients with PDC ≥80% for individual medication classes increased consistently and substantially at 12 months post- vs. pre-index, e.g., ACE-I 54.4% vs. 37.1%, BB 58.2% vs. 33.9%, loop diuretic 41.8% vs. 27.0%, (all P < 0.001). Similar results were found from comparisons of 0- to 24-month pre- and post-index periods and when statins and digoxin were added to the regimen.

CONCLUSIONS: Adherence to HF regimens significantly and substantially improved among HF patients after CRT. This may be due to closer patient monitoring and improved quality of life leading to greater medication compliance.

SPONSORSHIP: Research honoraria and payment of the MarketScan data rider fees were paid by Medtronic.

106 Minimizing Burden of Disease-Related Hospitalization Among Pulmonary Arterial Hypertension Patients  
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BACKGROUND: Pulmonary-arterial hypertension (PAH) is a rare, debilitating, and progressive disease that eventually leads to right heart failure and death. Hospitalization can be required to manage PAH-related morbidity events, and is recognized as a marker of clinical worsening. Macitentan, an endothelin-receptor antagonist (ERA), has demonstrated effectiveness in decreasing PAH-related morbidity (hospitalizations), and is among guideline-recommended therapies.

OBJECTIVE: To estimate the savings related to averted hospitalizations by evaluating number and costs in patients with PAH.

METHODS: A decision tree model estimates hospitalizations and costs associated with use of macitentan or placebo in a hypothetical 10 million-person population over one year from a commercial payer perspective. Published data informed the incidence and prevalence of PAH, dosing for PAH treatments (macitentan, and background therapies sildenafil and iloprost) as well as unit costs of hospitalization ($33,679) and drug therapies. Published SERAPHIN trial data informed placebo mortality and PAH-related hospitalization rates for placebo and macitentan 10 mg (overall population), as well as hazard ratios (HR) for decreasing hospitalization and mortality in discrete trial subgroups: incident (HR: 0.40), prevalent (HR: 0.47), macitentan monotherapy (HR: 0.45), combination therapy (HR: 0.62), and WHO functional classes II and III (HRs 0.58, 0.49). The model base-case analysis assumes constant mortality (2.6%) for the placebo arm across all patient groups.

RESULTS: In a plan of 10 million covered lives, 737 PAH cases would be eligible for treatment with macitentan, leading to 84 (50% reduction) fewer hospitalizations in a year and $3,847,353 in hospital-related savings. Average savings per PAH patient is $5,223. For subgroups considered, hospitalization-related savings ranged from 35.5% (patients on background therapy) to 57.4% (incident patients). Even for patients on macitentan monotherapy, hospitalizations fall by more than 52.3% for total savings of $1,334,364.

CONCLUSIONS: Macitentan use is beneficial to reduce the cost of care for PAH patients given reductions in disease-related hospitalizations. This finding is robust across patient subgroups, highlighting the benefit of macitentan use in a variety of patients, including new and previously identified patients, patients receiving monotherapy as well as combination therapies, and across functional classes. Averted hospitalizations remove burden for patients, adding humanistic value in addition to financial savings.

SPONSORSHIP: This study was funded by Actelion.

108 Comparison of All-Cause Healthcare Resource Utilization and Costs Among Patients with Nonvalvular Atrial Fibrillation, Newly Treated with Dabigatran or Warfarin  
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BACKGROUND: Dabigatran is a novel oral anticoagulant (NOAC) approved in the United States to reduce the risk of stroke in patients with nonvalvular atrial fibrillation (NVAF).

OBJECTIVE: To compare all-cause healthcare resource utilization (HCRU), costs, persistence, and discontinuation among NVAF patients newly treated with dabigatran or warfarin in the U.S.
METHODS: A retrospective matched cohort among newly diagnosed NVAF patients aged ≥ 18 years treated with dabigatran or warfarin during 01/01/2011-12/31/2013 was identified using a nationwide administrative claims database. All patients had continuous enrollment for at least 6 months prior to the first observed NVAF diagnosis to ensure they were newly diagnosed. All patients had continuous enrollment for 12 months before the index date (date of first claim for dabigatran or warfarin), followed for up to 12 months or until discontinuation or switch, disenrollment, end of study period, or inpatient death. Dabigatran and warfarin users were matched 1:1 using propensity scores. Per-patient-per-month (PPPM) HCRU and costs were reported. Descriptive and multivariate analyses were used to examine differences in outcomes.

RESULTS: A total of 18,980 dabigatran patients were matched to corresponding warfarin patients (mean age 67.8 vs. 68.1 years, 57% vs. 36% female, respectively). Compared with warfarin users, dabigatran users had significantly fewer hospitalizations (0.04 vs. 0.05), emergency room visits (0.12 vs. 0.16), office visits (1.19 vs. 1.65), and lower 30-day readmissions (14.5% vs. 17.4%), all P<0.001. Among those hospitalized, mean hospital length of stay was significantly lower among dabigatran users (3.86 days vs. 4.43 days, P<0.001). Mean total healthcare costs, inpatient costs, and outpatient costs were significantly lower for dabigatran users ($3,094 vs. $3,479; $916 vs. $1,210; $1,615 vs. $1,919, respectively, all P<0.001), but mean pharmacy costs were significantly higher than warfarin users ($225 vs. $10, P<0.001). Non-persistence and discontinuation rates were significantly higher for warfarin users than dabigatran users (66% vs. 62.1%, P<0.001; 58.0% vs. 57.0%, P=0.048). Consistent with these results, multivariate analyses demonstrated dabigatran users had significantly lower HCRU and costs and significantly higher persistence than warfarin users.

CONCLUSIONS: Among newly diagnosed NVAF patients, those newly treated with dabigatran had significantly lower HCRU, lower total, inpatient, and outpatient costs, and higher persistence than those treated with warfarin.

SPONSORSHIP: This work was supported by Boehringer Ingelheim.

110 Do ASCVD and HeFH Patients Adding Ezetimibe to Statin Therapy Achieve Treatment Success?

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BACKGROUND: Patients with atherosclerotic cardiovascular disease (ASCVD) and heterozygous familial hypercholesterolemia (HeFH) are at a high risk for subsequent cardiovascular (CV) events. Although different treatment goals have been proposed in these patients including a LDL-C ≤ 70 mg/dL and a 50% reduction in baseline LDL-C, they all include lowering low-density lipoprotein cholesterol (LDL-C) levels. Statin therapy is the first-line approach, and addition of ezetimibe is recommended in patients who do not reach treatment goals on statins alone.

OBJECTIVE: To describe post-ezetimibe treatment success in patients with ASCVD, using statins at baseline.

METHODS: IMS’s electronic medical record (EMR) database was used to identify ASCVD patients who had a LDL-C value ≥ 70 mg/dL between 1/1/2012 and 8/31/2014. The patient’s first LDL-C value in this period served as their baseline LDL-C and the index date. A subset of patients with an index LDL-C ≥ 190 mg/dL were classified as having comorbid HeFH, per the ACC/AHA criteria. All patients were required to use statin therapy at index and initiate ezetimibe in the 365 days post-index. Post-index LDL-C values were assessed 30 to 365 days post initiation of ezetimibe. Treatment success was defined as reaching LDL-C ≤ 70 mg/dL, or a ≥ 50% reduction in LDL-C. Only patients with a LDL-C value post ezetimibe initiation were included in the analysis.

RESULTS: There were 105,050 ASCVD patients using statins, mean (SD) age was 69.8 (10.1) years and 55.2% were male with mean (SD) index LDL-C of 85.7 (31.3) mg/dL. Only 1.23% (n=1,293) patients added ezetimibe to their statin regimen in the 365 days post-index. For patients with baseline LDL-C between 71-100 mg/dL, 39.2% reached LDL-C ≤ 70 mg/dL, however, only 16% of patients with baseline LDL-C between 101-130 mg/dL, and only 7.6% patients with baseline LDL-C ≥ 131 mg/dL reached LDL-C ≤ 70 mg/dL. A 50% reduction in LDL-C from baseline was observed only in 2.9%, 3.6% and 13.3% of patients with LDL-C values between 71-100 mg/dL, 101-130 mg/dL, and ≥ 131 mg/dL, respectively. Within the subset of comorbid HeFH patients (n=928, mean age=65.2 (11.1) years, 35.2% male), mean index LDL-C was 215.8 (31.3) mg/dL, only 4.4% initiated ezetimibe post-index. Only 5.3% of FH patients reached a LDL-C of ≤ 70 mg/dL and 23.3% experienced a ≥ 50% reduction, post-ezetimibe initiation.

CONCLUSIONS: The majority of ASCVD patients who added ezetimibe to statins failed to achieve treatment success within 1 year of initiating ezetimibe. Additional therapy may be warranted to support LDL-C goal achievement.

SPONSORSHIP: This work was funded by Amgen.
and 51% used other LLTs (vs. 3% non-PCSK9i users) as a part of their current treatment regimen. The most common physician reported reasons for change of therapy to PCSK9i were lack of efficacy (70%) and muscle related symptoms (myalgia 29%, myopathy 11%).

**CONCLUSIONS:** Patients using PCSK9i inhibitors had higher prior statin and ezetimibe use, and were more likely to be statin intolerant. The patients using PCSK9i therapy had higher baseline mean LDL-C value than non-PCSK9i users, prior to treatment initiation. Physicians used PCSK9i therapy due to lack of efficacy and muscle-related symptoms with other treatments.

**SPONSORSHIP:** This work was funded by Amgen.

### Evaluating the Strength of the Practical Utility of Statin Intolerance Definitions as Recommended by a Regional Managed Care and Clinical Expert Panel

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**BACKGROUND:** All major cardiovascular (CV) guidelines recommend the use of statins to reduce the risk of CV events; however, it is estimated that 5% to 25% of patients experience statin intolerance (SI) in the real-world. In November 2015, experts within a regional integrated delivery network (rIDN) discussed how to identify their patients with SI and proposed 3 SI identification algorithms (ALGs).

**OBJECTIVE:** To evaluate the strengths and differences among the 3 SI ALGs proposed by the rIDN panel.

**METHODS:** The methods detailing the panel construction and recommendations were previously presented (AMCP 2016). The recommendations were operationalized and applied to rIDN administrative data using both medical and pharmacy claims (Rx). Adult patients were selected based upon any statin Rx from 2011-2012, the first Rx as the index date. Included patients had continuous plan enrollment for ≥ 1 year pre-index (baseline) and ≥ 2 years post-index. All 3 ALGs used Rx to determine statin switching patterns, down titration, discontinuation, and the use of non-statin lipid lowering treatments. Specific ALG criteria: ALG1-Rx (as mentioned above) + medical claims (rhabdomyolysis, muscle weakness, and an outpatient creatinine kinase lab test); ALG2-Rx only; and, ALG3-same as ALG1, but restricted to statin-induced patients only. The ALGs were then applied to 4 different cohorts: C1 ≥ 2 statins in baseline with ≥ 1 statin Rx ≤ 6 months from index; C2 = patients with 1 statin Rx during baseline and no statin Rx ≥ 6 months prior to index; C3 = patients with 1 statin Rx during baseline and no statin Rx ≥ 6 months prior to index; C4 = no statin Rx in baseline.

**RESULTS:** Using the above criteria, 22,692 patients were identified: C1 (n = 13,128), C2 (n = 605), C3 (n = 1,469), and C4 (n = 7,490). Baseline demographic and clinical characteristics were significantly different among the 4 cohorts; C4 tended to be younger with fewer comorbidities and less concomitant drug use. Across the 3 ALGs and 4 cohorts, SI rates varied from 9% (C3/ALG2) to 18% (C2/ALG1); however, C2 was deemed unreliable and excluded given sufficient prior statin data. ALG3 resulted in the highest rates of SI (min 10.6%) as compared to the other 2 ALGs (min 9.9% [ALG1] -8.6% [ALG2]).

**CONCLUSIONS:** Rx patterns appear to be the strongest discriminator for identifying SI as the inclusion of medical claims provided small incremental gains. Pharmacy benefit managers (PBMs) and health plans could easily use ALG2 to understand their patients with SI and development of potential strategies for optimal lipid and cardiovascular disease management.

**SPONSORSHIP:** Funded by Regeneron and Sanofi U.S.
trials and observational studies vary considerably. Historically, SI estimates from claims databases have been challenging due to lack of validated algorithms. Recently, algorithms (ALGs) have been published to identify SI, but little is known of their similarities or differences.

**OBJECTIVE:** To compare SI classification algorithms for newly prescribed statin patients.

**METHODS:** Patients were selected from a regional integrated delivery network (rIDN) administrative claims based upon any statin pharmacy (Rx) claim from 2011-2012, the first Rx being the index date. Additionally, patients were ≥18 years at index, continuously enrolled in the plan for ≥1 year pre-index (baseline) and ≥2 years post-index (follow-up), and had no statin during baseline. Two ALGs for identifying SI patients were utilized. The methods detailing a rIDN expert panel (EP) ALG were presented (AMCP 2016) and an ALG using administrative claims (PYR) was recently published (Value in Health 2016). Both ALGs were operationalized using the rIDN claims. SI rates for EP ALG and PYR ALG were compared and measures of concordance evaluated.

**RESULTS:** Based on inclusion criteria, 7,490 patients were evaluated for SI. The EP ALG identified SI in 11.4% of patients compared to 5.4%. The PYR ALG was more restrictive in identifying SI, requiring ≥100 days after the last Rx to classify, the EP ALG used all data. The time to qualifying SI event differed between groups with the EP ALG occurring at approximately 148 days vs. PYR ALG at 380 days (P<0.0001); however, the ALGs also allowed for different follow-up times—EP used only 1 year and PYR used 2 years. For measures of concordance between the EP and PYR ALGs, specificity (0.97), negative predictive value (0.91) and Cohen's kappa (0.87) all showed good agreement; however, sensitivity (0.21) and positive predictive value (0.45) were poor. Other measures of concordance also indicated mixed agreement between the two ALGs.

**CONCLUSIONS:** The EP ALG corroborated the PYR ALG with similarities for the inclusion of medical claims for myalgias and the use of Rx claims to differentiate patients likely to underutilize statins for other reasons, not specific to SI. Nonetheless, both ALGs have a strong reliance on Rx claims wherein the main difference between the two for SI patient identification was in the application of those patterns.

**SPONSORSHIP:** Funded by Regeneron and Sanofi U.S.

**118 Alirocumab Efficacy and Safety in Statin-Treated Patients with or without Ezetimibe: Analysis of 3 Randomized Trials**

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**BACKGROUND:** Recent guidelines recommend non-statin lipid-lowering therapies (LLTs, e.g., ezetimibe [EZE] or PCSK9 inhibitors) for patients at high cardiovascular (CV) risk when LDL-C goals are not reached with maximally tolerated statins.

**OBJECTIVE:** To investigate the efficacy and safety of alirocumab (ALI) in patients with or without EZE.

**METHODS:** This analysis evaluated 3 placebo-controlled, 78-week, phase 3 ODYSSEY trials (FHII, N=486; FHIII, N=249; LONG TERM [LT], N=2,341). Patients had heterozygous familial hypercholesterolemia (HeFH) or non-FH and received background maximally tolerated statin ± other LLTs. In FHII/LI, patients received ALI 75 mg every 2 weeks (Q2W), with dose increase to 150 mg at W12 if they did not achieve their LDL-C treatment goal at W8. ALI dose was 150 mg Q2W in LT. The primary endpoint (% LDL-C reduction) in all studies was evaluated at W24. Efficacy data from FH I/II were pooled while LT was analyzed separately; safety was analyzed in a pool of all 3 studies.

**RESULTS:** The proportion of patients receiving background EZE was 44/732 (6.1%) in the pool of FHII/LI and 333/2,310 (14.4%) in LT. In FHII/LI, mean baseline LDL-C levels for ALI and placebo were 139.4 and 138.0 mg/dL with EZE, and 144.0 and 145.6 mg/dL without EZE. Mean LDL-C % changes from baseline to week 24 for ALI vs. placebo were -51.0% vs. 5.6% (with EZE) and -45.5% vs. 9.5% without EZE (P<0.0001). In LT, mean baseline LDL-C levels were
141.9 and 147.0 mg/dL with EZE, and 119.6 and 117.5 mg/dL without EZE. Mean LDL-C % changes from baseline to week 24 for ALI vs. placebo were -59.2% vs. 5.6% (with EZE) and -73.9% vs. -5.7% (without EZE, P < 0.0001). In FHI/II, risk-based LDL-C treatment goals of <70 or <100 mg/dL were achieved at week 24 by 78.3% (ALI) vs. 6.9% (placebo) of patients with EZE and 70.9% vs. 2.9% without EZE. In LT, risk-based LDL-C treatment goals of <70 or <100 mg/dL were achieved at week 24 by 77.7% vs. 4.7% with EZE and 81.3% vs. 9.2% without EZE. With the exception of a higher incidence of injection site reactions with ALI vs. placebo (with or without EZE), adverse events did not differ between groups, with or without EZE.

CONCLUSIONS: In high CV-risk patients treated with maximally tolerated doses of statins, alirocumab provided consistent and robust LDL-C reductions with a good safety profile, with or without concomitant EZE.

SPONSORSHIP: Funded by Sanofi U.S. and Regeneron.

120 Consistent Reductions in Atherogenic Lipid Parameters with the PCSK9 Inhibitor Alirocumab in Patients Not Receiving Background Statin

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BACKGROUND: With the approval of the PCSK9 inhibitor class, guideline recommendations on the most appropriate non-statin lipid-lowering agent vary for patients unable to tolerate statins.

OBJECTIVE: To evaluate the efficacy and safety of the PCSK9 antibody alirocumab (ALI) vs. ezetimibe (EZE) in 354 hypercholesterolemic patients at moderate to very high cardiovascular (CV) risk not receiving background statins.

METHODS: Data were pooled from 2 randomized, 24-week, EZE-controlled, double-blinded, Phase 3 ODYSSEY trials: MONO (NCT01644474), a monotherapy study, and ALTERNATIVE (NCT01709513), a trial in statin intolerant patients. Baseline LDL-C levels at screening of patients at moderate to very high cardiovascular (CV) risk were ≥70 and ≥190 mg/dL in MONO (n = 52 ALI, n = 51 EZE), and ≥70 or ≥100 mg/dL (depending on level of CV risk) in ALTERNATIVE (n = 126 ALI, n = 125 EZE). ALI dose was increased from 75 to 150 mg every 2 weeks at Week (W)12 if LDL-C was ≥70 mg/dL at W8 in MONO (30.4% of patients), and ≥70 or ≥100 mg/dL, depending on CV risk, at W8 in ALTERNATIVE (49.5% of patients). Endpoints were mean % changes in calculated LDL-C, ApoB, non-HDL-C and Lp(a) levels from baseline to W12 and W24.

RESULTS: Baseline characteristics were comparable between ALI and EZE groups. Patients on ALI had significantly greater LDL-C reductions from baseline to W12 (-47.4% vs. -16.7% EZE; P < 0.0001) and W24 (-45.6% vs. -14.8% EZE; P < 0.0001), and a higher proportion of patients on ALI reached LDL-C levels of <100 mg/dL (68.9% vs. 16.5% EZE; P < 0.0001) and <70 mg/dL (39.8% vs. 1.6% EZE; P < 0.0001) at W24. Significantly greater reductions in ApoB (-36.5% ALI vs. -11.2% EZE), non-HDL-C (-40.4% ALI vs. -14.7% EZE), and Lp(a) (-23.3% ALI vs. -8.9% EZE) were also observed (all P < 0.0001 vs. EZE). Treatment-emergent adverse event (TEAE) rates were comparable between groups (69.2% ALI vs. 78.4% EZE in MONO; 82.5% ALI vs. 80.6% EZE in ALTERNATIVE). Common TEAEs occurring in ≥5% of patients from either treatment group in both studies included nasopharyngitis, upper respiratory tract infection, back pain and arthralgia.

CONCLUSIONS: ALI treatment produced significantly greater reductions in LDL-C and other atherogenic lipoproteins vs. EZE without background statins, and enabled a greater proportion of patients to achieve LDL-C levels of <100 and <70 mg/dL vs. EZE. These data complement data from ODYSSEY Phase 3 trials performed on background statins, and show that alirocumab may be a safe and effective therapeutic option when statin therapy cannot be employed.

SPONSORSHIP: Funded by Sanofi U.S. and Regeneron.

121 Modeling the Pharmacy Budget Impact of Alirocumab on U.S. Health Plans

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1Sanofi U.S.; 2Regeneron; 3Policy Analysis

BACKGROUND: Alirocumab, a monoclonal antibody specific to PCSK9, is approved in the United States as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherothrombotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

OBJECTIVE: To estimate the budget impact of alirocumab use in adult patients with HeFH or clinical ASCVD who are on statins and require additional lowering of LDL-C to <70 mg/dL from the perspective of a U.S. healthcare payer.

METHODS: A budget impact model was developed to understand pharmacy costs of therapy with statins ± other lipid-modifying therapy (LMT) over a 3-year projection period for 2 scenarios: (1) alirocumab available as an add-on therapy to statins; (2) alirocumab not available. Input parameters were derived from randomized controlled trials, epidemiologic studies, and real-world database analyses.

RESULTS: For a representative health plan of 1 million members, a maximum alirocumab utilization rate of 5% to be achieved after 3 years, and an incremental cost of $14,610 per patient per year, the introduction of alirocumab resulted in an estimated $33.0 million increase in total pharmacy costs over the 3-year projection period. The increase in pharmacy costs per member per month (PMPM) was estimated to be $0.46 in the first year of the projection and $1.36 in the third year. In the sensitivity analysis, the maximum alirocumab utilization rate was assumed to be 10% after 3 years and the increase in pharmacy costs was estimated to be $0.91 PMPM in the first year of the projection and $2.73 in the third year. Results were sensitive to assumptions regarding the utilization of alirocumab, patient eligibility criteria, and the model time frame. Budget impact was examined by different heath plan types and the increase in pharmacy costs after the introduction of alirocumab was lowest for a Medicaid health plan ($11.3 million increase over the 3-year projection period when alirocumab was added).

CONCLUSIONS: The introduction of alirocumab as a potential add-on therapy to statin for patients with ASCVD or HeFH requiring additional lowering of LDL-C is likely to have a smaller impact on U.S. health plans than previously published estimates. Rebates and discounts to medication costs and offsets from potential reductions in cardiovascular related costs will further reduce the budget impact.

SPONSORSHIP: Funded by Sanofi U.S. and Regeneron.

122 Real-World Comparison of Major Bleeding and Associated Costs Among Treatment-Naive Nonvalvular Atrial Fibrillation Patients Initiating Apixaban, Dabigatran, Rivaroxaban, or Warfarin

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BACKGROUND: Recent large randomized controlled trials have shown that novel oral anticoagulants (NOACs) are associated with similar or lower rates of bleeding compared to warfarin.

OBJECTIVE: To compare the risk of major bleeding and its associated medical costs among nonvalvular atrial fibrillation (NVAF) patients initiating warfarin versus apixaban, dabigatran, or rivaroxaban.

METHODS: A retrospective cohort study was conducted using the Optum Database from January 1, 2012 through September 30, 2015. Adult NVAF patients with commercial or Medicare Advantage insurance newly prescribed warfarin, apixaban, dabigatran, or rivaroxaban with no prior anticoagulation in the baseline period were identified from January 1, 2013 through September 30, 2015. The first prescription date was defined as the index date. Major bleeding was defined as the first major bleeding requiring hospitalization (based on the first listed ICD-9-CM diagnosis code). A Cox proportional hazards model was used to estimate the adjusted hazard ratio (HR) of major bleeding within one year of the index date. Follow-up major bleeding medical costs were examined using a two-part generalized linear model that controlled for the probability of having a major bleed.

RESULTS: This study included 21,668 (44.6%) warfarin, 8,786 (18.1%) apixaban, 3,742 (7.7%) dabigatran, and 14,442 (29.7%) rivaroxaban newly treated NVAF patients. Warfarin initiators were older and had higher CHA2DS2-VASC and Charlson Comorbidity Index scores compared to the NOAC cohorts. As compared to patients who initiated warfarin, patients who initiated apixaban (HR = 0.51, 95% CI: 0.42-0.61) and dabigatran (HR = 0.65, 95% CI: 0.51-0.83) had a significantly lower risk of major bleeding. There was no significant difference in the risk of major bleeding among patients who initiated rivaroxaban (HR = 0.91, 95% CI: 0.80-1.03) as compared to warfarin initiators. Major bleeding-related medical costs per patient per month were significantly lower among apixaban patients compared to warfarin patients ($68 vs. $173; P < 0.001), while dabigatran ($170, P = 0.916) and rivaroxaban ($162, P = 0.611) showed numerically but nonsignificantly lower costs than warfarin.

CONCLUSIONS: Among newly anticoagulated NVAF patients in a real-world setting, patients who initiated apixaban or dabigatran were associated with significantly lower risk of major bleeding as compared to those who initiated warfarin. Patients who initiated apixaban had significantly lower major bleeding-related medical costs compared to those who initiated warfarin.

SPONSORSHIP: Sponsored by Pfizer and Bristol-Myers Squibb.
tests compared differences between groups with P < 0.05 considered statistically significant. Logistic regression identified the association of having a HCR benefit with using abxs inappropriately.

RESULTS: A total of 26,195 members (non-HCR: 22,867; HCR: 3,328) having a HCR benefit with using abxs inappropriately. AAB: 18,509 (70.7%), CWP: 4,134 (15.8%), URI: 3,552 (13.6%). Average age was 46.0 (AAB), 12.3 (CWP) and 10.6 (URI) years. Members received care mainly from an office visit (AAB: 78.2%, CWP: 76.1%, URI: 79.9%) and urgent care (AAB: 17.4%, CWP: 17.7%, URI: 13.7%). Most common prescribers were primary care physicians (PCP; AAB: 58.5%, CWP: 40.4%, URI: 39.9%) and physician assistants (PAs; AAB: 17.6%, CWP: 19.3%, URI: 19.0%). Factors significantly associated with having a HCR plan were as follows: where member received care (AAB: P = 0.015, CWP: P = 0.027), season (URI: P = 0.002, CWP: P < 0.001) and abx class (URI: P = 0.013). Among CWP, males were 23% more likely to have a HCR plan than females (OR = 1.23, P = 0.044). For URI, members seen in the emergency room (OR = 2.10, P = 0.042) or by a pediatrician (OR = 1.98, P = 0.042) were more likely to have an HCR plan than members seen in urgent care.

CONCLUSIONS: PCs and PAs most commonly prescribed abx inappropriately. Targeted education towards these prescribers may help improve performance of HEDIS measures related to abx use.

SPONSORSHIP: Blue Cross Blue Shield of Michigan.

J03 The Relationship Between Macrolide-Resistant Streptococcus Pneumoniae and Treatment Failure in Adults with Community-Acquired Bacterial Pneumonia by CDC Region in the United States

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BACKGROUND: Antimicrobial resistance has increased steadily in the United States since 2002 and is associated with poor health outcomes and increased costs particularly for patients with community-acquired bacterial pneumonia (CABP). However, the link between in-vitro resistance and real-world treatment failures for CABP is less established.

OBJECTIVE: To determine the relationship between macrolide-resistant S. pneumoniae and macrolide treatment failures in adult outpatients with CABP.

METHODS: A total of 710 non-duplicated isolates of S. pneumoniae were collected prospectively during 2014 from 38 medical centers located in the U.S. Isolates were tested for susceptibility by broth microdilution methods according to the recommendations of the Clinical & Laboratory Standards Institute (M100-S25). Treatment failure data was collected through a retrospective claims analysis using MarketScan Commercial & Medicare Supplemental Databases. Patients selected for inclusion were ≥ 18 years with an outpatient visit for CABP (ICD-9-CM codes 481.x, 482.x, 485.x, 486, 487.0) and a macrolide prescription (azithromycin or clarithromycin) monotherapy fill from June 2011 to May 2015. Failure was defined as macrolide refill, alternative antibiotic fill, emergency room visit or hospitalization for CABP 3-30 days post initial fill. Each separate dataset (susceptibility data and claims data) were then grouped into the 9 U.S. CDC census regions.

RESULTS: 112,054 patients met inclusion criteria in the claims dataset. Mean age was 49.1 (SD = 17.4), 46.4% were male, 83.2% were enrolled in a commercial health insurance plan and 90.6% were treated with azithromycin. Macrolide-resistant S. pneumoniae was highest in the West South Central and East South Central Regions (64% and 61% respectively) and lowest in the Pacific and Mountain Regions (42% and 31%). There was a positive correlation (P = 0.54) between macrolide treatment failure and macrolide resistance. In regions where resistance was > 50%, treatment failures were greater compared to regions where resistance was < 50% (20.6% vs. 17.9% respectively, P < 0.01). Of the patients who failed macrolide monotherapy, a greater number of patients required a new antibiotic in regions where resistance was > 50% compared to < 50% (72.2% vs. 67.7% respectively, P < 0.01).

CONCLUSIONS: There is a positive relationship between macrolide-resistant S. pneumoniae and macrolide treatment failure by region in patients with CABP. Additional studies should be conducted to further elucidate this relationship, most notably in patients with confirmed cases of S. pneumoniae.

SPONSORSHIP: AstraZeneca.
OBJECTIVE: To quantify the impact of antibiotic type on treatment failure in pediatric (age < 18 years) patients with CABP.

METHODS: We performed a retrospective analysis of pediatric patients with CABP using the Truven MarketScan Commercial & Medicare Supplemental Databases. The final population consisted of 156,413 patients < 18 years diagnosed with CABP (ICD-9-CM) during the enrollment window of June 2011-May 2015, having met all inclusion criteria. These patients were treated with one of the following index drug classes: beta-lactam (BL), macrolide (MAC), fluoroquinolone (FLU), or tetracycline (TET) monotherapy. Treatment failure (YN) was defined as index drug refill, non-index drug fill, or hospitalization or emergency room visit for CABP 3-30 days post-index fill. Descriptive statistics were used to summarize demographics and treatment outcomes. Bayesian statistics were used to evaluate the impact of index drug on treatment failure.

RESULTS: Out of the 156,413 pediatric patients, 53.1% were male. The average age was 7.1 (SD = 4.5) years. We focused on MAC and BL as FLU (0.42%) and TET (0.27%) together made up less than 1% of the index drug fills. Pediatric patients were almost 2X more likely to receive MAC initially (64.2%) compared to BL (35.0%). Patients had higher likelihood of failure if treated with BL (16.4%) compared to MAC (9.8%, P<0.05), suggesting the increased efficacy of MAC treatment for pediatric CAB. Regardless of the index drug, all patients were more likely to fail by non-index fill than any other failure type. Using Bayesian statistics, we explored underlying relationships of failure patterns. Specifically, 59.2% of the patients who failed BL treatment were switched to MAC. Similarly, 56.4% of patients who failed MAC treatment were switched to BL. However, a significant portion of patients who failed BL treatment were also prescribed a secondary BL (16.5%). In contrast, patients who failed MAC treatment were prescribed a secondary MAC to a much lesser extent (3.9%).

CONCLUSIONS: BL and MAC are the two most common drug classes used to treat children with CABP. However, patients treated with BL are significantly more likely to fail. Such analyses should help inform appropriate antibiotic choices to maximize treatment success.

SPONSORSHIP: Cempra.

J05

Antibiotic Treatment Failure in Adults with Community-Acquired Bacterial Pneumonia: An Analysis of a Large U.S. Claims Database

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BACKGROUND: Over 5 million patients present annually in the U.S. with community-acquired bacterial pneumonia (CABP) and are treated with an antibiotic yet failures beyond those resulting in hospitalization are often not reported in the literature.

OBJECTIVE: To compute failure rates of common antibiotic drug classes used to treat CABP in adults.

METHODS: This study was a retrospective claims analysis using MarketScan Commercial & Medicare Supplemental Databases. Patients were ≥18 years with an outpatient visit for CABP (ICD-9-CM codes 481.x, 482.x, 485.x, 486, 487.0) between June 2011 to May 2015, a beta-lactam (BL), macrolide (MAC), fluoroquinolone (FLU), or tetracycline (TET) monotherapy fill within 3 days of visit, 365 days continuous enrollment pre-index (first fill date), no hospital stay 0-2 days post-index, and no antibiotic fill or CABP diagnosis 30 days pre-index. Failure was defined as index drug refill, alternative drug fill, or emergency department (ED) visit or hospitalization for CABP 3-30 days post-index. Adjusted failure rates controlling for age, sex, CDC census region, and health plan design were obtained using logistic regression.

RESULTS: After excluding ceftriaxone (n=223) and ciprofloxacin (n=4,993) treated patients due to small sample sizes, 231,947 patients met all criteria. Patients were 52.2 ± 17.4 S.D. years old, 47.7% male, 25.1% of patients were treated with MAC (44.5%) and FLU (43.3%) and with BL (6.6%) and TET (5.6%). The adjusted overall failure rate was 19.0%. Nearly two-thirds (65.6%) of failures resulted in an alternative antibiotic fill, one-quarter an index agent refill (23.9%), 5.2% in hospitalization, and 3.9% in an ED visit. Adjusted failure rates were greatest for BL (23.0%) followed by TET (19.5%), MAC (18.7%), and FLU (18.6%). FLU failures had the greatest proportion of index refills (28.1%) followed by MAC (23.5%), BL (14.9%) and TET (12.4%). TET failures resulted in the greatest proportion of new agent fills (77.6%), followed by BL (76.2%), MAC (69.3%), and FLU (57.9%). FLU (range 44.3% to 60.1% unadjusted) was the most commonly filled alternative agent followed by MAC (range 33.3% to 49.3% unadjusted). Within class switches were 4.5% MAC, 5.3% BL and 11.7% FLU. Failures resulting in ED visits ranged from 2.9% (BL) to 4.6% (FLU) adjusted, and in hospitalization from 3.3% (MAC) to 8.1% (FLU).

CONCLUSIONS: Nearly 1 in 5 CABP patients treated with antibiotics failed their initial therapy demonstrating a significant unmet need in treating of this common infectious disease.

SPONSORSHIP: Cempra.

J06

Work Productivity and Caregiver Impact of Respiratory Syncytial Virus Hospitalizations Among U.S. Preterm Infants 29-35 Weeks Gestational Age

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BACKGROUND: Respiratory syncytial virus (RSV) is the leading cause of infant hospitalizations in the U.S., and preterm infants have an increased risk. The clinical consequences of RSV hospitalizations (RSVH) in preterm infants are well known; however, empirical evidence of how RSVH impacts caregivers is limited.

OBJECTIVE: To assess the impact of preterm infant RSVH on caregiver work productivity and caregiver stress.

METHODS: SENTINEL1 was an observational study of preterm infants 29-35 weeks gestational age hospitalized for RSV during the 2014-2015 RSV season (NCT02273882). The Work Productivity and Activity Impairment questionnaire for caregivers of children hospitalized for respiratory illness (WPAI-CHRI), which measures hours of work missed, absenteeism (ABS), presenteeism (PRE), overall work productivity loss (OWPL), and daily activity impairment (DAI) during...
the prior 7 d, was evaluated at discharge (D/C), 1 week, 2 weeks, and 1 month post D/C. Caregiver stress due to RSVH was also assessed at these times.

RESULTS: Caregiver data collected from 191 mothers and 77 fathers of 212 infants with community-acquired RSVH were studied. The mean and median hospital length of stay was 8 and 6 days, respectively. Among WPAI-CHRI caregiver respondents, 91 (48%) mothers and 72 (94%) fathers had paid employment. At D/C, 1 week, 2 weeks, and 1 month post D/C, respectively, employed mothers reported missing an average of 23, 14, 7, and 4 hours of work; reported ABS was 73%, 45%, 23%, and 16%; PRE was 64%, 52%, 33%, and 23%; OWPL was 91%, 71%, 43%, and 31%; among all responding mothers, DAI was 79%, 56%, 39%, and 24%. At D/C, 1 week, 2 weeks, and 1 month post D/C, respectively, employed fathers reported missing 24, 9, 4, and 2 hours of work, reported ABS was 58%, 23%, 9%, 4%; PRE was 64%, 49%, 29%, and 15%, OWPL was 81%, 51%, 31%, and 18%; among all responding fathers, DAI was 74%, 48%, 30%, and 18%. Emotional stress (e.g., worry, fear), disruption of family routine (e.g., travel for medical visits), medical concerns (e.g., monitoring infant’s breathing), and financial concerns were the most frequently reported RSVH-related caregiver concerns, which persisted through 1 month post D/C.

CONCLUSIONS: Preterm infant RSVH is a significant event that adversely affects caregivers, including missed work, diminished work productivity, emotional stress, financial concerns, and disruption of family routine. Caregiver burden due to RSVH extends beyond the hospitalization period and is an important consideration of the overall RSV disease burden that should not be overlooked.

SPONSORSHIP: This study was sponsored by AstraZeneca.

RESULTS: Treatment of children with uncontrolled allergic asthma during the 52-week study period.

METHODS: In private (PI) or government-funded (Medicaid; MD) plans, we identified children (6-11 years old) with severe or poorly controlled asthma (thereafter = asthma; ≥ 2 asthma medical claims with ICD-9-CM 493.x; 1st diagnosis = ID), ≥ 2 asthma medications claims 12 months after ID, and ≥ 1 claim for high-dose ICS or chronic OCS or ≥ 5 claims for SABA in 3 successive months 12 months after ID). We matched (1:1) children with asthma to those without asthma by demographics and compared mean healthcare costs per-patient-per-year (PPPY, 2014 $). In children with asthma, we tested the effect of allergen sensitization status on mean asthma-specific and overall costs via regression models, adjusting for demographics and OCS use.

RESULTS: The efficacy evaluation included 576 children: omalizumab (n = 384) vs. placebo (n = 192). A higher percentage of omalizumab-than placebo-treated children were free of: clinically significant exacerbations (52.9% vs. 39.6%, P = 0.003), any clinician-reported exacerbations (25.3% vs. 13.0%, P < 0.001), asthma-related hospital admissions (95.6% vs. 90.6%, P = 0.024), unscheduled doctor visits (71.6% vs. 62.5%, P = 0.032), and any emergency visit (66.4% vs. 53.1%, P = 0.003). Asthma-related emergency room visits were similar between the groups: 94.3% vs. 91.7%, P = 0.246. Omalizumab recipients missed few asthma-related mean (SD) school days than placebo recipients: 3.6 (5.7) vs. 4.9 (6.4), P = 0.0149.

CONCLUSIONS: Treatment of children with uncontrolled allergic asthma with omalizumab increased their likelihood of being free of exacerbations and some forms of healthcare resource use (hospitalizations and unscheduled office visits) and decreased their number of missed school days due to their asthma.

SPONSORSHIP: This study was funded by Genentech and Novartis.
without asthma. In children with severe or poorly controlled asthma, allergic status is associated with additional asthma-related costs, despite lower total costs. These effects were evident in private and government-funded health plans.

**SPONSORSHIP:** This study was funded by Genentech.

**J10** Treatment Escalation and Postescalation Exacerbation Among Asthma Patients Who Initiate an ICS-Containing Regimen

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**BACKGROUND:** Inhaled corticosteroids (ICS) are the cornerstone of asthma treatment and can be escalated if control is not obtained with ICS alone. However, many patients on ICS remain uncontrolled even after treatment escalation.

**OBJECTIVE:** To assess treatment escalation and the rate of exacerbations postescalation among asthma patients who initiate ICS or ICS-containing treatment.

**METHODS:** The study population includes asthma (ICD-9-CM 493.xx on ≥ 2 service dates) patients ≥12 years of age from a large U.S. administrative claims database, who initiated ICS or ICS-containing treatment (index date) between 1/1/2009 and 9/30/2014 and had at least one year of continuous enrollment before and after index date. Patients were excluded if they had other lung diseases or prescription treatment (index date) between 01/01/2004 and 11/30/2012 and followed up from the first ICS ± LABA fill until the earlier of the last ICS ± LABA fill (plus day's supply of last fill), disenrollment, death, or end of study period. Measured as proportion of days covered (PDC), adherence to ICS ± LABA was assessed between the first and the last fill for ICS period (time period with ICS prescriptions only) and ICS/LABA period (time period with ICS/LABA prescriptions only), respectively. Exacerbation was defined as: new diagnosis of 493.x, or asthma-related hospital admission or emergency department (ED) or urgent care visits. Rates of exacerbation events per 100 person-years were determined for ICS periods or ICS/LABA periods, respectively.

**RESULTS:** The study sample included 5,256 patients, the majority of which were female (58.4%) and >18 years of age (61.1%; mean ± SD age: 30 ± 18.7 years). Mean ± SD duration of follow-up after index controller fill was 371 ± 30.6 months. Adherence was slightly higher for patients who filled prescriptions for ICS/LABA relative to ICS (mean ± SD PDC: 47 ± 28.8% and 40.8 ± 29.1%, respectively). The proportion of patients with an OC fill was 45.1% or 43.9%, and the rate (95% CI) of OC fills was 44.4 (42.9, 45.8) or 41.7 (40.3, 43.1) per 100 person-years for patients filling ICS or ICS/LABA prescriptions, respectively. The rate (95% CI) of inpatient admissions, ED, and urgent care visits for asthma was 1.75 (1.48, 2.05), 13.55 (12.77, 14.35), and 2.71 (2.37, 3.09) per 100 person-years, respectively, for patients filling ICS, ICS ± LABA (1.97 [1.67, 2.3]), 12.79 (12.01, 13.6), and 2.76 (2.41, 3.15), respectively, for those filling ICS/LABA.

**CONCLUSIONS:** Adherence to ICS ± LABA was low and rates of exacerbations were high in this patient population, suggesting many patients with persistent asthma remain poorly controlled despite ICS ± LABA therapies and better management is needed to fill the care gap.

**SPONSORSHIP:** This study was funded by Boehringer Ingelheim.

**J11** Incidence of Acute Respiratory Distress Secondary to Opioid Morphine Equivalent Dose Among a Medicaid Population

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Xerox State Healthcare

**BACKGROUND:** Medicaid recipients are prescribed opioids at twice the rate of non-Medicaid patients. Providers may be unsure and patients may be unaware of the risk of acute respiratory distress (RD) with opioids. Based on pain guidelines and data analysis, state programs can implement morphine equivalent (ME) dosing limits that promote safe use of opioids.

**OBJECTIVE:** To describe trends in acute RD among recipients with and without a history of RD for three ME dose ranges.

**METHODS:** Medicaid recipients continuously eligible from 01/01/2014 to 12/31/2015 were identified via claims data. Individuals who had opioid utilization in 2014 were excluded. Those remaining were divided into 4 groups: those who did not fill an opioid in 2015 (Group 1), those who filled an opioid with a daily dose of < 50 mg ME (Group 2), those who filled an opioid between 50 mg and 80 mg,
ME (Group 3), and those who filled an opioid ≥90 mg ME (Group 4). Recipients with non-opioid claims during 2015 served as the control. RD was defined by ICD-9 and ICD-10 diagnosis codes for acute respiratory failure or acute respiratory distress syndrome. The baseline incidence of acute RD was assessed 7 to 14 days before the first opioid fill in 2015. The incidence of acute RD was compared for all groups during the three weeks following the first opioid fill. The groups were further analyzed by separating the recipients with and without a history of any RD in 2014.

RESULTS: A total of 233,924 recipients were eligible for the study. Group 1 included 211,510 recipients, Group 2 = 19,330, Group 3 = 1,941, and Group 4 = 1,143. The incidence of acute RD among recipients (with and without prior RD) was similar across the 3-week time period for Groups 1, 2, and 3, while Group 4 saw an increase in acute RD from 1.05% at baseline to 3.10% in week 2. In the subgroup with no history of RD, the incidence of acute RD mirrored that of all combined recipients. Those who had a ME≥90 mg (Group 4) increased from 0.92% at baseline to 1.55% in week 2. However, in recipients with a prior history of RD both Groups 3 and 4 saw increases in acute RD through week 3. The increase from baseline to week 3 was 5.08% to 14.41% for Group 3 and 18.92% to 29.73% for Group 4.

CONCLUSIONS: The data indicates rates of acute RD increase most at a daily opioid ME≥90 mg, and the rate of acute RD is higher among recipients with a history of RD. Medicaid programs should implement daily opioid ME limits for recipients, including those at high risk due to prior history of RD, to improve safe use of opioids.

SPONSORSHIP: Funded internally by Xerox State Healthcare.

Impact of 2014 American Academy of Pediatrics Guidance for RSV Immunoprophylaxis

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BACKGROUND: The 2014 American Academy of Pediatrics guidance on respiratory syncytial virus immunoprophylaxis (RSV IP) recommended against its use in infants 29-34 weeks gestational age (wGA) without chronic lung disease (CLD) or congenital heart disease (CHD). The impact of this change on RSV IP utilization and RSV outcomes is not yet understood.

OBJECTIVE: To compare RSV IP utilization and RSV hospitalization (RSVH) rates during the 2014-2015 season vs. the combined 2010-2014 seasons.

METHODS: Infants born July 1, 2009 to June 30, 2015 were identified in the MarketScan Multistate Medicaid (MED) and Commercial (COM) databases; DRG and ICD-9-CM codes were used to select full-term (FT) and preterm infants without CLD or CHD. Outpatient RSV IP use was identified by drug (NDC) or administration (CPT or HCPCS) codes and RSVH was identified by diagnosis codes between November-March. RSVH rates were calculated per 100 infant-seasons with MED and COM infants weighted by prevalence of U.S. births (51% MED, 49% COM). To adjust for seasonal variation, rate ratios (RR) for preterm infants were calculated relative to FT infants.

RESULTS: 1.7 million MED and 1.5 million COM births were identified; 3.5% MED and 2.9% COM infants were born at 29-34 wGA. RSV IP use among infants < 6 months of age was 13%, 5%, and 1% in 2014-2015 among infants 29-30, 31-32, and 33-34 wGA, respectively (decreases of 73%, 86%, and 92% vs. 2010-2014). RSVH rates in 2014-2015 were 21.9, 15.2, 12.7, 10.1, and 3.9 for infants < 3 months and 9.3, 6.8, 4.5, 3.8, and 1.8 per 100 infant-seasons for those 3-6 months born at 29-30, 31-32, 33-34, and 35-36 wGA, and FT, respectively. RSVH rates for infants <3 months increased in 2014-2015 for infants 29-30 (87%), 31-32 (27%), and 33-34 wGA (21%), and decreased for infants 35-36 wGA (19%) and FT (25%). Among infants 3-6 months, RSVH rates in 2014-2015 increased for infants 29-30 (35%) and 31-32 wGA (10%), and decreased for infants 33-34 wGA (9%), 35-36 wGA (19%), and FT (25%). RSVH rates remained stable for infants 6-12 months in 2014-2015 for all wGA groups. For infants <3 months, the RR increased in 2014-2015 vs. 2010-2014 among 29-30 (2.2 vs. 5.7, 157%), 31-32 (2.4 vs. 3.9, 66%), and 33-34 wGA (2.1 vs. 3.3, 58%) infants. For infants 3-6 months, the RR increased among 29-30 (2.9 vs. 5.2, 79%), 31-32 (2.6 vs. 3.8, 47%), and 33-34 wGA (2.1 vs. 2.5, 21%).

CONCLUSIONS: There was a substantial decline in RSV IP use in the 2014-2015 season and a concurrent increase in RSVH among infants 29-34 wGA. RSVH rates and rate increases in 2014-2015 were highest in infants with lower wGA and younger chronologic age during RSV season.

SPONSORSHIP: AstraZeneca.

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

L02 Burden of Atopic Dermatitis: Comorbidities, Healthcare Resource Utilization, and Costs in U.S. Commercial and Medicare Adult Populations

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BACKGROUND: Atopic dermatitis (AD) is an immune-mediated, chronic inflammatory skin condition characterized by severe itch.

OBJECTIVE: To evaluate the severity of AD and associated comorbidity burden, healthcare resource utilization (HCRU), and costs among adult U.S. Commercial and Medicare populations.

METHODS: This retrospective analysis used Commercial and Medicare insurance claims databases from a national health insurer associated with Optum to identify adults diagnosed with AD (≥1 claims with diagnosis code of ICD-9-CM 691.8) from June 30, 2010 to September 30, 2014. AD patients were matched 1:1 to non-AD controls based on demographic characteristics. AD patients were further stratified by disease severity using treatment as surrogate (higher severity group: systemic immunosuppressant, corticosteroids, or phototherapy; lower severity group: topical corticosteroids or calcineurin inhibitors only, or no treatment). Comorbidity burden, all-cause HCRU and costs were compared between AD and non-AD cohorts, and between higher and lower AD severity groups.

RESULTS: Analysis was conducted on a total of 166,212 adult patients from the Commercial database (mean [SD] age: 43 [14.6] years; 61.8% female) and 62,120 patients from the Medicare database (mean [SD] age: 75 [6.7] years; 59.2% female). Compared with non-AD patients, AD patients in both Commercial and Medicare cohorts had significantly greater comorbidity burden (Charlson Comorbidity Index: 0.46 vs. 0.34 and 1.92 vs. 1.75, respectively). Pre-defined AD-related comorbid conditions were all significantly more prevalent among AD patients vs. controls (all P <0.05) in both Commercial and Medicare populations. Specifically, AD patients had significantly more atopic conditions relative to controls, including asthma (10.7% vs. 4.5% and 9.6% vs. 6.0%, respectively), allergic rhinitis (22.4% vs. 8.1% and 15.3% vs. 7.2%, respectively). Relative to controls, HCRU and total annual costs were significantly higher per AD patient (Commercial: $10,461 vs. $7,187; Medicare: $16,945 vs. $13,714; both P <0.001). AD patients with higher disease severity had higher comorbidity
burden, HCRU, and an almost two-fold increase in total annual costs per patient vs. those with lower disease severity (Commercial population: $14,580 vs. $7,192; Medicare: $21,779 vs. $12,490, both P<0.0001).

CONCLUSIONS: AD was associated with significantly higher comorbidity burden, HCRU and total costs in U.S. Commercial and Medicare adult populations. Among AD patients, higher disease severity was associated with even greater comorbidity and economic burden.

SPONSORSHIP: This study was sponsored by Sanofi and Regeneron.

L05 Positive Predictive Value of an Algorithm to Identify Moderate-to-Severe Psoriasis in a Claims Database

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BACKGROUND: Most diagnostic coding systems (e.g., ICD-9) do not allow for direct capture of disease severity information; thus, algorithms must be used to infer severity in studies utilizing claims databases.

OBJECTIVE: To assess the validity of an algorithm to identify moderate-to-severe psoriasis (Ps) in the U.S. Department of Defense (DoD) database.

METHODS: During the study period (January 1, 2008-October 31, 2013) 147,323 patients with a Ps ICD-9-CM code (696.1) were identified; patients with a dermatologist Ps diagnosis and documentation of phototherapy and/or systemic therapy were then classified as having moderate-to-severe Ps (n=16,284). Manual review of medical records

L04 Ixekizumab in the Treatment of Moderate-to-Severe Plaque Psoriasis: A 3-Year U.S. Pharmacy Benefit Impact Analysis

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BACKGROUND: TALTZ (ixekizumab) is an interleukin (IL)-17A antagonist that was recently approved by the FDA for the treatment of moderate to severe plaque psoriasis (PsO). TALTZ is administered by subcutaneous injection. The recommended dose is 160 mg at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

OBJECTIVE: To estimate the 3-year pharmacy budget impact of adding TALTZ to the current mix of biologics indicated for the treatment of moderate to severe PsO in the U.S.

METHODS: A budget impact model compared costs before and after adding TALTZ to a hypothetical 1 million-member commercial health plan. The model factored the U.S. approved dosing regimen and estimated the biologic agents’ acquisition, administration, initiation and monitoring costs. The percent of patients with moderate-to-severe PsO was derived from public literature. Patients were categorized into biologic naive and biologic experienced and entered the model cyclically every 4 weeks. Biologic-naive patients were simulated through up to 3 lines of biologic therapy with clinical success determined by Psoriasis Area and Severity Index (PASI) scores derived from clinical trials (base case, PASI 75). Biologic-experienced patients were simulated through a single line of biologic treatment. Discontinuation rates were included for all biologics. One-way sensitivity analysis was conducted changing key model parameters.

RESULTS: A total of 1,827 patients were modeled over 3 years (285 were biologic naive and 1,542 were biologic experienced). Assuming no mandated step-therapy for biologic-naive patients, the overall health plan pharmacy costs of adding TALTZ to formulary was estimated to increase by $0.043 per member per month (PMPM) over 3 years ($0.012 PMPM and $0.031 PMPM increase from modeling biologic naive and biologic experienced, respectively). Assuming 1 or 2 mandated step therapies for biologic-naive patients, the overall health plan pharmacy costs of adding TALTZ to formulary was estimated to increase by $0.040 PMPM or $0.035 PMPM over 3 years ($0.009 PMPM or $0.012 PMPM increase from modeling biologic naive, respectively). From sensitivity analyses, the model was most sensitive to TALTZ WAC followed by the number of treated PsO patients.

CONCLUSIONS: Overall, adding TALTZ to a healthcare plan has a relatively small cost impact on pharmacy budget over 3-year time horizon, and grants patients with moderate-to-severe PsO with access to an innovative and clinically efficacious alternative biologic therapy.

SPONSORSHIP: Eli Lilly and Company.
was conducted for 250 patients randomly selected from the moderate-to-severe cohort; patient charts were searched for disease severity indicators (e.g., clinical measurements such as body surface area and progress notes indicating provider rating of severity). The positive predictive value (PPV) of the claims algorithm, using chart data as the gold standard, was calculated both considering patients whose severity level could not be determined from the chart as true positives (TP), and considering them false positives (FP). Because the same systemic treatments can be used for both Ps and psoriatic arthritis (PsA), mild PsA may be erroneously classified as moderate-to-severe Ps based on receipt of systemic therapy for PsA. Thus, PPV was also calculated among strata with PsA (n = 88) and those without.

RESULTS: Treating undetermined patients (n = 4) as TP resulted in a PPV of 0.85 (95% CI, 0.80-0.89). If undetermined cases are assumed to be FP, PPV dropped slightly to 0.83 (95% CI, 0.78-0.88). Among the subgroup of patients with PsA, the PPV was 0.83 (there were no undetermined patients in the PsA subgroup); among non-PsA patients, the PPV ranged from 0.83-0.86.

CONCLUSIONS: The algorithm used to identify patients with moderate-to-severe PsA demonstrated reasonable PPV. A visit to a dermatologist in which a diagnosis of Ps was recorded, in combination with use of systemic therapy or phototherapy, identified a cohort in which ~85% of patients would be expected to have moderate-to-severe Ps based upon chart review. The algorithm performed equally well regardless of PsA status. This algorithm may be useful to researchers identifying moderate-to-severe PsA patients in claims database studies. As the validity of coding algorithms may vary across databases (because of the dependence of PPV on disease prevalence), use of this algorithm outside of the DoD database may require further database-specific validation.

SPONSORSHIP: Lilly USA.
**L08 Medication Adherence and Persistence in Patients with Psoriasis, Psoriatic Arthritis, and Rheumatoid Arthritis: A Systematic Literature Review**

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**BACKGROUND:** Psoriasis (PsO), psoriatic arthritis (PsA), and rheumatoid arthritis (RA) are debilitating disorders. Treatment can improve patient outcomes; however, lack of medication adherence and persistence (MAP) can cause disease flare-ups, increased disability, and premature death.

**OBJECTIVE:** To appraise the current understanding of MAP rates and barriers among patients with PsO, PsA, and RA.

**METHODS:** A systematic literature review (SLR) of U.S. based studies published from 2000-2015 on MAP among patients with PsO, PsA, and RA was conducted in Medline, Embase, PsycINFO, Cochrane, and PubMed databases and relevant conference proceedings since 2013. Investigators of identified studies defined MAP differently.

**RESULTS:** From 2,417 identified abstracts, 74 studies met the selection criteria. Infliximab (IFX), adalimumab (ADA), and etanercept (ETN) were the most commonly analyzed biologics. Wide ranges of MAP rates were seen. Within the 49 RA studies, overall adherence rates ranged from 16-83% for ETN, 21-85% for ADA, and 38-90% for IFX. Additionally, overall persistence rates ranged from 35-89% for ETN, 42-94% for ADA, and 41-96% for IFX. Similar wide ranges were seen in PsO (N = 21) and PsA (N = 10) studies. In 2 of 3 studies with ETN, ADA, and IFX, IFX patients had higher rates of adherence. Of 10 studies comparing ETN, ADA, and IFX, 8 showed higher persistence rates in IFX patients as well. In 3 RA studies, patients on triple therapy (MTX + Sulphasalazine + Hydrochloroquine) had lower odds of being adherent (N = 2) or persistent (N = 3) when compared to patients using biologics + methotrexate. Of 4 studies that compared persistence rates in experienced versus new biologic users, all 4 reported new biologic users were less persistent. Younger age, female gender, non-white race, and lower relative individual or neighborhood income were factors reported with reduced MAP in some of the studies.

**CONCLUSIONS:** MAP rates in PsO, PsA, and RA vary widely. Among ETN, ADA and IFX users, MAP rates were slightly higher among IFX users. Experienced biologic users have higher persistence rates than new users. Misaligned definitions for MAP and the lack of standardization with regard to dosing schedules across treatments prevent comparison on equal terms and may account for wide rate variation. Consistent measures of MAP are needed to support developing MAP improvement measures for PsO, PsA, and RA patients.

**SPONSORSHIP:** Lilly USA.
RESULTS: A total of 14,898 PsA patients were matched to 35,037 controls, with a mean age of 53.4±54.8, 44.4%+44.6% male, and a mean length of follow-up of 3.0 years. Adjusting for patients’ characteristics, multivariate analysis suggested that PsA was associated with significantly higher hazard ratios (HR) of developing autoimmune disorders (18.26, including psoriasis, ankylosing spondylitis, rheumatoid arthritis, Crohn’s disease, ulcerative colitis, multiple sclerosis, and other), uveitis (2.21), osteoporosis (1.82), obesity/overweight (1.59), depression (1.52), cardiovascular disease (1.46), fatigue (1.53), diabetes (1.41), anxiety (1.28), eczema (1.25), smoking (1.22), and alcohol use (1.14), compared with controls (P<0.001 in all cases except alcohol use P=0.011).

CONCLUSIONS: PsA patients are estimated to be associated with significantly higher risk of developing new comorbidities than matched control patients without PsA. This highlights the importance of adequately controlling PsA and monitoring the development of new comorbidities.

SPONSORSHIP: This study was funded by Novartis.

L12 Treatment Patterns Among Psoriasis Patients from a Large National Payer Database: A Retrospective Study

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BACKGROUND: Psoriasis (PsO) is not treated with a standardized stepwise approach and attainment of remission remains challenging for many PsO patients. Understanding treatment patterns provide insights on PsO patient management and potential standardization.

OBJECTIVE: To characterize treatment patterns of PsO patients in a large single payer database.

METHODS: Retrospective study of 128,308 adult PsO patients in the HealthCore Integrated Research Database, July 30, 2006-August 31, 2014. Patients had ≥6-month cancer-free pre-index enrollment and ≥12-month follow-up, and were indexed at the time of PsO diagnosis (ICD-9-CM code 696.1x) by a dermatologist, or 2 or more PsO diagnoses on ≥2 days ≥30 days apart, or ≥1 diagnosis followed by a claim for PsO therapy.

RESULTS: Most patients were female (53%), mean age 50 years (±16 years) with 3.6 years (±2.1 years) of follow-up. Overall, 16,346 (13%) patients were not prescribed treatment during the study period. Time to first treatment by therapy class was 2 months (Topical [T]), 13 months (Systemic [S]), 13 months (Phototherapy [P]) and 14 months (Biologic [B]). After diagnosis, [T] was received by 86% of patients at any time, [S] by 13%, [B] by 6%, and [P] by 5%. Among those who received treatment (including combinations), first line therapies included [T] 95%, [S] 4%, and [B] 2%. Second line therapies included [T] 48%, [S] 71%, and [B] 30%. Third line therapies included [T] 74%, [S] 38%, and [B] 44%. Within treated, the most common treatment patterns included [T only] 84%, [T followed by S] 7%, [T followed by B] 2%, [T followed by S followed by B] 2%, and [Others] 5%. The most common treatment patterns showed first line treatment changes (n=15,841) of 33% from [T] to [S], 23% from [T] to [T & S], and 11% from [T] to [B]; second line treatment changes (n=6,808) of 28% from [S] to [T], 13% from [S] to [T & S], and 9% from [B] to [T], and third line treatment changes (n=2,090) of 14% from [T] to [S], 11% from [B] to [T & B], and 10% from [T] to [B].

CONCLUSIONS: Topicals were the most common treatment in PsO. No treatment was received for 13% of patients. The most common treatment changes were first line from [T] to [S], second line from [S] to [T], and third line from [T] to [S]. Topical therapies were utilized early (2 months) while [S], [P], and [B] were utilized later (13, 13, and 14 months, respectively). Biologics were used rarely, prescribed for 6% of patients at any time, and increasing later in the sequence.

SPONSORSHIP: Sponsored and funded by Eli Lilly and Company.

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

M01 Patient-Perceived Overall Treatment Effectiveness and Reasons for Discontinuation of Psoriasis Therapy Among Patients with Psoriasis from the United States: Results from Real-World Observational Data

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BACKGROUND: Psoriasis is a chronic inflammatory skin disease characterized by inflammation and epidermal thickening of the skin due to uncontrolled keratinocyte proliferation. Psoriasis is a chronic, relapsing, inflammatory skin disease, and is one of the most common chronic disorders in the United States. Psoriasis affects approximately 3% of the adult population and is estimated to cost the U.S. healthcare system $30 billion annually. Psoriasis is not only a disease of the skin but can be associated with systemic manifestations, including cardiovascular disease, diabetes, and depression. Psoriasis is also associated with a significantly increased risk of developing other autoimmune disorders, including rheumatoid arthritis, lupus, inflammatory bowel disease, and type 1 diabetes. Psoriasis patients are estimated to be associated with significantly higher risk of developing new comorbidities than matched control patients without PsA. This highlights the importance of adequately controlling PsA and monitoring the development of new comorbidities.

OBJECTIVE: To examine the frequency and costs of above-label dosing in PsA patients on etanercept (ETA), adalimumab (ADA), certolizumab (CER), golimumab (GOL), and ustekinumab (UST).

METHODS: MarketScan claims database identified adult PsA patients from 01/01/2011-12/31/2013 with ≥1 ICD-9-CM diagnosis for PsA (696.0) and ≥1 pharmacy claim for ETA, ADA, CER, GOL, or UST. Patients’ first biologic claim was the index date, followed by a 1-year follow-up period and an additional 3 months to confirm continuous biologic use ending 3/31/2015. Intravenous biologic therapy was not evaluated due to limited dosing information in claims. Exclusion criteria were patients who switched to a different biologic following index biologic or were diagnosed with other autoimmune diseases. Above-label use was defined as a daily maintenance dose >10% than the labelled dose. Based on the number of days of above-label use, patients were stratified by <30, 30-179, and ≥180 days. In addition, healthcare costs during follow-up were compared to prior year for these patients.

RESULTS: Among the 4,245 PsA patients identified, 2,342 were treated with ETA, 1,788 with ADA, and 115 with GOL. Due to small sample size and approvals for PsA in late 2013, CER (n=0) and UST (n=14) cohorts were excluded. At least 30 days of above-label use was identified in 15% of ADA, 9.6% of ETA, and 4.3% GOL patients. The ETA and ADA cohorts reported higher all-cause annual healthcare costs per patient as days above-label increased (ETA: $10,561 < 30 days; $16,213 ≥ 180 days; and GOL: $17,623 30-179 days; $16,251 ≥180 days, respectively). Limited observations were available for the GOL cohort due to small sample size. Compared to the prior year, the mean all-cause healthcare costs increased in each cohort (ETA: $30,625 < 30 days; $55,359 ≥ 180 days; ADA: $31,620 < 30 days; $54,176 ≥180 days; and GOL: $37,224 < 30 days; $47,993 ≥180 days, respectively).

CONCLUSIONS: Even minimal above-label use in PsA patients treated with ETA and ADA had an increase in total healthcare costs. More research to understand reasons for above-label use could aid decision makers in their treatment choices.

SPONSORSHIP: Novartis.
BACKGROUND: Real-world data on treatment responses in Psoriasis (Ps) patients are lacking in the United States (U.S.) because dermatology practices had not tracked these outcomes systematically and consistently. Electronic medical records (EMRs) offer opportunities to conduct real-world research using structured, point-of-care data.

OBJECTIVE: To investigate patient-perceived overall treatment effectiveness (POTE), patterns of medication change, and reasons for discontinuing Ps therapy using the largest dermatology-specific EMR system in the U.S.

METHODS: Data from this retrospective cohort study were collected from adult patients (at least 18 years) with a dermatology provider-given diagnosis of Ps over 1 year (2014-2015) using the Modernizing Medicine Electronic Medical Assistant (EMA). POTE was measured at follow-up using patient responses to the question: “I believe this treatment is effective in clearing my skin of Ps,” which were scored on a 5-point Likert scale (1 = “strongly agree” to 5 = “strongly disagree”). Patients also reported whether they adhered to the recommended treatment regimen. Providers selected a reason(s) that a patient discontinued treatment.

RESULTS: A total of 2,200 patients with Ps provided POTE data. The highest proportion of patients who strongly agreed that their treatment was effective were those on biologics (73%), followed by phototherapy (61%), oral systemics (57%), and topicals (39%). Overall, patients who reported “strongly agree” were more likely to be adherent to treatment (59%) than patients who were non-adherent (1%). Treatment switching was common, with the highest percentages of patients either switching to topical therapies or having multiple switches during the study period. Overall, the most common reasons for discontinuation were loss of efficacy (60%) and side effects (27%); other factors for discontinuation that were less common included inability to afford or comply with treatment. Patients on biologic therapies had the highest rate of treatment discontinuation (52%), compared with patients from the oral systemic (34%) and phototherapy (6%) groups.

CONCLUSIONS: Patients who used biologic therapies were most likely to report that their treatment was effective in clearing Ps. Greater patient-perceived effectiveness was associated with higher adherence. Medication switching and discontinuation were common with the most common reason for discontinuation being loss of efficacy.

SPONSORSHIP: This study was sponsored by Eli Lilly and Company.

M03 Patterns of Treatment in Mycosis Fungoides Cutaneous T-cell Lymphoma: A Retrospective Claim-Based Analysis of a Large Commercial Insured U.S. Population

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BACKGROUND: Mycosis Fungoides Cutaneous T-cell Lymphoma (MF-CTCL) is a disease in which lymphocytes become malignant and affect the skin. National Comprehensive Cancer Network guideline defines the standard of care; however, there have been limited data on treatment patterns in real-world clinical practice.

OBJECTIVE: To examine MF-CTCL specific treatment patterns among MF-CTCL patients.

METHODS: A retrospective cohort study was conducted using the HealthCore Integrated Research Database to identify patients aged 18 and older with a diagnosis of MF-CTCL (ICD-9-CM codes 202.1x, 202.2x) between July 1, 2006 and July 31, 2013. MF-CTCL specific index treatments were identified within 60 days following MF-CTCL diagnosis. Because patients may have multiple MF-CTCL specific drug or non-drug therapies, index treatments were selected through an algorithm. Frequency of index drug discontinuation (treatment gap ≥45 or ≥60 days depending on index drug), restart of index drug, switching to a different MF-CTCL specific drug, adherence (medication possession ratio ≥70%), and augmentation of index drug were measured during follow-up.

RESULTS: In this study, 1,981 MF-CTCL patients were identified, of whom 51% of patients did not receive any MF-CTCL specific treatment within 60 days after MF-CTCL diagnosis. Among those treated (N = 967), the most frequent index drug and non-drug treatment were topical corticosteroids (36%) and UVB phototherapy (13%). In total, 702 patients initiated drug treatment, 7% of whom remained on their index drug while 22% restarted index drug, 36% switched to another treatment, and 4% augmented treatment. About 7% of patients were adherent to their index drug.
CONCLUSIONS: The study results highlight the high unmet needs in the treatment of MF-CTCL. The low adherence to and high discontinuation of drug therapy may be reflective of the disease coming under remission after a few months of treatment.

SPONSORSHIP: Actelion Pharmaceuticals U.S.

M04 Patient and Provider Preferences for Melanoma Treatment: A Discrete Choice Experiment and Willingness-to-Pay Estimates for Immunotherapy and BRAF/MEK Inhibition

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BACKGROUND: New melanoma therapies are changing treatment paradigms. Comparison of their effectiveness, safety and cost profiles is an important part of treatment planning. Evaluating treatment characteristics that drive decision making may enhance discussion between patients and providers.

OBJECTIVE: To characterize willingness-to-pay thresholds for immunotherapy and BRAF/MEK inhibition for the treatment of metastatic melanoma.

METHODS: A survey, including a discrete choice experiment (DCE), was utilized to evaluate patient and provider trade-offs for effectiveness and adverse events of melanoma treatments and to estimate out-of-pocket willingness-to-pay (WTP) thresholds. Participants included adult patients with melanoma receiving care at the Huntsman Cancer Institute (HCI), and physicians, pharmacists, and nurses at HCI. Stakeholder focus groups were conducted to identify treatment attributes important to patients and providers. Descriptive and comparative statistics were used to evaluate responses. DCE responses were analyzed with a multinominal logit model.

RESULTS: The response rate was 41.9% (N = 220) for patients and 37.7% (N = 20) for providers. Melanoma treatment attributes that are important to patients and providers were categorized as overall survival (OS), immunotherapy-related side effects (IM), and skin toxicities (SK). The average monthly WTP for one additional year of OS for patients and providers was $932 and $1,008, respectively. The average monthly WTP for a 1% incremental decrease in IM was $-50 and $-56 and SK was $-20 and $-51, respectively. Among patients, the average monthly WTP for combination immunotherapy (nivolumab + ipilimumab) was $2,626 and for BRAF/MEK inhibition was $1,029. Among providers, the average monthly WTP for combination immunotherapy was $2,734 and for BRAF/MEK inhibitions was $540. Sensitivity analysis of OS for patient’s WTP for immunotherapy indicated a range of $1,303 to $3,399. For BRAF/MEK inhibition, the range was $563 to $1,494.

CONCLUSIONS: DCE is an effective methodology to examine preferences in melanoma treatment. Our study suggests that patients and providers exhibit a higher WTP for immunotherapy treatment compared to BRAF/MEK inhibitors influenced predominately by overall survival differences.

SPONSORSHIP: This research was supported by an unrestricted grant from Bristol-Myers Squibb Research and Development to the University of Utah Pharmacotherapy Outcomes Research Center.

M06 Cost-Effectiveness of Tumor Necrosis Factor Inhibitor Cycling Versus Switching to a Disease-Modifying Antirheumatic Drug with a New Mechanism of Action Among Patients with Rheumatoid Arthritis

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BACKGROUND: Patients with rheumatoid arthritis (RA) and an inadequate response to treatment with a tumor necrosis factor inhibitor (TNFi) often receive another TNFi (TNFi cycling) or switch to a disease-modifying antirheumatic drug (DMARD) with a new mechanism of action (MOA), such as a non-TNFi biologic or a targeted oral DMARD. Cost-effectiveness comparisons of the two approaches are needed.

OBJECTIVE: To examine the cost per effectively treated patient with RA in the first year after TNFi cycling or new MOA switching.

METHODS: A claims-based algorithm was applied to patients with RA in the Optum database who received a TNFi (adalimumab, certolizumab pegol, etanercept, golimumab, or infliximab) and either cycled to a different TNFi or switched to a new MOA (abatacept, tocilizumab, or tofacitinib) between January 2012 and December 2014. Effective treatment for 12 months post-switch was based on six algorithm criteria: (1) adherence ≥80%; (2) no dose increase; (3) no addition of a synthetic DMARD; (4) no switch to another targeted DMARD; (5) no new/increased oral glucocorticoid; and (6) ≤1 intra-articular injection. Cost was determined from paid amounts for targeted DMARDs, adjusted for price changes. Cost per effectively treated patient was calculated from the average 12-month post-switch cost per patient for targeted DMARDs, divided by the proportion of patients with effective treatment. Bivariate analysis was used to compare cohorts.

RESULTS: The study included 581 new MOA switchers and 935 TNFi cyclers (mean±SD age, 53.6±11.2 vs. 51.9±11.3 years, P = 0.005; female sex, 83% vs. 79%, P = 0.066; and Medicare Advantage, 18% vs. 15%, P = 0.064). During the 12 months post-switch, new MOA switchers had significantly lower targeted DMARD costs than TNFi cyclers ($29,001 vs. $34,917, P < 0.001), and were significantly more likely to achieve all criteria for effective treatment (25% vs. 20%, P = 0.022) and selected algorithm criteria (≥80% adherence: 42% vs. 36%, P = 0.008; no biologic dose increase: 98% vs. 89%, P < 0.001; no subsequent switch: 70% vs. 60%, P < 0.001). Drug cost per effectively treated patient was $113,849 for new MOA switchers vs. $170,929 for TNFi cyclers, mostly driven by cost differences for adherence, biologic switching, and biologic dose increase.

CONCLUSIONS: Among patients with RA who required a switch from TNFi treatment, switching to a new MOA versus TNFi cycling was associated with lower drug cost, more effective treatment, and lower cost per effectively treated patient, mostly driven by differences in medication adherence, subsequent switches, and dose increases.

SPONSORSHIP: Regeneron and Sanofi sponsored this work.

M08 Treatment Patterns and Outcomes in Patients with Rheumatoid Arthritis on Biologics Who Switch to New Disease-Modifying Antirheumatic Drugs in Integrated Healthcare Delivery Networks

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BACKGROUND: The formation of integrated healthcare delivery networks (IDNs) is a rapidly emerging trend in the United States with the objective of coordinating multiple points of patient care to manage the cost and quality of care. Use of validated, objective measures in health records supports evidence-based treatment decisions and may improve outcomes, particularly when switching therapies. Recent studies have reported better outcomes for patients with rheumatoid arthritis (RA) who switch from a tumor necrosis factor inhibitor (TNFi) to a new mechanism of action (MOA) disease-modifying anti-rheumatic drug (DMARD), such as a non-TNFi biologic or a targeted oral DMARD, but TNFi cycling is still prevalent.

OBJECTIVE: To examine overall trends and variation across IDNs in the treatment patterns and clinical outcomes among patients with RA who cycled between TNFi or switched from a TNFi to a new MOA DMARD.

METHODS: Using the nationwide OptumOne electronic health record database, this retrospective analysis included adults with RA who either cycled between TNFi or switched from a TNFi to a new MOA DMARD. A descriptive analysis was conducted overall and across individual IDNs to examine the demographic and clinical characteristics of TNFi cyclers and new MOA switchers, and to evaluate the documentation and values of their disease activity measures pre- and post-switching.

RESULTS: The study included 13,228 patients, including 4,690 new MOA switchers and 8,538 TNFi cyclers: mean ± SD age, 56.4 ± 12.9 vs. 52.7 ± 12.9 years, P < 0.001; and female sex, 80% vs. 78%, P < 0.001. A majority of TNFi cyclers and new MOA switchers were IDN members (61% vs. 58%, P = 0.009). TNFi cycling declined over time (from 67%-74% in 2008-2011 down to 61%-62% in 2013-2015), with significant variation in TNFi cycling across IDNs (from 54.2% to 82.1%). Disease activity was poorly documented in the electronic health records. Routine Assessment of Patient Index Data 3 (RAPID3) data were available before/after the switch for 5.9%/7.2% of TNFi cyclers and 6.7%/8.2% of new MOA switchers, with large variation in RAPID3 data availability across IDNs (from 0% to 30.9%). Clinical disease activity index (CDAI) and DA$28 were recorded for < 1% of patients in either cohort.

CONCLUSIONS: Among patients with RA in U.S. IDNs who need to switch from a TNFi, a majority cycle through TNFis but documentation of disease activity during switching is incomplete and inconsistent. There is a significant unmet need in documentation of disease activity, limiting the ability to understand treatment effectiveness and decisions about treatment changes using electronic health records.

SPONSORSHIP: Regeneron and Sanofi sponsored this work.

METHODS: Among 12 Blue Cross Blue Shield clients with an average commercially insured population of 13.8 million members per month, we identified 4.4 million continuously enrolled members from 2012 to 2015 less than 70 years of age to assess: (1) the monthly tofacitinib utilization trend, (2) DMARD use in the year prior to tofacitinib, and (3) tofacitinib persistency. Prior DMARD use and persistency analyses were further limited to tofacitinib utilizers with a rheumatoid arthritis (RA) diagnosis. Tofacitinib discontinuation was defined as > 90-day gap in therapy. Tofacitinib persistency was assessed via Kaplan-Meier (KM) analysis accounting for censoring when members were persistent through December 31, 2015.

RESULTS: Among the 4.4 million continuously enrolled members, 887 utilized tofacitinib during December 2012 through December 2015, with 415 utilizers in December 2015. The utilization growth rate was a consistent 10.5 members per month. An RA diagnosis was found for 862 (97.2%) of the 887 tofacitinib utilizers. A DMARD claim in the year prior was found in 771 (89.4%) of the 862 tofacitinib utilizers with RA. In the year prior to tofacitinib, 50.1% had a methotrexate claim and 61.3% had a biologic DMARD claim. During treatment with tofacitinib, 34.7% of members had a methotrexate claim. Mean tofacitinib follow-up (tofacitinib initiation to December 31, 2015) was 497 days. The tofacitinib KM discontinuation rates were 30.2% at 6 months and 44.3% at 12 months.

CONCLUSIONS: Since tofacitinib approval, utilization has increased steadily. Despite its approved indication, 1 in 10 members have no DMARD claims history in the year prior to initiating tofacitinib. At 6 months, more than a quarter of members discontinued tofacitinib and more than 4 of 10 discontinued at 1-year follow-up. Payers should develop care and utilization management programs that encourage adherence and the most cost effective RA treatment strategies. Adherence as a measure for outcomes based contracting should be considered.

SPONSORSHIP: Prime Therapeutics.

M09 Tofacitinib Utilization Patterns and Persistency Among 4.4 Million Continuously Enrolled Commercially Insured Members over 4 Years

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BACKGROUND: The improved efficacy and tolerability of subcutaneous (SC) methotrexate (MTX) over oral MTX may be associated with delayed use of biologic therapies. The impact of this delay on medical costs for rheumatoid arthritis (RA) patients is currently unknown.

OBJECTIVE: To describe the treatment pathways and total medical costs over 5 years for RA patients in the United States (U.S.) who initiated oral MTX.

METHODS: We used data from the Symphony Health Integrated Dataverse (IDV), which captures anonymous health claims for ~274 million patients and 92% of all prescription drugs dispensed. We selected patients with RA (ICD-9-CM codes 714.0 and 714.30) who initiated treatment with oral MTX in 2009 and had RA-related claims for each year through 2014. We grouped patients into four treatment pathways during 2009-2014: those who (1) stayed on oral MTX, (2) added/swapped to biologic therapy, (3) switched to SC MTX, and (4) switched to SC MTX and then added/swapped to biologic therapy. We assigned costs by linking procedures to Medicare fee schedules and National Drug Codes to dispensed metric quantities via Medispan Unit Price (average wholesale price). Total direct costs (limited to pharmaceuticals, office visits, hospitalizations, and emergency department visits) were compared among treatment pathways.

M10 The Economic Implications of Different Rheumatoid Arthritis Drug Treatment Pathways

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RESULTS: We identified 35,640 patients who started oral MTX in 2009. (1) 15,599 (44%) continued oral MTX alone through 2014, (2) 17,528 (49%) added/switched to a biologic agent (average time to biologic: 478 days), (3) 1,802 (5%) switched to SC MTX, and (4) 711 (2%) switched to SC MTX and then added/switched to a biologic (average time to biologic: 1,037 days). Total medical costs per patient varied by pathway: $47,463 for patients who stayed on oral MTX, $212,170 for those who added/switched to a biologic; $59,058 for those switched to SC MTX, and $175,038 for those who switched to SC MTX and then to biologic therapy. Non-drug costs were similar across groups and ranged from $21,358 (SC MTX/biologic) to $24,477 (SC MTX), indicating that patients received similar underlying medical care despite different RA treatments.

CONCLUSIONS: Patients on oral MTX added or switched to a biologic sooner and incurred higher total costs than those who switched to SC MTX or switched to SC MTX and then added/switched to a biologic. The cost differences between treatment pathways resulted primarily from drug costs. Further work such as a prospective health economic study may demonstrate the cost effectiveness of optimally utilized methotrexate.

SPONSORSHIP: Medac Pharma.

M12 Real-World Utilization of Biologic Anti-inflammatory Medications by Disease State in a Regional Managed Care Plan

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BACKGROUND: Biologic anti-inflammatory medications are a complex set of specialty medications with many overlapping indications for use. Formulary decision makers are concerned with providing adequate coverage for all appropriate uses of this class of drugs. Historically, coverage decisions are often made by FDA-approved indication; however, real-world data of medication-specific utilization by disease state is lacking.

OBJECTIVE: To identify the real-world distribution of utilization of individual biologic anti-inflammatory drugs by disease state.

METHODS: A retrospective analysis was performed using pharmacy and medical claims data from an integrated, regional health plan covering approximately 900,000 lives across commercial, Medicare, and Medicaid lines of business. All members were assessed for a pharmacy or medical claim for a biologic anti-inflammatory medication in the calendar year 2015. A look-back was then performed for 12 months prior to the index date, defined as the first claim for a biologic anti-inflammatory medication, to find inflammatory disease diagnoses by ICD-9 and ICD-10 codes.

RESULTS: A total of 2,713 inflammatory diagnoses were found to be associated with a claim for a biologic anti-inflammatory medication. Adalimumab, etanercept, certolizumab pegol, and infliximab were the highest utilized drugs in the class. 1,173 diagnoses were associated with claims for adalimumab: 276 (24%) for Crohn’s disease, 249 (21%) for rheumatoid arthritis (RA), 220 (19%) for ulcerative colitis (UC), 196 (17%) for psoriasis, 97 (8%) for ankylosing spondylitis (AS), 94 (8%) for psoriatic arthritis (PsA), and all other conditions were < 5%. 876 diagnoses were associated with claims for etanercept: 473 (54%) for RA, 113 (13%) for AS, 104 (12%) for PsA, 101 (12%) for psoriasis, 54 (6%) for juvenile idiopathic arthritis, and all other conditions were < 5%. 178 diagnoses were associated with claims for certolizumab pegol: 81 (46%) for RA, 44 (25%) for Crohn’s disease, 23 (13%) for UC, 14 (8%) for AS, 9 (5%) for PsA, and all other conditions were < 5%. 148 diagnoses were associated with claims for infliximab: 64 (43%) for Crohn’s disease, 31 (21%) for UC, 28 (19%) for RA, 11 (7%) for AS, and all other conditions were < 5%.

CONCLUSIONS: These results provide insight into real-world utilization of biologic anti-inflammatory medications in a regional managed care setting. The utilization by disease state for each drug may provide formulary decision makers with valuable information on potential utilization trends.

SPONSORSHIP: This study was conducted by SelectHealth with no external funding.
**M14 Patient-Reported Outcomes in Psoriatic Arthritis with Axial Involvement**

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**BACKGROUND:** Although spinal involvement has been well studied in ankylosing spondylitis, very few studies in psoriatic arthritis (PsA) have characterized patients with axial involvement.

**OBJECTIVE:** To describe the influence of axial involvement on baseline patient-reported outcome (PRO) measures in patients with PsA in the U.S.-based Corrona psoriatic arthritis/spondyloarthritis (PsA/SpA) registry.

**METHODS:** This study included all patients with PsA enrolled in the Corrona PsA/SpA registry between March 2013 and March 2016 with non-missing data on axial involvement, defined as having a physician-reported presence of spinal involvement at enrollment, or an MRI or x-ray showing sacroiliitis. Patient-reported outcomes were recorded at the time of enrollment for patients with and without axial involvement, and statistical comparisons between subgroups were evaluated using P values from t-tests for continuous variables and chi-squared tests for categorical variables.

**RESULTS:** A total of 1,530 patients with PsA in the Corrona PsA/SpA registry had non-missing data on physician-reported axial involvement, including 192 patients (12.9%) with axial involvement and 1,338 patients (87.5%) without axial involvement. Both subgroups were similar with regards to most demographic characteristics. Patients with axial involvement were significantly less likely to have minimal disease activity (30.1% vs. 46.2%; P < 0.001) and reported significantly worse mean pain (47.7 vs. 36.2; P < 0.001), fatigue (50.2 vs. 38.6; P < 0.001), physical function (HAQ, 0.9 vs. 0.6; P < 0.001) and quality of life (EQ5D, 0.7 vs. 0.8; P < 0.001) at enrollment compared to patients without axial involvement. They were also significantly more likely to experience ≥ 30 minutes of morning stiffness (77.8% vs. 60.9%; P < 0.001) and have greater impairments in all Work Productivity and Activity Impairment domains including overall work (32.3% vs. 16.8%; P < 0.001) and activity impairment (37.0% vs. 18.1%; P < 0.001).

**CONCLUSIONS:** Data from the Corrona PsA/SpA registry showed that in patients with PsA, presence of axial involvement was associated with significant and widespread impairment of patient-reported outcomes at the time of registry enrollment.

**SPONSORSHIP:** AbbVie, Amgen, BMS, Crescendo, Genentech, Horizon Pharma USA, Janssen, Eli Lilly, Novartis, Pfizer, and UCB have supported Corrona through contracted subscriptions. Financial support for this study was provided by Novartis.

**M16 A Descriptive Analysis of Real-World Treatment Patterns of Innovator Infliximab and Biosimilar Infliximab in a Treatment-Naive Turkish Rheumatologic Disease Population**

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**BACKGROUND:** Biosimilar infliximab (CT-P13) became available for use in Turkey in July 2014.

**OBJECTIVE:** To examine treatment patterns of innovator infliximab (IFX) and CT-P13 in a treatment-naive Turkish rheumatologic population after CT-P13 availability.

**METHODS:** Adult patients with ≥ 1 diagnosis code for rheumatoid arthritis (RA) were identified in a Turkish healthcare database during the study period (December 1, 2010-December 1, 2015). Eligible patients had continuous medical/pharmacy enrollment ≥ 12 months before and ≥ 6 months after IFX or CT-P13 initiation (index date). Patients were naïve to IFX or CT-P13 within 12 months before index date. Demographics, concomitant diseases and medications, and treatment patterns, e.g., dose, interval, discontinuation, and switch were summarized. Confirmed discontinuation was defined as switch to another biologic medication or absence of an index biologic claim for ≥ 120 days without censoring.
RESULTS: A total of 1,044 patients initiated either medication. The majority (80%; n = 831) initiated IFX. The IFX cohort had a mean age of 42 years; 56% were women; mean follow-up was 12 months. The CT-P13 cohort consisted of 213 patients with mean age of 43 years; 58% were women; and mean follow up of 9 months. Approximately one-third of patients in each cohort had a co-diagnosis of ankylosing spondylitis. Other concomitant diseases and medications appeared balanced between cohorts. Patients in the IFX cohort had an average of 5.2 infusions and mean dose of 4.7 vials per infusion approximately every 8 weeks. Patients in the CT-P13 cohort had an average of 3.6 doses and mean dose of 5.8 vials per infusion approximately 9 weeks apart. In the IFX cohort, confirmed discontinuation occurred in 55% driven in part by switching; 24% of IFX patients had ≥ 1 biologic switch with 8% initially switching to CT-P13. Mean time to confirmed IFX discontinuation was 155 days. In the CT-P13 cohort, confirmed discontinuation was observed in 63%; 31% switched to another biologic therapy; and 20% initially switched to IFX. Mean time to confirmed CT-P13 discontinuation was 107 days.

CONCLUSIONS: These findings in a single country indicate that real-world utilization patterns may differ between innovator IFX and CT-P13, with predominantly more patients initiating IFX, greater CT-P13 discontinuation and a higher proportion of patients switching from CT-P13 to IFX. Further studies are needed to understand the reasons for these observed differences.

SPONSORSHIP: This study was funded by Janssen Scientific Affairs.

M17 Clinical and Expenditure Outcomes Associated with Anti-TNF Biologic Dosing Variation in Managed Care Patients with Rheumatoid Arthritis Who Were Newly Initiated on a Biologic Medication

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BACKGROUND: While literature suggests that anti-tumor necrosis factor biologic (biologic) dosing patterns have quality of care and economic implications in patients (pt) with rheumatoid arthritis (RA), there is a dearth of evidence where biologics were dosed below or above FDA-approved dosing ranges.

OBJECTIVE: To assess biologic dosing variation and associated one-year clinical and expenditure outcomes.

METHODS: This was a retrospective, longitudinal cohort study conducted in a managed care organization. Adult patients with RA who were newly initiated on adalimumab (ADA), etanercept (ETA), or infliximab (IFX) between 7/1/2006 and 02/28/2014 were included. Patients had no prior biologic dispensing/infusion in the 180 days prior to their initiation date and were followed for one year after initiation. Patients were categorized as a Low Outlier or High Outlier if they had at least one dispensing/infusion at <90% or >110%, respectively, of the indicated index biologic dose range. Biologic expenditures were calculated using Wholesale Acquisition Costs. Outcomes were assessed across biologic outlier and non-outlier groups.

RESULTS: A total of 434 patients were included: ADA (n = 49), ETA (n = 315), and IFX (n = 70) patients. Patients were middle-aged, primarily female, predominantly white, and had a high burden of chronic disease. Ten percent (45/334) of patients were identified as a Low (n = 20) or High (n = 25) Outlier. Approximately 2% of ADA and ETA patients and 20% of IFX patients were Low Outliers while 31% of ADA patients and 3% of ETA patients were High Outliers. A trend towards higher one-year biologic cost was present when comparing Low to High Outliers with median cost lowest for IFX Low Outliers ($18,378, P < 0.05) and highest for ADA High Outliers ($58,724, P < 0.05). Persistence with any biologic was lowest for the ADA Low Outliers (0%) and highest for the IFX Low Outliers (93%, P < 0.05). The ETA Non-Outlier group had the highest rate of RA-related medical office (95%) and rheumatology office visits (88%, both P < 0.05). RA-related emergency department visits and hospitalizations were rare across all groups. The IFX Non-Outliers and ETA Low Outliers had the largest reductions in C-reactive protein values. The IFX Non-Outliers had the largest mean reduction in tender joint count (-4.8, P < 0.05).

CONCLUSIONS: Approximately one in ten study patients were biologic dosing outliers. High Outliers are particularly concerning as they had high expenditures yet no evidence of substantial gains in clinical improvement.

SPONSORSHIP: This study was sponsored by Janssen Scientific Affairs.

M18 Specialty Drug Use Among ACA Members: The Case of Chronic Inflammatory Diseases

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BACKGROUND: The Affordable Care Act (ACA) has expanded health coverage to millions of previously uninsured persons. Early reports on ACA members indicate that they have riskier health profiles and use more medical services than their commercial counterparts. However, there is limited information on how such utilization compares after adjusting for risk profile, especially for high cost specialty drugs. Within ACA, it is also unknown how richness of benefit impacts such utilization. This study explores these gaps using specialty drugs for chronic inflammatory diseases (CID) as an example. CID is the second largest expenditure category within specialty drugs, after cancer, with one of the highest spending growth rates.

OBJECTIVE: To examine risk-adjusted differences in specialty drug use between ACA and other commercial plan members and the impact of benefit design on specialty drug use within ACA.

METHODS: Anthem medical and pharmacy claims data from calendar years 2014-2015 for members age ≥ 18 with at least 12 months of continuous enrollment in medical and pharmacy benefits were analyzed. Members in plans with metal designation were grouped as ACA and other fully insured commercial plan members were grouped as non-ACA. The difference in likelihood of using specialty drugs between the two groups were estimated from logistic regression model adjusting for age, gender, comorbidity, individual plan indicator, and presence of CID. Separately, the ACA population was examined to assess the impact of benefit design on likelihood of specialty drug use within ACA.

RESULTS: Compared to non-ACA (N = 1,910,201), the ACA members (N = 631,052) were older (mean age 45 vs. 43, P < 0.001) and more likely to be female (52% vs. 49%, P < 0.001). The prevalence of CID was higher among ACA members (risk ratio = 1.04, P < 0.01). The unadjusted rate of specialty drug use was lower among ACA members (0.41% vs. 0.49%, P < 0.001). In adjusted analysis, the odds of specialty drug use were 9% lower in ACA compared to non-ACA members (adjusted odds ratio, aOR = 0.91, P < 0.001). Within the ACA cohort, those enrolled in platinum or gold plans were more likely to use specialty drug than those in silver or bronze plans (aOR 1.55, P < 0.001).

CONCLUSIONS: Despite their older age and higher disease prevalence, ACA members are less likely to use specialty drugs for CID than non-ACA members. Generosity of plan was positively associated with odds of specialty drug use within ACA, suggesting that greater utilization among commercial members could arise from their richer benefit design than ACA members.

SPONSORSHIP: Funding for this study was provided by Anthem.
**M19 Costs in Persistent or Switching Rheumatoid Arthritis Patients Newly Initiating a Biologic**

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**BACKGROUND:** Different biologic treatment patterns may have cost implications to managed care. Limited evidence exists on costs of Rheumatoid Arthritis (RA) patients switching between biologic therapies.

**OBJECTIVE:** To estimate total costs among patients with RA that are persistent or switch from newly initiated biologic therapy.

**METHODS:** This retrospective cohort study used administrative claims data from the HealthCore Integrated Research Database (HIRD). Patients were selected if they had ≥ 1 claim for abatacept (ABA), adalimumab (ADA), certolizumab (CER), etanercept (ETA), golimumab (GOL), infliximab (INF), rituximab (RIT), or tocilizumab (TOC) for RA between January 1, 2009 and November 30, 2015 and continuous enrollment from 180 days pre-index (no biologic therapy) and 365 days post-index; aged 18-63 years on the index date (the first biologic claim); and at least one diagnosis for RA in pre-index period. Persistent was defined as continuous use of the index biologic without > 45-day gap, and switch as the initiation of a non-index biologic. All-cause total costs were described for one-year post-index for all patients, and for one-year post-switch for switchers.

**RESULTS:** 7,468 RA patients were included with mean (SD) age 49.0 (10.0) years. In the one-year post-index 3,372 (45.2%) remained persistent with the index biologic and 1,246 (16.7%) switched biologics. Persistent patients had mean (SD) total costs of $41,901 ($30,977) and switching patients’ costs were $44,244 ($54,171) in one-year post-switch. Persistent patients had total mean (SD) costs in USD for ABA: 46,524 (23,465); ADA: 40,900 (19,590); CER: 44,407 (16,902); ETA: 37,638 (16,942); GOL: 38,363 (12,481); INF: 42,468 (25,700); RIT: 68,722 (80,795); TOC: 73,202 (115,951). Switching patients had total mean (SD) costs in USD for ABA: 52,295 (35,402); ADA: 43,656 (39,420); CER: 57,080 (45,167); ETA: 41,183 (26,178); GOL: 41,183 (13,076); INF: 53,444 (153,076); RIT: 41,511 (51,023); TOC: 51,885 (66,083) in one-year post-switch.

**CONCLUSIONS:** Patients who switched biologics incurred higher all-cause total costs in the year post-switch than those that were persistent for a year. Of all biologics approved for RA, etanercept was associated with the highest all-cause total costs in both persistent and switching cohorts, respectively. Efforts to keep patients on initial biologic may reduce all-cause costs.

**SPONSORSHIP:** Janssen Scientific Affairs supported this study.

**M21 Reduced Variation in Drug Utilization, Infusion Time, and Cost for Intravenous Golimumab Compared to Infliximab: A Real-World Retrospective Analysis**

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**BACKGROUND:** Infliximab (IFX) and intravenous golimumab (GLM-IV) are anti-TNF agents indicated for rheumatoid arthritis (RA) with different weight-based doses, induction schedules, and infusion times.

**OBJECTIVE:** To describe patient characteristics, utilization patterns, and costs in IFX-treated RA patients later using GLM-IV.

**METHODS:** Patients 18 years with ≥ 1 RA diagnosis (ICD-9 CM; 714.0), ≥ 6 months continuous enrollment before IFX initiation and ≥ 1 GLM-IV claim after IFX discontinuation were identified in a health claims dataset. The IFX index date was the first IFX infusion of the most recent IFX episode before GLM-IV index (date of first GLM-IV claim). Patient characteristics, average vials per infusion (VPI), infusion interval and billed infusion times were studied over variable length follow up. Expected cost of 1st year IFX or GLM-IV was modeled from commercial plan perspective using reimbursed drug plus administration cost. VPI were estimated by dividing paid cost by drug wholesale acquisition cost. Where appropriate, claims with $0 cost were removed from the analysis.

**RESULTS:** A total of 188 IFX patients transitioned to GLM-IV were identified. At GLM index, the population was 78% female; mean age 58 years; 75% commercially insured. The proportion of maintenance infusions occurring > 3 and ≤ 5 weeks was 19% (IFX) vs. 4% (GLM-IV); > 5 and ≤ 7 weeks was 30% (IFX) vs. 3% (GLM-IV); and > 7 and ≤ 9 weeks was 40% (IFX) and 82% (GLM-IV). Average VPI was 5.5 (IFX) and 4 (GLM-IV). A second hour billing code was observed for 95.5% IFX vs. 2.6% of GLM-IV infusions. Mean reimbursed drug plus administration cost per infusion was $4,621 (IFX) and $3,087 (GLM-IV). Expected first-year reimbursed cost per patient was $36,968 (IFX; 8 infusions/year) and $35,609 (GLM-IV; 7 infusions/year). When observed treatment interval variation was considered, the cost of first-year IFX therapy exceeded GLM-IV by $7,010 per patient.

**CONCLUSIONS:** From a commercial plan perspective, GLM-IV use demonstrated greater consistency in dosing patterns, reduced billed infusion time and fewer VPI resulting in significant cost savings in the first year of treatment. These findings may be relevant for healthcare decision makers interested in understanding potential variation in healthcare delivery or implementation of cost saving measures.

**SPONSORSHIP:** Janssen Scientific Affairs supported this study.

**M22 One- and Two-Year Adherence with Biologic Therapy Among Patients with Rheumatoid Arthritis**

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**BACKGROUND:** Rheumatoid arthritis (RA) is a chronic disease requiring continuous therapy to reach low disease activity targets and to delay long-term adverse health effects.

**OBJECTIVE:** To evaluate adherence with biologic therapy among patients with RA in the first and second year after treatment initiation.

**METHODS:** Patients with RA initiating a biologic (abatacept, adalimumab, certolizumab, etanercept, golimumab, infliximab) between January 2009 and December 2012, with 2 years of continuous enrollment following biologic initiation (index) were identified in the IMS PharMetrics Plus database. Index agent adherence was defined by a proportion of days covered (PDC)>80% and assessed for fixed one- and two-year periods post-index.

**RESULTS:** Of the 10,374 eligible patients, 76% were female, median age was 51 years at index, and 78% were previously on a non-biologic disease-modifying antirheumatic drug (DMARD). Among all patients, 46% were adherent during the first year, while 11% of patients demonstrated a PDC of ≤ 20%. Over 2 years, 34% of patients were adherent. One-year adherence by index agent ranged from 36%-64% while adherence over two years ranged from 27%-47%. Subcutaneous agents were most common, and among patients who used etanercept (n = 4,426, 43% of population) and adalimumab (n = 3,926, 37% of population), 44% and 46% were adherent over one year, while 32% and 33% were adherent over two years. The two infused agents (infliximab and abatacept) demonstrated the highest one-year adherence (64% and 48%) and infliximab had the highest adherence at two years (47%). Golimumab and certolizumab had the lowest adherence over one and two years.
**M23** Patient Characteristics and Real-World Utilization of Intravenous Golimumab in a Population of Rheumatoid Arthritis Patients Observed in the Corrona Registry

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**BACKGROUND:** Golimumab (GLM-IV) is the second anti-TNF approved for intravenous administration to patients with moderate to severe rheumatoid arthritis (RA). GLM-IV utilization has not been widely studied since FDA approval in July, 2013.

**OBJECTIVE:** To describe patient characteristics and compare actual and expected GLM-IV utilization in a U.S. RA population.

**METHODS:** A U.S. rheumatology registry (Corrona) was used to identify adult RA patients initiating GLM-IV between July 2013 and September 2015. Patients with ≥6 months follow-up and a verifiable dose were included. Descriptive statistics were used to summarize demographic/clinical characteristics, methotrexate (MTX) and disease-modifying anti-rheumatic drugs (DMARDs) at GLM-IV initiation, the percent of patients treated with 1st or 2nd line vs. 3rd or 4th line GLM-IV, and the average number of GLM-IV vials used within 6-month increments. Patient weight, recommended dosing interval and GLM-IV dose (2 mg per kg) were used to calculate expected GLM-IV utilization rounded to the next whole vial.

**RESULTS:** 231 RA patients initiating GLM-IV were identified; 50% (n=116) had at least one follow-up visit and of these, 83% were female, mean age was 61 years and RA duration was 13 years. GLM-IV was prescribed as 1st or 2nd line in 22% (n=26) of patients and as 3rd or 4th line in the majority (78%; n=90). At initiation, average tender joint count was 8, swollen joint count was 5.6. Mean body weight was approximately 83 kg. GLM-IV was used in combination with MTX in 54%; 23% of patients were on DMARDs excluding MTX, and 23% were on GLM-IV monotherapy. The average number of GLM-IV vials used in an average 6-month period with vial rounding was 13 ±5 vials. The expected number of vials for an average 6-month period in an 83 kg patient was estimated at 13.3 vials or approximately 3.3 vials per infusion.

**CONCLUSIONS:** In this population of RA patients, GLM-IV was used in relatively older patients with long-standing active disease who failed prior biologics therapies. Observed GLM-IV utilization was consistent with expected GLM-IV dosing recommendations in the package insert, interestingly only 23% were on monotherapy.

**SPONSORSHIP:** This study was sponsored by Corrona. The Corrona RA registry has been supported by contracted subscriptions by AbbVie, Amgen, BMS, Crescendo, Genentech, Horizon Pharma USA, Janssen, Eli Lilly, Novartis, Pfizer, and UCB.

**M24** Prevalence and Cost of Autoimmune Specialty Drug Use by Indication in a 4.4 Million-Member Commercially Insured Population Continuously Enrolled 4 Years, 2012 to 2015

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**BACKGROUND:** A set of drugs commonly grouped as autoimmune (AI) specialty drugs has been a key pharmacy (Rx) and medical drug (MedDrug) cost driver. Many AI drugs have overlapping indications, presenting an opportunity for managed care plans to encourage the most cost effective treatments. AI drugs also provide an opportunity to explore indication-based pricing.

**OBJECTIVE:** To estimate the number of members using and cost of AI drugs in a commercially insured population by year, 2012 to 2015, by indications deduced from integrated pharmacy and medical claims data.

**METHODS:** Among 12 clients with total average of 13.8 million commercially insured members per month, all members continuously enrolled from 2012 to 2015 were identified and all of their claims. ICD-9 and 10 medical claim diagnosis codes were grouped into a set of FDA approved and plausible off-label indication categories. AI drugs were defined as abatacept, adalimumab, anakinra, apremilast, canakinumab, certolizumab, etanercept, golimumab, infliximab, secukinumab, tocilizumab, tofacitinib, ustekinumab, and vedolizumab, plus rituximab MedDrug coded for rheumatoid arthritis. Each member with AI drug use was assigned to a single indication-based category based on the most frequently coded indication on any AI MedDrug claims, then any medical claims for which the servicing provider was the same as an AI prescriber, then any medical claims. The number of users and sum of plan plus member payments without adjustment for rebates or coupons was calculated by year, type of claim, indication, and drug.

**RESULTS:** There were 4.4 million members in the sample with mean age 38.8 years. A total of 27,341 members used an AI drug, increasing from 16,247 in 2012 to 22,543 in 2015 (365.5 to 507.1 per 100,000) and $360 million in 2012 to $729 million in 2015 ($6.74 to $13.66 per member per month). AI drugs accounted for 8.1% of all Rx + MedDrug benefit costs in 2012 and 9.9% in 2015. AI MedDrug accounted for 31.3% of users in 2012 and 27.0% in 2015. In 2015, 97.6% of users were assigned to 5 indications, 1.5% to 17 other indications, and 0.9% were unassigned. Over 4 years, the mean number of different AI drugs per user was 1.4.

**CONCLUSIONS:** Autoimmune specialty drugs now account for about 1 of every 10 dollars of drug expense in a commercially insured population. Integrated analysis of medical claims is essential as more than 25% of use is covered by medical benefits. Medical claim provider and diagnosis coding can be used to categorize use by indication, which may be helpful in designing strategies to manage cost effective use and for indication-based pricing.

**SPONSORSHIP:** Prime Therapeutics.

**M27** Utilization Patterns of Subcutaneously Administered Biologic Medications Within a Sample of Rheumatoid Arthritis Patients

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**BACKGROUND:** Adherence to medication is crucial to the maximum therapeutic benefit of biologic treatment. The plethora of currently approved biologic agents makes comparison of the various medications more difficult, particularly when drug dosing and administration schedules vary.

**OBJECTIVE:** To investigate real-world utilization and adherence patterns of subcutaneous (SC) biologic treatment in a population of patients with RA.

**METHODS:** The earliest incident adalimumab (ADA), certolizumab (CER), etanercept (ETA), and golimumab (GLM) biologic cycles of treatment were identified in the Truven MarketScan and Optum
Clininformatics research databases for adult patients with an RA diagnosis (ICD-9: 714.xx) between 2009-2013. Members were required to have ≥2 index biologic fills and continuous eligiblity for at least 6 months prior to biologic initiation. Members were followed until the end of their treatment, eligibility was lost, or the end of the data was reached. Utilization measures included biologic placement, treatment gaps measured as the number of days between expected refill dates, dose escalation, defined as any appearance of a twofold increase in dose from the starting dose, and medication adherence assessed by the proportion of days covered (PDC). Members with >80% of the days in their treatment period covered by the index medication were categorized as adherent. One-way ANOVA and chi-square tests of equality of proportions were conducted to assess group differences.

RESULTS: Modal monthly calculated dosages were in line with recommended prescribing guidelines for all four treatments. GLM and CER were significantly less likely to be administered as a first line biologic compared to ADA and ETA; however, GLM members were more likely to be adherent (P < 0.05). ADA and GLM members displayed the greatest refill consistency within the Truven database as evidenced by lower gaps between refills (P < 0.05). Consistent with the label, ADA cycles were more likely to show a dose escalation (P < 0.001). Nearly two-thirds of all treatment cycles persisted for ≥6 months, with the greatest proportion from the ETA group across both databases. (P < 0.001).

CONCLUSIONS: Significant differences in biologic utilization patterns were observed among the four treatment groups. ADA and ETA were the most common first line biologics, though GLM cycles were associated with greater refill consistency and levels of adherence. These findings have implications for healthcare decision makers interested in quality improvement or optimization of adherence in patients treated with subcutaneous biological therapies.

SPONSORSHIP: Sponsored by Janssen Scientific Affairs.

M28 Healthcare Costs Among Rheumatoid Arthritis Patients Treated with First-Line Subcutaneous or Intravenous Biologic Agents: A Difference-in-Difference Analysis in 2 National Claims Databases

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BACKGROUND: Understanding the cost implications of subcutaneous (SC) and intravenous (IV) biologic agents for rheumatoid arthritis (RA) is important in a real-world setting to help inform health care decisions.

OBJECTIVE: To evaluate cost implications of first-line biologic agents used for RA through a difference-in-difference analysis.

METHODS: This was a retrospective study using data from 2 large U.S. administrative claims databases (DB1 and DB2). Adult patients with an ICD-9-CM code for RA (714.0x) and ≥1 pharmacy claim for a SC or IV biologic agent from 08/01/2010-9/30/2014 were eligible. Patients were continuously enrolled 12 months pre and post index prescription. Patients with other conditions for which biologics may be used or who received multiple biologics were excluded. A difference-in-difference analysis was conducted to evaluate differences in the pre-post healthcare costs between abatacept cohort and those treated other biologic agents. Statistical differences were assessed using a t-test, with the abatacept cohort as the reference.

RESULTS: 1st Line SC: In DB1, RA-related total costs for the abatacept cohort increased by $21,586 ± $15,349, which was significantly less than adalimumab ($24,006 ± $14,073; P = 0.0083). This increase was also less than certolizumab ($21,998 ± $17,095) and etanercept ($23,457 ± $15,937), though differences were not significant. Increases for the abatacept cohort were greater than the golimumab cohort ($21,126 ± $11,329), but not significantly. In DB2, RA-related total costs for the abatacept cohort increased by $16,231 ± $19,128, which was significantly less than adalimumab ($21,791 ± $12,686; P = 0.0002), certolizumab ($21,863 ± $13,078; P = 0.0040), golimumab ($20,379 ± $13,335; P = 0.0430), and etanercept ($22,452 ± $12,715; P < 0.0001). 1st Line IV: In DB1, RA-related total costs for abatacept increased by $22,287 ± $13,228, which was significantly less than rituximab ($27,163 ± $23,855; P = 0.0022). Costs increases were numerically higher for infliximab ($25,981 ± $40,189) and tocilizumab ($23,197 ± $31,296) compared to abatacept. In DB2, RA-related total costs for abatacept increased $20,829 ± $14,415, which was significantly less than infliximab ($30,392 ± $15,576; P < 0.0001), but significantly more than tocilizumab ($13,221 ± $20,347; P = 0.0102). Abatacept costs were numerically higher than rituximab ($20,478 ± $11,174).

CONCLUSIONS: Increases in costs were slightly higher for IV than for SC agents. In 1st line SC cohorts across databases, the abatacept cohort had the lowest or next to lowest increase in RA-related total costs. Trends were similar in 1st line IV cohorts, with two agents having lower increases in costs vs. abatacept, but only in one database.

SPONSORSHIP: Bristol-Myers Squibb

M29 Work Loss Associated with Hospitalization Due to Infection in Patients with Rheumatoid Arthritis

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BACKGROUND: Biologic DMARDs improve quality of care in rheumatoid arthritis (RA), but can interfere with immune response, increasing risk of infection and potentially leading to hospitalization and increased direct healthcare costs. Previous work suggests lower infection risk with abatacept relative to other agents, but there has been little discussion of the relationship between infection-related hospitalization, work loss and indirect costs.

OBJECTIVE: To quantify work loss and indirect costs associated with infection-related hospitalization, particularly among RA patients.

METHODS: Healthcare claims and workplace attendance/cost data from the MarketScan Commercial and Medicare Supplemental and Productivity Management (HPM) Database were used to conduct a retrospective cohort study of patients with ≥1 inpatient admission for serious infection from January 1, 2008 to December 31, 2012 (date of first hospitalization = index date); who were ≥18 years old at index; who had ≥6 months of continuous enrollment before (baseline) and after (follow-up) index; and with eligibility in the HPM database for baseline and follow-up periods. RA patients were identified as those with ≥2 medical claims with an RA diagnosis on different days during baseline. Analyses compared work loss (absences, short-term [STD] and long-term [LTD] disability; measured as hours lost) and costs of work loss in the 6 months before and after infection-related hospitalization, examined in all patients and in RA patients. Chi-square tests were used to compare categorical variables; paired t-tests were used for continuous variables.

RESULTS: 36,693 (RA: 480) patients met the inclusion criteria and reported absence data; 115,902 (RA: 1,346) reported STD data; and 106,934 (RA: 1,396) reported LTD data. RA patients with an absence claim decreased during follow-up, but mean absence hours and cost of workplace absences increased 32% (P < 0.01). RA patients with an STD or LTD claim increased following hospitalization, and STD hours (118.7 vs. 230.8) and LTD costs ($1,856 vs. $3,607) doubled (P < 0.01). LTD costs ($326 vs. $743) and hours (20.8 vs. 47.5) also increased...
significantly after hospitalization. Results were similar for the general population, but increases in work loss and costs were greater in RA patients.

CONCLUSIONS: Work loss and indirect costs increased substantially after hospitalization for infections, more so for RA patients than for the general population. In addition to direct costs, indirect costs associated with work loss and disability due to hospitalization for infection should be considered as part of RA treatment decisions.

SPONSORSHIP: Truven Health Analytics on behalf of Bristol-Myers Squibb

**M33** Are Patients with Ankylosing Spondylitis Really Different from Nonradiographic Axial SpA? Results from the Corrona Psoriatic Arthritis/Spondyloarthritis Registry

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BACKGROUND: Only a few European studies have shown that most of the clinical features and assessments of axial spondyloarthritis (axSpA) are similar in patients with/without radiographic changes. However, some differences may be predictive of more severe disease.

OBJECTIVE: To characterize the axSpA population in the U.S.-based Corrona psoriatic arthritis/spondyloarthritis (PsA/SpA) registry.

METHODS: The study included patients with axSpA enrolled in the registry between March 2013 and July 2015, further stratified into 2 cohorts: ankylosing spondylitis (AS) and non-radiographic axSpA (nr-axSpA) based on the 1984 NY modified criteria for AS and ASAS criteria for axSpA without sacroiliac radiographic changes, respectively. Patient characteristics were evaluated at the time of enrollment; between-group differences were evaluated using chi-square tests and t-tests were for categorical and continuous variables, respectively.

RESULTS: Of the 407 patients identified with axSpA, 310 were diagnosed with AS and 97 with nr-axSpA. Patients with AS were slightly older (49 vs. 44 years) and more likely to be male (65% vs. 57%) compared to patients with nr-axSpA. Both cohorts had similar mean functional disability (HAQ, 0.6 vs. 0.6), quality of life (EQSD, 0.7 vs. 0.7) and overall activity impairment (26.8% vs. 31.6%). While clinical features did not differ between the AS and nr-axSpA patients, signs of inflammation measured by acute phase reactants were significantly higher in patients with AS compared to nr-axSpA (mean ESR, 14.4 vs. 8.6; mean CRP, 110.8 vs. 44.5 mg/L; P < 0.05), consistent with other national cohorts. In addition, patients with nr-axSpA were more likely to have enthesitis (47.4% vs. 29.0%) and dactylitis (12.4% vs. 9.0%). History of biologic use (64.8% vs. 74.2%), current biologic use (61.3% vs. 63.9%) and current prednisone use (5.5% vs. 6.2%) was similar between AS and nr-axSpA cohorts.

CONCLUSIONS: This is the first characterization of patients with axSpA from the U.S. Corrona registry with stratification into AS and nr-axSpA. Patients with nr-axSpA were younger and more likely to be female compared to patients with AS. Both groups had similar clinical characteristics, quality of life, disability and work impairment.

SPONSORSHIP: AbbVie, Amgen, BMS, Crescendo, Genentech, Horizon Pharma USA, Janssen, Eli Lilly, Novartis, Pfizer, and UCB have supported Corrona through contracted subscriptions. Financial support for this study was provided by Novartis.

**M34** Reasons for Biologic Therapy Discontinuation in Patients with Ankylosing Spondylitis: Analysis of the Corrona Psoriatic Arthritis/Spondyloarthritis Registry

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BACKGROUND: Clinical trials have demonstrated the efficacy of biologic therapy in patients with ankylosing spondylitis (AS); however, there are limited real-world data available linking the importance of adherence to treatment with improvement of clinical outcomes.

OBJECTIVE: To characterize and compare patients with AS who continued and discontinued their biologic therapy within 12 months of initiation in the U.S.-based Corrona psoriatic arthritis/spondyloarthritis (PsA/SpA) registry.

METHODS: This descriptive analysis included all patients with AS aged ≥18 years enrolled in the Corrona PsA/SpA registry between March 2013 and March 2016 who received a biologic (all anti-tumor necrosis factor agents) at the time of registry enrollment and had ≥1 follow-up visit. Patients were assigned to a cohort depending on their continued or discontinued use of their index biologic agent at the time of the first follow-up visit (mean [SD] follow-up, 8.8 [4.6] months). Patient characteristics at enrollment were compared between the two cohorts, and reasons for discontinuation of the index biologic by the first follow-up visit were also described.

RESULTS: Of the 167 patients with AS who met the inclusion criteria, 32 patients (19.2%) discontinued their index biologic therapy by the first follow-up visit, including 12 patients who switched to another biologic therapy. Although baseline characteristics were mostly similar between the two cohorts, patients who discontinued their index biologic were significantly older (52.6 vs. 46.8 years; P = 0.04); were more obese (BMI = 30.0 kg/m²; 56.7% vs. 33.3%); and had greater disease activity (mean BASDAI score, 4.8 vs. 3.7; P = 0.027) and functional limitation (mean BASSFI score, 4.6 vs. 2.8; P = 0.022) compared with patients who continued their biologic therapy. Among the 9 patients (28.1%) with physician-reported reasons for discontinuation, lack of effect (n = 5) was the most common reason, followed by other reasons (n = 2), side effects (n = 1) and social reasons (n = 1).

CONCLUSIONS: Patients with AS who discontinued their biologic therapy by the first follow-up visit were significantly older, more obese and had greater disease activity at enrollment compared to those who remained on the therapy.

SPONSORSHIP: AbbVie, Amgen, BMS, Crescendo, Genentech, Horizon Pharma USA, Janssen, Eli Lilly, Novartis, Pfizer, and UCB have supported Corrona through contracted subscriptions. Financial support for the study was provided by Novartis.

**M35** Response to Biologic Therapy in Patients with Ankylosing Spondylitis: Analysis of Patient-Reported Outcomes from the Corrona Psoriatic Arthritis/Spondyloarthritis Registry

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BACKGROUND: A limited number of real-world studies have evaluated response to biologic therapies in patients with ankylosing spondylitis (AS).
OBJECTIVE: To describe changes in patient-reported outcomes (PROs) in patients with AS based on their response to index biologic therapy in the U.S.-based Corrona psoriatic arthritis/spondyloarthritis (PsA/SpA) registry.

METHODS: This study included all patients with AS aged ≥18 years enrolled in the registry between March 2013 and March 2016 who received a biologic therapy (all anti-tumor necrosis factor agents) at the time of enrollment and had ≥1 follow-up visit with Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) assessments. Responders were defined as patients who remained on their therapy and achieved a ≥2-point or ≥50% improvement in BASDAI at the first follow-up visit (mean [SD] follow-up, 8.4 [4.0] months). Non-responders discontinued their therapy due to lack of efficacy or did not achieve a minimum clinically important difference in BASDAI at the first follow-up visit. Unadjusted differences in PROs between the 2 cohorts were calculated.

RESULTS: Of the 153 patients with AS who met the inclusion criteria, 31 patients (20.2%) were classified as responders and 98 patients (64.1%) as non-responders; the remaining 24 patients were excluded from this study as they discontinued their biologic due to non-efﬁcacy or unknown reasons. At the first follow-up visit, responders demonstrated a significant improvement in multiple PRO measures relative to non-responders, including mean changes from baseline in HAQ (-0.24 vs. 0.05; P = 0.012) and activity impairment (-18.1% vs. -1.0%; P < 0.001), pain (-26.5 vs. 4.3; P = 0.001), and in domains of Work Productivity and Activity Impairment (WPAI), such as impairment while working (-20.1 vs. 0.3; P = 0.002), pain, fatigue and domains of WPAI compared with non-responders.

CONCLUSIONS: Nearly two-thirds of patients with AS in the Corrona PsA/SpA registry did not respond to their index biologic therapy at the first follow-up visit. Biologic therapy responders demonstrated significant improvements in multiple PRO measures, such as HAQ, pain, fatigue and domains of WPAI compared with non-responders.

SPONSORSHIP: AbbVie, Amgen, BMS, Crescendo, Genentech, Horizon Pharma USA, Janssen, Eli Lilly, Novartis, Pfizer, and UCB have supported Corrona through contracted subscriptions. Financial support for this study was provided by Novartis.

M36 Healthcare Utilization and Costs in Patients with Ankylosing Spondylitis in a Real-World Setting

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BACKGROUND: Ankylosing Spondylitis (AS) is a chronic inﬂammatory disorder that mainly affects the sacroiliac joints and axial skeleton.

OBJECTIVE: This study examined healthcare resource utilization (HCRU) and costs among AS patients compared to a matched control cohort without AS.

METHODS: Adults with ≥1 inpatient or 2 outpatient diagnoses of AS (ICD-9-CM 720.0) in 1/1/2008-6/30/2014 were extracted from MarketScan Databases. Of those identiﬁed, patients with ≥1 AS diagnosis in 2013 were included, and the ﬁrst AS diagnosis in 2013 was the index date. Patients had ≥12 months pre-period and were followed for ≥12 months. A control cohort of patients with no AS diagnosis anytime in 2007-2013 was matched to AS patients on calendar year, age, gender, and region. Per patient per month (PPPM) HCRU and costs (total paid amount in 2015 $) during the 1-year post period were compared between AS and control patients, and within the AS cohort, between biologic users and non-users. Generalized linear models were estimated to examine the marginal impact of having AS and biologic treatment on costs.

RESULTS: A total of 6,679 AS patients (55% biologic users) and 19,951 matched controls (mean age: 50.8 years for AS vs. 51.7 for controls; male: 60.5% vs. 60.8%) met the study criteria. Compared with controls, AS patients had signiﬁcantly higher inpatient admissions (12.0% vs. 6.0%), emergency room visits (23.0% vs. 15.0%), PPPM number of office visits (0.9 vs. 0.5), hospital-based outpatient visits (0.4 vs. 0.3), and number of medications (3.0 vs. 1.6), P<0.01 in all cases. AS patients had higher PPPM total costs ($2,690 vs. $693), with outpatient pharmacy cost ($1,173 vs. $145) and outpatient medical costs ($1,102 vs. $383) as the main cost drivers (P<0.001). Among AS patients, biologic users had higher PPPM total costs than non-users ($3,437 vs. $1,762), mainly due to higher pharmacy costs ($1,909 vs. $309). Multivariate analysis found that AS was associated with $1,866 higher total costs PPPM than non-AS controls and biologic treatment was associated with $2,264 higher total costs than non-users.

CONCLUSIONS: AS patients experienced signiﬁcantly higher HCRU and costs than patients without AS. Among AS patients, biologic users had higher costs than non-users. Future studies on the impact of having AS and biologic treatment on productivity loss and indirect costs will help understand the full economic burden associated with AS.

SPONSORSHIP: This study was funded by Novartis.

M37 Oral Bisphosphonate Treatment Patterns in Osteoporotic Women Aged 55 and Older in the United States

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BACKGROUND: Osteoporotic fractures represent a major health burden in the United States. Bisphosphonates (BP) are recommended as the ﬁrst line of therapy for osteoporosis (OP) and have been shown to reduce the risk of osteoporotic fractures. However, adherence to these drugs is suboptimal and may be associated with reduced treatment efﬁcacy.

OBJECTIVE: To describe treatment patterns among women with OP who initiated an oral BP.

METHODS: A retrospective cohort study was conducted using the HealthCore Integrated Research Database from 01/01/2006 to 05/31/2015. Postmenopausal women ≥55 years of age who were new users of oral BP with ≥1 pharmacy claim of alendronate, risedronate, or ibandronate between 06/01/2010 and 05/31/2013 were included. Patients were required to have ≥1 year continuous enrollment before and ≥2 years after the ﬁrst observed oral BP claim (deﬁned as the index date). Patients with ≥1 claim for OP-related medication or estrogen use 1 year before the index date or ≥1 claim for Paget’s disease or malignant neoplasm during the study period were excluded. Treatment patterns were evaluated for the index BP for 2 years after the index date. Patients were classiﬁed as having one of four mutually exclusive treatment patterns: (1) persistent (<45-day gap between subsequent ﬁlls), (2) augmenters (<45-day gap between subsequent ﬁlls with an added OP-related therapy), (3) switchers (initiating a new OP-related therapy within 45 days of index BP use), or (4) discontinuers (≥45-day gap between subsequent ﬁlls). The classiﬁcation was based on whichever pattern was observed ﬁrst.
RESULTS: A total of 8,613 women with a mean (SD) age of 67 (9.5) years were included in the study. Alendronate was the most frequently prescribed index oral BP (73.5%), followed by risdrostone (16.8%) and ibandronate (9.7%). After the initiation of an oral BP, 1,464 (17.0%) women remained persistent with the index oral BP, 15 (0.2%) augmented the index oral BP, 344 (4.0%) switched to another OP therapy, and 6,790 (78.8%) discontinued the index oral BP during the follow-up period. Among the discontinuers, 3,894 (57.3%) completely discontinued all OP therapy, 2,377 (35.0%) restarter the index oral BP, 276 (4.1%) switched to a non-index oral BP, 89 (1.3%) to an injectable BP, 40 (0.6%) to an oral non-BP, and 114 (1.7%) to an injectable non-BP.

CONCLUSIONS: Discontinuation of an oral BP within two years after initiating treatment among osteoporotic women was frequent, thus highlighting the need to understand the reasons for discontinuation and explore other treatment options among those with a risk of fracture.

SPONSORSHIP: Merck & Co.

M38 Burden of Osteoporosis Treatment Discontinuation Among Senior Women: Analysis of Fractures and Resource Utilization
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BACKGROUND: Discontinuation of anti-osteoporosis treatment is common and may impede the reduction of fracture risk.

OBJECTIVE: To determine the burden of anti-osteoporosis treatment discontinuation in terms of fractures and health care resource use.

METHODS: This was a retrospective analysis of medical and pharmacy claims data from the Humana database in the U.S. Patients were women age ≥65 years with Medicare benefits who filled a prescription of an oral bisphosphonate between January 2008 and September 2011. Index date was defined as the date of the first prescription fill +90 days, baseline period was defined as the 15 months before the index date and follow up period as the 24 months after the index date. Based on treatment utilization during initial 3 months and the follow-up, patients were classified as non-users receiving only a single index prescription in 3 months or persistent users (MPR ≥ 80%) at all times. Outcomes were assessed during 13-24 months follow-up and included new osteoporotic fractures and all-cause, osteoporosis-related health care resource use. Propensity score weights were used to control for selection bias. We compared outcomes between persistent users and non-users using bivariate analyses and logistic regression.

RESULTS: A total of 2,745 persistent users and 3,538 non-users were identified. Less than 10% of included patients had history of fractures during the baseline. After propensity score weighting, all baseline characteristics did not differ significantly. Relative to persistent users, non-users were more likely to experience any new fracture (odds ratio (OR) 1.51, 95% confidence interval (CI) 1.11-2.06), hip fracture (OR 4.01, 95% CI 1.67-9.63), and other fracture (OR 1.56, 95% CI 1.00-2.43) during the follow-up, the difference in clinical vertebral fracture was not significant (OR 1.24, 95 CI 0.80-1.91). Non-users exhibited greater odds of all-cause inpatient and emergency department resource use (OR 1.65, 95% CI 1.43-1.90, and OR 1.70, 95% CI 1.50-1.92, respectively).

CONCLUSIONS: Compared to persistent users, patients who discontinued oral bisphosphonate treatment after the first prescription fill (non-users) were more likely to experience osteoporotic fractures, with a 4-fold increase in hip fractures and increased health care resource use within 2 years of discontinuation.

SPONSORSHIP: This study was sponsored by Merck & Co.

M39 Costs and Health Care Resource Use Among U.S. Patients with Incident and Subsequent Osteoporotic Fractures
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BACKGROUND: The costs and health care resource use of patients with subsequent osteoporotic fractures in the year following an incident osteoporotic fracture are not well defined.

OBJECTIVE: To assess the all-cause costs and health care resource use among patients with subsequent fractures in the year after an incident osteoporotic fracture compared to those that do not experience a subsequent osteoporotic fracture.

METHODS: Data were obtained from Humana Medicare Advantage claims (the Medicare group) and Optum Insight Clinformatics Data Mart commercial claims (the Commercial group). Patients included in the study had a claim for a qualifying fracture occurring between 2008 and 2013 (incident fracture), were continuously enrolled in the health plan for 1 year before and after the incident fracture, and were aged ≥65 (Medicare) or ≥50 (Commercial) years. Subsequent fractures were defined as a fracture occurring ≥ 3 to ≤ 12 months after the incident fracture. After propensity matching we determined the total medical and pharmacy costs accrued within one year of the incident fracture by patients with and without a subsequent fracture by resource use type. Health care costs were compared between patients with and without a subsequent fracture using McNemar's test.

RESULTS: A total of 45,603 patients were identified for inclusion in the Medicare group and 54,145 in the Commercial group. The mean ages of Medicare and Commercial patients were 78.1 years and 61.8 years. Subsequent fractures occurred in 11.6-16.7% of patients. In both analyses, subsequent fracture rates were highest among patients with multiple incident fractures (24.5-26.2%), followed by those with hip (22.2-25.5%) and vertebral (14.5-20.2%) incident fractures. The mean total health care cost for the Medicare group was $27,944 and differed significantly between patients with and without a subsequent fracture ($34,897 vs. $20,790; P<0.001). The primary contributors to this cost difference were inpatient services and long-term care ($6,412 and $4,327 higher, respectively). The mean total health care cost for the Commercial group was $29,316 and also differed significantly between patients with and without a subsequent fracture ($39,501 versus $19,131, P<0.001). The primary drivers of the cost difference in the Commercial group were other medical costs and inpatient services ($6,865 and $5,952 higher, respectively).

CONCLUSIONS: Among patients with an incident fracture, those who experience a subsequent fracture in the following year have significantly higher health care costs than those who do not.

SPONSORSHIP: This study was sponsored by Merck & Co.

M40 Fracture Liaison Service Return on Investment (Cost Offset) Calculator
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BACKGROUND: Fracture Liaison Service (FLS) is proven model of care to address the 80% care gap in Osteoporosis. In order to gain support for the FLS model of care, health care professionals need to show the value on patient care, quality and return on investment.

OBJECTIVE: To develop an interactive calculator to provide estimates of the impact of an FLS program on health care costs and revenues, with the collaboration of the National Bone Health Alliance (NBHA),

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Research Triangle Institute (RTI), UAB School of Medicine, and other partners.

METHODS: The FLS return on investment (cost offset) calculator will provide those considering adoption of FLS with a tool that demonstrates the impact of FLS in reducing fractures and details the expected changes in costs and revenues. The interactive nature of the calculator will allow a user to use characteristics specific to their patient population and identify optimal patient groups for targeting high-impact FLS program.

RESULTS: The FLS ROI calculator is being constructed for two related objectives. First, the calculator will provide a variety of estimates of the costs (and thus potential cost savings) associated with healthcare use following fractures using statistical modeling techniques. These estimates will vary by multiple strata of population characteristics, risk factors and geography which will allow for estimates tailored to specific providers, payers, managed care organizations and other stakeholders and policy makers. To improve scientific rigor the estimates will furthermore be adjusted by results from the literature on the effectiveness of FLS and other interventions and by sensitivity analyses around statistical model assumptions. The second objective is as a decision support tool for NBHA. In addition to tailored cost savings, the calculator also yields predictions of fracture prevalence. NBHA and other stakeholders can use these estimates to help make optimal decisions about which facilities or organizations to target for FLS implementation.

CONCLUSIONS: The calculator and its underlying model are being supported by contemporary data on relevant patient populations. These data provide the prevalence of fractures and related costs across geographic, demographic, diagnostic and provider/payer characteristics.

SPONSORSHIP: The development of the ROI Calculator was provided with unrestricted support by Amgen.

N01 The Economic Burden of Hyperkalemia Among Patients with Chronic Kidney Disease and/or Heart Failure

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BACKGROUND: There are limited published data on the epidemiology of hyperkalemia, but these data indicate that hyperkalemia is more common in patients with chronic kidney disease (CKD) and/or heart failure (HF).

OBJECTIVE: To estimate the prevalence of hyperkalemia in the U.S. for both the general population and patients with CKD and/or HF.

METHODS: Adult patients with CKD (excluding dialysis) and/or HF were selected from a large U.S. commercial claims database with more than 2 million individuals with potassium lab data available (01/01/2011-12/31/2014). Patients who had at least 1 calendar year of data with at least 1 potassium lab result and continuous enrollment throughout the year were included. Hyperkalemia was defined as having at least two serum potassium measurements >5.0 mEq/L or one diagnosis code of hyperkalemia (ICD-9, 276.7) or one prescription fill of a sodium polystyrene sulfonate. Prevalence of hyperkalemia was estimated for the overall population and among patients with CKD (excluding dialysis) and/or HF. CKD was identified by ICD-9 diagnosis codes or estimated glomerular filtration rate, HF was identified by ICD-9 codes, and dialysis was excluded using procedure codes. Prevalence of hyperkalemia for each calendar year was calculated as the number of patients with hyperkalemia divided by the total number of eligible patients within the year. In addition, hyperkalemia prevalence stratified to the U.S. population was calculated using hyperkalemia prevalence stratified by age and gender, then multiplied by the corresponding U.S. census population of that age-gender stratum.

RESULTS: A total of 1,888,433 patients were included in the analysis (2011-2014). The prevalence of hyperkalemia in the overall population ranged from 1.2% to 1.6% across calendar years. A total of 861,300 CKD (excluding dialysis) and/or HF patients were included and the prevalence of hyperkalemia in this subgroup ranged from 2.1% to 2.5%. Conversely, 71.2% to 74.8% of all patients with hyperkalemia had CKD (excluding dialysis) and/or HF. The prevalence of hyperkalemia...
increased as age increased in the overall population, ranging between 0.3%-0.4% in the 20–24 years group to 4.8%-6.8% in the 85 years and above group. The standardized prevalence of hyperkalemia from 2011-2014 ranged between 2.9-3.7 million adults in the general U.S. population.

CONCLUSIONS: The prevalence of hyperkalemia was 2%-3% in patients with CKD (excluding dialysis) and/or HF. Annually, approximately 3 to 4 million adults in the U.S. are estimated to have hyperkalemia.

SPONSORSHIP: This research was funded by ZS Pharma.

N05 Factors Associated with Nonadherence to Overactive Bladder Medications in an Integrated Managed Care Organization

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BACKGROUND: Prior studies showed that nonadherence to overactive bladder (OAB) medication may lead to poor outcomes, including treatment failure, resistance to therapy, disease progression, and increase in office visits and medical expenditures. A failure to recognize nonadherence can lead to unnecessary dose escalation, medication switches, and poor quality of life.

OBJECTIVE: To measure nonadherence to OAB medications and identify patient factors associated with nonadherence.

METHODS: A retrospective cohort study was conducted using the Kaiser Permanente Southern California (KPSC) database to identify patients with an incident OAB prescription (Rx) between 01/01/2007 and 12/31/2013. Index date was defined as the first written OAB Rx. Inclusion criteria were: ≥ 18 years of age on the index date; no history of an OAB Rx within 12 months prior to index date, membership and drug benefit eligibility during 12 months pre/post index date. Adherence was calculated using the proportion of days covered (PDC) with a PDC < 80% considered nonadherent. Descriptive statistics and multivariate logistic regression analysis were conducted to identify factors associated with patients who were nonadherent versus adherent while controlling for clinical and demographic characteristics.

RESULTS: 4,643 patients were included in the study of which 3,547 (76.4%) were nonadherent. Compared to adherent patients, nonadherent patients were younger (64±14.4 vs. 68±12.8 years, P < 0.0001); more likely to be female (72.7% vs. 68.0%, P = 0.0025); less likely to be diabetic (19.8% vs. 26.2%, P < 0.001) or hypertensive (57.1% vs. 65.2%, P < 0.001); had lower mean Charlson Comorbidity Index (CCI) score (2.65 vs. 3.22, P < 0.001); and fewer older Rxs dispensed in the prior 12 months. Adherent patients were more likely to use an anticholinesterase (5.29% vs. 1.97%, P < 0.001) and 5-alpha reductase inhibitor (6.57% vs. 3.98%, P < 0.003). Multivariate logistic regression analysis showed statistically significant factors more likely to be associated with nonadherence vs. adherence were history of depression (OR: 1.32, CI: 1.10-1.58), urinary tract infections (OR: 1.27, CI: 1.06-1.53), falls (OR: 1.23, CI: 1.02-1.48), and being sicker [CCI=0 vs. CCI≥2 (OR: 1.29 CI: 1.07-1.54)].

CONCLUSIONS: Patients who are nonadherent to their OAB medication are significantly different than adherent patients. Within an integrated system, this information will provide a guide on how to identify nonadherent OAB patients and develop programs to improve their adherence.

SPONSORSHIP: Supported by a research grant from Astellas Pharma.

N06 Impact of 2015 Update to the Beer’s Criteria on Estimates of Prevalence and Costs Associated with Potentially Inappropriate Use of Antimuscarinics for Overactive Bladder

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BACKGROUND: Our previous research demonstrated that potentially inappropriate medication (PIM) use is highly prevalent among Medicare Advantage (MA) members initiating antimuscarinic (AM) medications for treatment of overactive bladder (OAB), and that PIM is associated with greater healthcare costs.

OBJECTIVE: To compare the impact of the 2015 update to the 2012 version of the Beer’s Criteria (BC) on prevalence and cost estimates of PIM in members newly treated with AMs for OAB.

METHODS: The study was a retrospective database analysis using claims data. MA members age ≥ 65 years and newly initiated on AM OAB treatment were identified. Members were assigned into PIM and non-PIM groups based on the presence of qualifying medical conditions and/or drug-drug interactions using, alternatively, the 2012 and 2015 versions of the BC. Patients were segmented into three mutually exclusive groups: (1) members who qualified under both 2012 and 2015 BC; (2) members who qualified based on the 2012 BC Only; and (3) members who qualified based on the 2015 BC Only. Comparisons were conducted for the 2015 BC Only vs. the 2012 BC Only groups using bivariate tests (t-test, Wilcoxon rank sum, chi-square). Adjusted costs were modeled using a generalized linear model adjusting for baseline characteristics.

RESULTS: A total of 66,275 members were included. Overall prevalence of PIM of OAB AMs was higher using 2015 BC compared to the 2012 BC (23.1% vs. 20.6%). Dementia was the most common PIM-qualifying condition under both versions. The 2015 BC resulted in identification of more females, more whites, and a younger population with PIM. Compared to 2012 BC Only group, the 2015 BC Only group had lower Elixhauser comorbidity score (2.5 ± 2.4 vs. 3.4 ± 2.6, P < 0.001). Prevalence of high cost clinical conditions were lower when the 2015 BC was used, including: cancers, diabetes, cardiovascular diseases, pulmonary, and renal conditions. The 2015 BC Only group had lower median unadjusted healthcare costs ($7,104 vs. $8,301, P < 0.001). After adjusting for demographic and clinical characteristics, the 2015 BC Only group had greater total healthcare costs compared to the 2012 BC Only group (P < 0.001).

CONCLUSIONS: In this cohort of MAPD members newly initiated on AM OAB treatment identification of PIM based on the 2015 BC compared to the 2012 BC resulted in substantial shifts in demographic, clinical, and economic characteristics. The findings suggest that the 2015 BC result in the identification of members with less medical morbidity.

SPONSORSHIP: This research was funded by Astellas and conducted as part of the Astellas-Humana Research Collaboration.

N07 Overactive Bladder in an Integrated Health Delivery System: A Retrospective Cohort Study

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BACKGROUND: Overactive bladder (OAB) is common and morbid. Most prior studies have described treatment of OAB patients using prescribing or claims data, which likely had poor sensitivity and were, by definition, more likely to include patients on OAB medication.
OBJECTIVE: To describe treatment patterns of patients with OAB identified using coded and free text data from the electronic health record (EHR).

METHODS: We conducted a retrospective cohort study of adults cared for in a large, integrated health delivery system who had an “EHR OAB phenotype,” identified using validated combinations of coded data (e.g., diagnosis codes, problem lists) and free text data (e.g., clinical notes). To examine independent predictors of OAB medication prescribing, we used multivariable logistic regression. We identified patients with EHR OAB phenotype between July 2011 and June 2012 and followed them for 2 years. The main outcomes were the proportion of patients with primary care vs. specialty visits, medication prescribing, and use of non-medication treatment.

RESULTS: Of 963,303 adults who received care during the study period, there were 7,362 adults with an EHR OAB phenotype. Fifty percent of OAB patients were over 65 years old, 74% were female, and 83% were white. The distribution of care included primary care physician (PCP)/specialty co-management (for 25% of patients), PCP care only (18%); urology only (13%); gynecology only (3%); urogynecology only (1%); or some other combination of specialty care (40%). Forty percent of patients were prescribed one or more OAB medications. Independent predictors of receipt of an OAB medication prescription included increasing age (odds ratio [OR], 1.4 for every 10 years; 95% confidence interval [CI], 1.4 to 1.5), women (OR, 1.6 compared to men; 95% CI, 1.4 to 1.8), diabetes (OR, 1.3; 95% CI, 1.1 to 1.5), and certain sources of care compared to PCP-only care: PCP/specialty co-management (OR, 1.8; 95% CI, 1.5 to 2.0), urology only (OR, 2.2; 95% CI, 1.8 to 2.6), and multiple specialists (OR, 1.4; 95% CI, 1.2 to 1.8). Very few patients received non oral medication treatment: biofeedback (<1%), botulinum toxin (2%), or sacral nerve stimulation (1%).

CONCLUSIONS: Although OAB is common and morbid, in a longitudinal study using an EHR OAB phenotype to identify patients, most patients receive neither medication nor non-medication treatment as documented in the medical record.

SPONSORSHIP: Astellas Pharma.

N08 Assessing the Budget Impact of Increasing the Mirabegron Initial Usage Period from 4 to 12 Weeks

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BACKGROUND: Mirabegron, a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB), was approved based on phase 3 trials in which 12 weeks of treatment resulted in significant improvement in the mean number of incontinence episodes, micturition frequency, and volume voided per micturition. Although guidelines recommend reviewing oral OAB treatment after 4 to 8 weeks to ensure tolerability and efficacy, maximal response with mirabegron is achieved at 12 weeks. This analysis investigates the economic consequences of an inadequate initial mirabegron usage period.

OBJECTIVE: To estimate the budget impact of increasing the mirabegron usage period from 4 to 12 weeks from a U.S. commercial payer perspective.

METHODS: Costs were compared in a Markov model with scenarios of 12- or 4-week mirabegron usage in patients with treatment-naive OAB over a 3-year time horizon. Modeled treatments were mirabegron, antimuscarinics (AMs), onabotulinumtoxinA (onabotA), sacral neuromodulation (SNM), and percutaneous tibial nerve stimulation (PTNS). All patients began an oral OAB treatment but could progress to onabotA treatment, SNM, or PTNS. The monthly probability of discontinuing or switching treatment was based on analysis of claims data and published literature. Prescription costs were based on most recent published wholesale acquisition prices. OnabotA, SNM, PTNS, and costs related to comorbidities, including OAB-related urinary tract infections, rashes, and depression, and treatment-related adverse events (AEs), including those associated with anticholinergic burden and onabotA, were based on published literature. Sensitivity analysis assessed robustness of results.

RESULTS: Over 3 years in a 1 million-member plan, compared to the 4-week mirabegron scenario, the 12-week scenario resulted in a reduction in per member per month (PMPM) costs by almost $0.03. Specifically, total medical costs and AE prescription costs decreased by $2.6 million and $0.1 million, respectively, and OAB medication costs increased by $2.0 million. Overall, total plan cost decreased by $0.9 million. Sensitivity analysis indicated results were most sensitive to cost of onabotA injections (PMPM cost reductions ranged from $0.02 to $0.11).

CONCLUSIONS: Compared to a 4-week mirabegron usage period, a 12-week usage period resulted in moderate economic cost savings by reducing onabotA, SNM, and PTNS usage. The analysis showed that longer utilization of mirabegron may result in cost savings for the plan.

SPONSORSHIP: The work was funded by Astellas Pharma Global Development.

N10 Real-World Analysis of Metastatic Castration-Resistant Prostate Cancer Patients Treated with Enzalutamide or Abiraterone Acetate Plus Prednisone: Baseline Characteristics and Prevalence of Comorbidities

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BACKGROUND: Enzalutamide (ENZ) and abiraterone acetate plus prednisone (AA) are novel oral therapies for metastatic castration-resistant prostate cancer (mCRPC). Patients with mCRPC are predominantly age >65 years with comorbid diseases. An increasing number of treatments for mCRPC (including AA) require co-administration of corticosteroids. Although these may improve the symptoms of some comorbid conditions, they can exacerbate others and additional monitoring is required. The efficacy of ENZ and AA for mCRPC has been demonstrated in clinical trials, but treatment sequencing in clinical practice remains a critical question.

OBJECTIVE: To describe baseline characteristics and prevalence of comorbidities in patients with mCRPC treated with various sequences of ENZ or AA.

METHODS: A longitudinal, retrospective U.S. claims database analysis identified patients with mCRPC treated with ENZ or AA from January 1, 2010 to September 30, 2015. The Clinformatics Data Mart Database (OptumInsight, Eden Prairie, MN) included both Medicare and commercially insured patients. Various treatment sequences were identified, including ENZ only and AA only. For each sequence, baseline characteristics, chemotherapy history, insurance type, comorbid conditions, and concomitant corticosteroid use were summarized from the database. Independent predictors of receipt of an ENZ or AA medication prescription included increasing age (odds ratio [OR], 1.4 for every 10 years; 95% confidence interval [CI], 1.4 to 1.5), men (OR, 1.6 compared to women; 95% CI, 1.4 to 1.8), diabetes (OR, 1.3; 95% CI, 1.1 to 1.5), and certain sources of care compared to PCP-only care: PCP/specialty co-management (OR, 1.8; 95% CI, 1.5 to 2.0), urology only (OR, 2.2; 95% CI, 1.8 to 2.6), and multiple specialists (OR, 1.4; 95% CI, 1.2 to 1.8).

CONCLUSIONS: The work was funded by Astellas Pharma Global Development.
Between 1Q2014 through 1Q2016 there were 21.3 million opioid claims were also defined as non-ADF/ADP, ADF, or ADP based on their label. Of the 13 comorbidities that could be exacerbated by corticosteroids, 10 were more prevalent in the ENZ-only versus the AA-only cohort, including: diabetes without complications (42 vs. 35%), renal disease (39 vs. 32%), and chronic pulmonary disease (31 vs. 23%). Of the 13 comorbidities that could be exacerbated by corticosteroids, 10 were more prevalent in the ENZ-only versus the AA-only cohort, including cardiovascular events (84 vs. 77%), diabetes (43 vs. 35%), and glaucoma (12 vs. 5%).

CONCLUSIONS: The results of this real-world study suggest that the prevalence of comorbidities was higher in ENZ-treated than in AA-treated patients. Furthermore, comorbidities sensitive to corticosteroids were highly prevalent in both the ENZ and AA cohorts. Clinicians and payers should consider the appropriate treatment sequence in mCRPC to align with patient specific comorbidity burden.

SPONSORSHIP: Astellas Pharma and Medivation.

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

U00-U99 Codes for Special Purposes and AMCP Unclassified Abstracts (e.g., Care Management, Specialty Pharmacy, Rare Diseases, Star Ratings, Pharmacist Services, MTM, Med. Rec., Outcome Analyzers, Part D, Multidisease Studies, ACO, ACA)

R02 Short-Acting, Long-Acting, and Abuse-Deterrent Opioid Utilization Patterns Among 15 Million Commercially Insured Members

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BACKGROUND: The opioid epidemic is a problem. The FDA has approved 6 abuse deterrent formulation (ADF) products. An additional 6 products have data suggesting they may have abuse deterrent properties (ADP), however they have not been granted FDA approval for label changes. All ADF and ADP products are long acting opioids. Legislation exists in 20 states to mandate coverage of abuse deterrent formulations prompt the need for insurers to understand opioid utilization trends.

OBJECTIVE: To describe utilization patterns of short-acting, long-acting, ADF, and ADP opioids from January 2014 through March 2016 among 15 million commercially insured members and provide guidance to managed care decision makers.

METHODS: We queried pharmacy claims among 15 million commercially insured members between January 1, 2014 and March 31, 2016. Opioid pharmacy claims were identified using their Medi-Span Generic Product Identifier. Buprenorphine/naloxone products FDA approved for opioid dependence treatment were excluded. All pharmacy claims were normalized to 30-day supplies. For example, a 90-day supply constituted three separate claims. Descriptive statistics were used to describe trends in daily utilization of opioids. Opioids were differentiated into short and long acting. Long-acting opioids were also defined as non-ADF/ADP, ADF, or ADP based on their label.

RESULTS: Between 1Q2014 through 1Q2016 there were 21.3 million opioid claims among the 15 million monthly eligible commercial members. Short acting opioids represented 92% of opioid claims and 8% were long acting. Among long acting opioid claims, 65.8% were non-ADF/ADP, 26.7% were ADF, and 7.5% ADP. Oxycodone extended release ADF represented 96.7% of all ADF claims. Exalgo, Opana ER, and Nucynta ER made up 92% of the ADP claims. Short-acting opioid claims per 100,000 members started at 14,300 in 1Q2014 and ended at 795. ADF started at 303 and ended at 760 claims per 100,000 members. ADP started at 84 and ended at 96 claims per 100,000 members.

CONCLUSIONS: Short-acting opioid claims declined over the 27-month analysis period while long-acting and ADF/ADP opioids increased. Insurers need to understand their own utilization patterns to help forecast expenditures associated with new ADF opioids. Future research could focus on the relationship between ADF opioids and decreased opioid overdoses.

SPONSORSHIP: Prime Therapeutics.

U01 Survey of Medicaid Medication Therapy Management Programs: Variability in State Initiatives

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BACKGROUND: States’ interest in improving care quality, and lowering health care and pharmaceutical costs, has spurred experimentation with medication therapy management (MTM) programs to optimize medication regimens and population health management, improve medication adherence, and manage medication costs. State Medicaid programs are contracting MTM services, however, very little is known about the variability of these programs.

OBJECTIVE: To characterize and discuss the variability of state Medicaid MTM covered services, program implementation challenges, and future considerations for Medicaid MTM program enhancements.

METHODS: An initial screening question was sent to all state Medicaid pharmacy directors to identify states that had current or past Medicaid MTM programs. Twenty-five states (50%) responded they had MTM programs and were invited to complete a detailed survey. The survey data focused on the type/extent of pharmacist-provided MTM services, patient eligibility criteria/enrollment strategies, MTM delivery settings/referral patterns, MTM program evaluations, program costs, sustainability models, key implementation challenges, and future program enhancements. A reminder was sent to non-respondents after 2 weeks.

RESULTS: Of the respondent states, 14/25 (56%) reported that they had supported or are still supporting a Medicaid MTM initiative. Nine of these 14 states (64%) completed the entire survey. Many Medicaid MTM programs followed Medicare Part D requirements. Highly variable findings were due to different Medicaid eligibility criteria, pharmacist integration with health team, access to EMRs, MTM delivery methods/settings to optimize drug therapy regimens. Implementation challenges were (1) lack of sustainable funding, consider MTM as a component of intensive care management programs and statewide strategies for care delivery/payment reform; calculate estimated savings from reduced hospitalizations/ED visits; (2) pharmacist integration on care teams: pharmacists can be co-located/embedded/contracted for MTM services, pharmacists enhanced shared decision-making on care team, access to EMRs, MTM program implementation challenges; (3) lack of EHR access: pharmacists need patient health information via EMRs to make comprehensive assessments and recommendations for care plans and improved care coordination; (4) low patient engagement: < 10% eligible patients enroll in MTM programs; consider opt-out process and population health strategy for high-risk patients; (5) MTM continuity: annual MTM visits fail to catch medication-related problems in patients with multiple comorbidities; (6) program implementation; consider opt-out process and population health strategy for high-risk patients; (7) MTM integration with health team, access to EMRs, MTM delivery settings/referral patterns, MTM program evaluations, program costs, sustainability models, key implementation challenges, and future program enhancements.
conditions and prescribers; consider up to 4 MTM visits/year; and (6) MTM payment model: need to consider capitation/alternative payment models. Need for program enhancements: as states tackle broader work on care delivery and payment reform initiatives, Medicaid programs need to weigh the intended goals and design elements of a MTM programs with expected results on care quality and total cost of health care. For maximal impact, comprehensive programs should be positioned as part of broader medical benefits to improve care management and coordinated services for beneficiaries with complex medications needs or suboptimal patient outcomes.

CONCLUSIONS: Findings regarding implementation challenges and future program enhancements can be considered in the CMS Enhanced MTM Part D and commercial payer programs. MTM implementation improves with pharmacists on care teams; MTM evaluation funding is critical to measure program impact; robust criteria are needed to determine MTM program impact on care quality improvement and total healthcare cost savings.

SPONSORSHIP: None.

U06 Value, Utility, and Challenges with the Academy of Managed Care Pharmacy Format Dossier: Implications of Version 4.0

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BACKGROUND: The intent of the Academy of Managed Care Pharmacy (AMCP) Format dossier is to provide detailed clinical and economic information in a transparent manner to support formulary consideration of new and existing drugs, tests, or devices.

OBJECTIVE: To determine the value, utility, and perceived challenges of the AMCP Format dossier from the perspective of healthcare decision makers.

METHODS: A web-based survey was fielded in June 2016 to members of Xcenda’s proprietary Managed Care Network, a market research panel consisting of U.S. payer practitioners. All responses were blinded. Only descriptive analyses were conducted.

RESULTS: Survey respondents (N = 47) represented 41 unique health plans. Of the respondents, 55% were pharmacy directors and 34% were medical directors. Collectively, over 173 million covered lives were represented. While all respondents were familiar with the AMCP Format, 69% request dossiers during the formulary review process ≥50% of the time. Since January 2016, respondents requested a mean of 9.8 dossiers from manufacturers. The eDossier platform is used frequently or always by 43% of respondents. The most valuable sections for decision making (% of respondents with score of ≥ 5 on 7-point Likert scale) were Clinical Evidence (94%; mean score 6.3) and Executive Summary (96%; mean 6.1). The most challenging variable for utility of an AMCP dossier was the document complexity, length, and/or review time (66%; mean 4.7); lack of relevance to the plan and lack of transparency were also challenging. The majority of respondents (85%) rated the greatest dossier weakness as a lack of comparative effectiveness data. Respondents were also asked to respond to changes in the updated Format version 4.0. Of the types of evidence suggested for inclusion in Section 3.0, respondents rated the most valuable (% of respondents with score of ≥ 5 on 7-point Likert scale) as follows: randomized controlled trials (96%; mean 6.0) and real-world evidence, including meta-analyses/indirect treatment comparisons (70%; mean 4.9), and retrospective studies (70%; mean 4.8). Most respondents (68%) believe that these and other changes to the Format v4.0 would positively impact the dossier’s utility. Most respondents (77%) also indicated that value frameworks would be valuable to include in the dossier.

CONCLUSIONS: The majority of payers use the AMCP dossier to inform decision making but are challenged by document length or complexity. The changes introduced by the AMCP Format version 4.0, particularly the focus on transparency and quality metrics, are expected to improve the dossier’s utility.

SPONSORSHIP: Xcenda.
How Accurate Are Payers’ Budget Impact Predictions for New Drugs? An Empirical Analysis

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BACKGROUND: Concern about the price of newly launched drugs appears to be rising among the general public and among healthcare payers specifically. The media often report pre-launch estimates of the impact new drugs are expected to have on healthcare costs. We could find no published evaluations of how accurate these pre-launch estimates are.

OBJECTIVE: To evaluate the accuracy of pre-launch predictions of the future budget impact of newly approved drugs, with the goal of improving these predictions.

METHODS: We searched for predictions of cost impact for a sample of 15 recently launched drugs, representing a wide range of clinical conditions, population sizes, and treatment costs. Pre-launch estimates were obtained from several sources including medical news publications, non-profit research organizations, and news reports. Post-launch actual cost impact was measured in terms of sales revenue, using data obtained from publicly available earnings reports of the drug manufacturers. The measure of accuracy was the ratio of Predicted Cost (P) to Actual Cost (A). Predicted Cost is an accurate estimate of Actual Cost if P/A = 1; it is an overestimate if P/A > 1 and an underestimate if P/A<1. We grouped pre-launch estimates into those by individual analysts, which we termed “informal” analyses, and those that presented a summary of multiple analysts’ estimates reported by not-for-profit organizations, or were from governmental bodies, payers, or other large healthcare organizations, which we termed “formal.”

RESULTS: We found 24 pre-launch estimates for 14 drugs. The mean ratio of predicted to actual cost impact was 11.4 (SD 22.0; median 3.1; range 0.3-86.7). Of the 24 pre-launch estimates, 9 were informal analyses and 16 were formal. Stratifying predictions by these groups, the mean (median) ratio did not differ significantly: 9.4 (2.3) vs. 12.3 (3.1; P = 0.61). For pre-launch estimates that reported methods, we evaluated potential causes for the observed errors.

CONCLUSIONS: Pre-launch predictions of the budget impact of newly developed drugs are, on average, 10 times greater than actual one-year post-launch cost. At the extremes, predicted cost varied between 1/3 of actual costs and 87 times actual cost. The source of the estimate did not impact the size of overestimation. The accuracy of predictions of the cost impact of newly developed drugs should be constantly evaluated in order to improve these predictions.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals.

Use of Nationally Proposed Quality Measures to Evaluate Trends and Variations in Contraceptive Use Among Commercially Insured Women in the United States

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BACKGROUND: The contraceptive use measures recommended for national endorsement by the National Quality Forum are being implemented to measure the use of effective contraceptive methods among women enrolled in Medicaid.

OBJECTIVE: To evaluate trends and regional variations of contraceptive use based on these measures in a commercially insured population of women.

METHODS: Women 15-44 years old with continuous insurance enrollment in each year from 2005-2014 were identified from the MarketScan commercial claims database. In accordance with the proposed measures, percentages of women who (1) adopted/continued use of the most effective or moderately effective (MEME) methods of contraception and (2) adopted/continued use of a long-acting reversible contraceptive (LARC) method were calculated in 2 populations: all women at risk for unintended pregnancy (UP), and, in women who had a live birth, within 3 and 60 days of delivery.

RESULTS: During the 10-year study period, the percentages of women at risk for UP who adopted/continued use of MEME contraception methods increased among 15-20 year old girls (24.5%-35.9%) and 21-44 year old girls (26.2%-31.5%); however, the increase was greater among 15-20 year old women than 21-44 year old women. The percentages of women at risk for UP who adopted/continued use of a LARC method also increased among 15-20 year old girls (0.1%-2.4%) and 21-44 year old girls (0.8%-3.9%). Among 15-20 year old women, LARC use increased more in the North Central (0.1%-2.3%) and West (0.1%-2.3%) than in the South (0.1%-1.2%) and Northeast (0.1%-1.5%). Among 21-44 year old women, LARC use increased most in the West (1.0%-4.7%), followed by the North Central (0.6%-3.8%), South (0.7%-3.8%) and Northeast (0.9%-3.3%). Among 15-20 year old women who had a live birth, use of MEME contraception methods increased from 24.1% to 38.6% and use of a LARC method from 1.6% to 13.2% 60 days post-delivery during the study period. Among 21-44 year old women who had a live birth, use of MEME contraception methods increased from 32.5% to 37.7% and use of a LARC method from 1.7% to 6.9% 60 days post-delivery during the study period. Regional variations also existed with these measures.

CONCLUSIONS: This assessment of contraceptive use among commercially insured women in the U.S. indicates an overall trend of increasing utilization in the commercial sector, albeit with age group and regional variations. If implemented, compliance with the measures will have implications for health plan policy and education of healthcare providers and patients.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals.

Journal Editors: The Accelerator or the Brake for Real-World Evidence?

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BACKGROUND: Spurred by a proliferation of data sources, interest in comparative effectiveness research, and published guidelines supporting the conduct of rigorous real-world studies, the past decade has seen increasing submissions of real-world evidence (RWE) manuscripts to peer-reviewed journals. RWE can inform payers about treatment effectiveness in more diverse populations, among subpopulations of patients, and in real-world settings. Peer-review publication is a common pre-requisite for consideration in medical and pharmacy coverage and policy determinations. Therefore, publication can serve as a potential rate-limiting step in the translation of evidence into practice. Editors’ perceived value of RWE may influence how they review RWE manuscripts and decide if they will be rejected prior to or will be sent for peer review, and the rate of publication.

OBJECTIVE: To examine current views of journal editors regarding (1) the value of RWE studies and (2) the challenges editors face in managing, reviewing, and publishing RWE manuscripts.
METHODS: Editors’ views on the value of RWE and editorial procedures for RWE manuscripts were obtained. Journals were selected via a protocol based on journal impact score and type (general medicine (GM), specialty care (SM), health policy/services research (HSR)). Editors participated in a telephone interview, survey, and/or in-person roundtable discussion.

RESULTS: In total, 79 journals were approached, resulting in 15 telephone interviews (GM = 2; SM = 5; HSR = 8), 17 survey responses (GM = 2; SM = 6; HSR = 9) and 8 roundtable participants. Among interviewed editors, all viewed RWE favorably. Reported characteristics of high-value RWE manuscripts included: novelty/relevance of research question, rigorous methodology, data-research question alignment, and extent data-source advantages are realized (e.g., generalizability). Journals provide little RWE guidance or training to reviewers. Interviewed editors report receiving more RWE than RCT manuscript submissions, but editorial processes are reported as similar. Possible response bias is a noted limitation.

CONCLUSIONS: Journal editors are important to hastening the dissemination of research findings. This study indicates that these editors are acting as accelerators, fueling the dissemination of RWE studies, rather than as brakes slowing the speed of RWE dissemination. Editors suggest that with rigorous, transparent methodology, RWE can be a valuable source of information that complements other sources.

SPONSORSHIP: This research was sponsored by the National Pharmaceutical Council.

U11 Use of Selected Prescription “Lifestyle” Drugs Among ACA Population
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BACKGROUND: The enrollees with coverage under Affordable Care Act (ACA) have been shown to have higher rates of certain diseases and higher use of medical services and prescription drugs compared with employer-insured persons. One explanation for the higher use might be propensity for undisciplined use among those new to health coverage. Because of their discretionary nature, “lifestyle” drugs—medications taken mostly for life or function improvement rather than actual disease modification intended to reduce mortality or morbidity—present an opportunity to explore this argument.

OBJECTIVE: To compare use of selected “lifestyle” drugs in ACA population to a benchmark of other commercially insured enrollees

METHODS: This observational study used Anthem claims data from years 2014-2015 for members age ≥18 with 12 months of continuous coverage. Members were assigned to ACA cohort if they had plans with metal designation and non-ACA if they had other fully insured commercial plan, excluding Medicare and Medicaid. We descriptively analyzed the use of oral contraceptives, erectile dysfunction drugs, sedatives, nasal anti-allergy drugs, and androgens, defined as ≥1 prescription fill. Chi-squared tests were used to determine if use rates varied across groups. Linear trend tests were applied to assess the impact of generosity of benefit design (Bronze, Silver, Gold, Platinum) on use rates.

RESULTS: Compared to non-ACA enrollees (N = 1,910,201), the ACA enrollees (N = 631,052) were older (mean age 45 vs. 43, P < 0.001) and more likely to be female (52% vs. 49%, P < 0.001). The comorbidity measured by Elixhauser Comorbidity Index (ECI) was similar between two cohorts. The use of “lifestyle” drugs was lower in ACA population: oral contraceptives (Relative Risk, RR 0.87, P < 0.001), erectile dysfunction (RR 0.39, P < 0.001), sedatives (RR 0.92, P < 0.001), nasal anti-allergy (RR 0.88, P < 0.001), and androgens (RR 0.70, P < 0.001). Within ACA, enrollment in more generous metal plan was linearly and significantly associated with higher use of “lifestyle” drugs with odds ratio ranging from 1.23 for oral contraceptives (P < 0.001) to 1.97 for androgens (P < 0.001) per one level increase in plan metal designation (e.g., from Bronze to Silver plan).

CONCLUSIONS: We did not observe evidence of undisciplined use as proxied by higher use of “lifestyle” drugs among ACA members overall, compared to other fully insured benchmark population. Within ACA, greater plan generosity was associated with higher drug use. Less generous benefit design (e.g., higher cost share) could be one of the factors behind lower use for ACA.

SPONSORSHIP: This study was funded by Anthem.
U12 Innovative Methods to Expand Medication Therapy Management Services: Coupling Interprofessional Team-Delivered Services with Integration of Onsite Providers and Support Staff

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BACKGROUND: Have you considered innovative approaches to expand the reach of your medication therapy management (MTM) services? Initial MTM outreach is usually conducted during a conversation with the patient. Yet, this direct interaction is not feasible for some patients. New approaches incorporating providers or caregivers can help expand MTM services to these patients. Nurses may also constitute an untapped resource in provision of MTM services. To address the above problem, SinfoniaRx, in collaboration with the University of Arizona Medication Management Center (UAMMC), implemented two MTM programs that utilize nurses and pharmacists to facilitate completion of comprehensive medication reviews (CMRs) with patients’ providers or caregivers.

OBJECTIVE: To implement innovative, interprofessional MTM services that utilize providers and support staff.

METHODS: Two novel approaches that integrate nurse- and pharmacist-delivered MTM services were implemented: (1) Provider Outreach Program (POP) and (2) Long Term Care Outreach Program (LTCP). Both approaches involve collaboration with various medical providers to meet Centers for Medicare & Medicaid Services (CMS)-mandated CMR requirements. The POP involved onsite collaboration with primary care outpatient clinics. The program’s registered nurse partnered with relevant staff (e.g., clinic manager, medical assistants) to obtain medication records and facilitate the telephone review between the pharmacist and patients’ providers directly. The LTCP involved collaboration with facility staff (e.g., nurse case manager, nursing director) to provide MTM reviews for qualified residents. The program’s registered nurses worked with facility staff to obtain relevant information, coordinating exchange between the program’s pharmacist and the patient’s facility caregiver regarding any medication-related concerns.

RESULTS: The interprofessional programs facilitated CMR completion and expansion of MTM services to unique healthcare settings. Integrating registered nurses proved particularly valuable in establishing relationships with the primary care and LTC facilities. This also allowed the program’s nurses to convey the value of MTM and importance of collaboration to their onsite nurse colleagues.

CONCLUSIONS: Integrating registered nurses into outreach programs led to expansion of MTM services into previously untargeted clinical settings, allowing for provision of CMRs for more patients. Yet, further study is needed to determine the impact of interprofessional teams on patient outcomes and associated costs of such programs.

SPONSORSHIP: University of Arizona College of Pharmacy and SinfoniaRx.

U15 Evaluation of Patient Migration Patterns and Their Associated Costs Within a National Medicare Advantage Prescription Drug Plan Imposing an Oxycodone HCL Extended-Release Access Restriction

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BACKGROUND: Health plans use formulary restrictions (e.g., prior authorization, step edit, tier change, non-formulary [NF]) in an effort to control cost and promote quality, safety and appropriate prescription utilization. Some Medicare payers perceive inclusion of certain agents such as oxycodone HCl extended-release tablets (OER) on formulary is associated with disproportionately attracting high cost members to the plan.

OBJECTIVE: To evaluate patient migration and their subsequent healthcare costs among OER-users who remained versus those who disenrolled from a national Medicare Advantage Prescription Drug Plan (MAPD) following OER NF restriction, compared to a plan year with no restriction.

METHODS: A retrospective, longitudinal cohort study design using IMS pharmacy (LRx) and medical (Dx) claims data was used. Adult (≥18) MAPD enrollees with ≥2 OER scripts 6 months prior to the NF restriction date (1/1/2013, index date) were selected. Patients were required to have continuous activity in LRx and Dx for 6 months pre- and post-index. A comparison group (1/1/2012, index date: a non-restriction year) was selected using the same criteria. Both groups were followed 6 months post-index. Total, pharmacy and outpatient medical costs (charges) were compared between patients who remained versus those who left the plan following the index dates, using a difference in differences approach.

RESULTS: 1,001 patients were indexed to 2013 and 762 to 2012. Among the 2013 restriction cohort, 94% remained in the plan, with those leaving being slightly older (mean age 63.7 vs. 62.3; P=0.430) and with higher morbidity (mean Charlson Comorbidity Index 2.08 vs. 1.81; P=0.333). There was no significant difference in per person per month (PPPM) healthcare cost (HC) between those who stayed and those who left (PPPM total HC $2,881 vs. $2,223; P=0.180, PPPM pharmacy cost (PC) $1,259 vs. $994; P=0.114). Similar results were observed for the 2012 non-restriction cohort, where 87% remained, and there were no 6-month post-index cost differences between them and those who left the plan. Difference in difference statistics confirmed that there were no significant net cost differences between the stayed vs. left cohorts (Δ PPPM difference (2013-2012) were $646 ($P=0.249) and $280 ($P=0.210), for total HC and PC costs).

CONCLUSIONS: Imposition of an OER NF restriction does not appear to substantially affect patient migration away from a MAPD plan, and there was no important post-index cost difference observed between OER-using patients remaining in the plan compared to those that left.

SPONSORSHIP: This study was funded by Purdue Pharma.

U16 The Largest Private Health Care Payers Cover Rheumatoid Arthritis Drugs Inconsistently and Report Reviewing a Different Evidence Base in Their Coverage Policies

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BACKGROUND: Because health care payers conduct their own assessments how they cover drugs can vary, which in turn can affect patients’ access to care.

OBJECTIVE: To examine how the largest private health care payers cover rheumatoid arthritis drugs and to determine what evidence they report reviewing in their coverage policies.

METHODS: First, we identified coverage policies for rheumatoid arthritis drugs from the largest private payers’ (in terms of covered lives) websites. Included coverage policies were current as of April 1, 2015. Second, for each drug, we compared the coverage policies with the corresponding FDA-labeled indications and categorized them as equivalent to the labeled indication, more restrictive than the labeled indication, less restrictive than the labeled indication, or mixed (that is, more restrictive than the labeled indication in one way, but less
restrictive in another). Third, we compared each coverage policy with the American College of Rheumatology’s (ACR) 2012 treatment recommendations and categorized the policy using the same relative restrictiveness criteria. Fourth, we reviewed each policy and identified the evidence that the payers’ reported reviewing. We categorized the evidence into six categories: randomized controlled trials (RCTs); other clinical studies (e.g., non-RCTs or observational studies); health technology assessments; clinical reviews (including systematic reviews and meta-analyses); cost-effectiveness analyses; or clinical guidelines.

RESULTS: We found 94 coverage policies for 10 drugs across the 10 payers. Sixty-nine percent of coverage policies were more restrictive than the corresponding label. 15% were consistent, 3% were less restrictive, and 13% were mixed. Thirty-four percent of coverage policies were consistent with the ACR’s recommendations, 33% were more restrictive, 17% were less restrictive, and 17% were mixed. Payers most frequently reported reviewing RCTs in their coverage policies (an average of 2.3 per policy). The payers reported reviewing an average of 0.8 ‘other clinical studies’, 0.5 technology assessments, 1.1 clinical reviews, and 1.4 clinical guidelines per policy. Only one payer reported reviewing cost-effectiveness studies. The evidence base that the payers reported reviewing varied in terms of composition and volume.

CONCLUSIONS: The included payers most often covered rheumatoid arthritis drugs more restrictively than the corresponding FDA labeled indication and the ACR’s treatment recommendations and reported reviewing a different evidence base in their coverage policies.

SPONSORSHIP: This study was funded by Genentech.

Impact of Medication Adherence on Healthcare Costs and Utilization in Medicare Beneficiaries with Chronic Conditions

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BACKGROUND: Consistent adherence to chronic disease medications improves health outcomes and reduces healthcare costs. Unfortunately, adherence rates in the United States are suboptimal, creating potentially avoidable costs. Prior attempts to determine the actual value of adherence may not adequately address potential biases within the study population.

OBJECTIVE: To improve on prior attempts at measuring the effect of medication adherence on overall healthcare cost in three major chronic conditions: diabetes, hypertension, and hyperlipidemia.

METHODS: Pharmacy and medical administrative claims data was extracted for a 24-month study period from a national Medicare Advantage Prescription Drug plan to measure healthcare costs and adherence. To be eligible for analyses, patients had to be continuously enrolled during the measurement period and not be considered a cost outlier. For each therapy area, two cohorts were constructed: adherent and non-adherent, where adherence was defined using proportion of days covered greater than or equal to 80%. From there, one year of total healthcare costs were compared between adherent and non-adherent patients. To address the expected confounding, a modern epidemiologic method based on standardized mortality ratio (SMR) propensity score weighting was employed, an approach that has not been used in previous research on the topic.

RESULTS: Medication adherence has the potential to significantly reduce average annual healthcare spending by $2,507 (diabetes), $3,472 (hypertension) and $4,162 (hyperlipidemia) after adjusting for increased pharmacy utilization and baseline confounding. Reduction in emergency room visits (150 per 1,000) and inpatient stays (190 per 1,000) was most significant in adherent hypertensive patients.

CONCLUSIONS: Findings suggest proper adherence to medication regimes reduces healthcare costs and associated medical utilization. Significant cost offset findings provide support for continuing incentivized quality improvement programs. The pressure faced by payers to continue to reduce healthcare costs while simultaneously improving quality of care for their members is ever increasing. Investing in programs and analytics to properly target and improve medication adherence are proving beneficial.

SPONSORSHIP: None.
Payers’ Use of ICER Reports in Decision Making

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BACKGROUND: The public availability of value assessments to assist with reimbursement decision making is not new. For over 10 years, organizations in other countries, such as NICE (United Kingdom), CADTH (Canada) and PBAC (Australia) have released reports documenting reimbursement recommendations. But often these reviews are completed well after formulary decisions are made in the U.S. and in any case may not be relevant to U.S. payers. Publication of the Institute for Clinical and Economic Review (ICER) reports creates a shift in the widespread availability of independent economic evidence shortly after FDA product approval. What remains unknown is how these reports will impact reimbursement and value assessment trends in the U.S.

OBJECTIVE: To investigate how U.S. payers are utilizing the ICER reports and whether these new resources are impacting the formulary decision-making process.

METHODS: In May 2016 users of the AMCP eDossier System, a web-based platform to support P&T recommendations and formulary decision-making, were invited to participate in an online survey detailing their use of the ICER reports.

RESULTS: Of the 99 respondents, 59% had experience reviewing the reports or were aware that their organizations utilized them. The respondents represented those familiar with all facets of the formulary decision-making process. The majority of use for the ICER reports occurred during the drug research process (64%), during the P&T review phase (56%) and during coverage policy development (33%). The most often cited use of the assessments was as an evidence source (35%), followed by use to inform or validate analyses. Secondarily the ICER reports were used in determining product affordability and developing prior authorization criteria.

CONCLUSIONS: Overall, health care decision makers found the ICER reports to be a useful evidence source in preparing P&T recommendations and to inform or validate analyses. Secondarily the ICER reports were used in determining product affordability and developing prior authorization criteria.

SPONSORSHIP: None.

Branded Extended-Release Opioid Use in a National Health Plan: Adverse Selection or Adverse Retention?

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BACKGROUND: For Medicare payers with Part D programs (i.e., Medicare Advantage with Prescription Drug [MAPD] and stand-alone Medicare Prescription Drug plans), adverse selection posits that formulary inclusions of certain drugs may overly attract high healthcare utilizers. This may lead to formulary exclusions of brand drugs to control plan costs.

OBJECTIVE: To assess the association of formulary exclusion of branded oxycodone hydrochloride extended-release (OER) on the rate and cost of members utilizing OER over time in a national health plan.

METHODS: Medicare claims data were used from 2008 to 2015 from a national health plan that excluded OER from Part D formularies as of January 1, 2010. Total cost of care was measured as the sum of medical and pharmacy claims allowed amount among OER users by year. We present findings for MAPD members by dual-eligible Medicaid status (non-duals—age 65+; duals—age 19+).

RESULTS: For MAPD members, there was a decrease in OER use from 2008 to 2012 and a rebounding in use from 2013 to 2015; this trend was coupled with an increase in user cost of care. For non-duals, the rate of OER use in 2008 was 359.8 members per 100,000 filling ≥ 1 OER Rx. Rates decreased in 2009 (199.5), 2010 (133.5) and were lowest in 2011 (99.6) and 2012 (80.5) per 100,000. Rates rose in 2013 (116.7), 2014 (144.6) and 2015 (130.8) per 100,000. Duals exhibited a similar pattern of OER use. After 2010, non-dual OER users presented year over year increases in per user per month (PUM) total cost of care (2010 (+$274.22), 2011 (+$219.47) and 2012 (+$116.23). Costs declined in 2013 ($339.60) and 2014 ($286.24) due to declines in PUM medical costs but upturned in 2015 ($688.55) due to an increase of $108.44 PUM pharmacy costs. Duals presented steady year over year increases in PUM total costs (2010 (+$781.14), 2011 ($360.34), 2012 ($353.72), 2013 ($55.10), 2014 ($178.63), 2015 ($918.85) fueled by increasing medical costs from 2010 to 2013 then increasing pharmacy costs in 2014 and 2015.

CONCLUSIONS: The findings indicate excluding OER from Medicare formularies in 2010 may have sped an already downward trend in OER use. After initial declines, usage began to rebound in subsequent years. An increase in total cost of care among MAPD OER users after formulary exclusion suggests these plans may have retained OER users with high healthcare utilization. Of note, August 2010 also marked the launch of a reformulated abuse-deterrent form of OER.

SPONSORSHIP: This study was funded by Purdue Pharma.

Payer Utilization of Economic Models in the AMCP Format for Formulary Submissions: A Web-Based Survey

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BACKGROUND: The AMCP Format for Formulary Submissions is intended to provide health care decision makers with information about the safety, efficacy, and value of new health technologies in a prespecified format that includes an electronic economic model.

OBJECTIVE: To determine managed care decision makers’ utilization of and perspectives on economic models provided within the AMCP Format.

METHODS: A web-based survey was conducted in June 2016 with members of Xcenda’s Managed Care Network, a standing market research panel comprised of healthcare executives, medical and pharmacy directors, and other managed care experts. All responses were blinded. Survey items included multiple choice options and Likert scales. Descriptive analyses were conducted.

RESULTS: A total of 47 managed care decision makers participated in the survey representing 41 unique health plans. Of the respondents, 55% were pharmacy directors and 34% were medical directors, representing a total of 173 million covered lives. Payers are more likely to use internally developed models for formulary decision making than models provided by manufacturers. Among healthcare payers, 40% and 51%, respectively, find budget impact and cost-effectiveness models valuable in the formulary review process. However, less than half of dossiers contain model reports (41%), static model/screenshots (36%), interactive models (29%), or are accompanied by a live model demonstration (29%). For model reports in dossiers, payers find the
results (82%) and limitations (75%) sections to be the most valuable sections. Payers are most likely to use models for high cost diseases (55%), high cost products (53%), and specialty products (47%). Among decision makers, the biggest perceived limitations with manufacturer provided economic models were: use of unreasonable assumptions (64%), lack of transparency (57%), and lack of appropriate comparators (51%).

CONCLUSIONS: The AMCP Format recommends the inclusion of an interactive model and report within the dossier. However, in actuality, few dossiers meet these criteria and as a result, payer use of economic models may be limited by the extent to which they are provided. Addressing key perceived payer limitations of models may also help to enhance their use.

SPONSORSHIP: Xcenda.

U23 Does Florida Medicaid’s State-Mandated Formulary Provision Influence Prescription Drug Utilization and Costs?
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BACKGROUND: Medicaid managed care plans participating in Florida’s Statewide Medicaid Managed Care program were required to use a state-mandated preferred drug list (PDL) instead of their own drug formularies starting July 2014.

OBJECTIVE: To examine health plan drug utilization and plan costs for members in a Florida Medicaid managed care health plan after implementation of the state-mandated PDL policy and compare the changes to those among Medicaid members in a comparable Medicaid managed care health plan from a state where no such policy was implemented.

METHODS: A retrospective cohort study with a pre-post design was conducted using de-identified administrative claims data from a large pharmacy benefit manager. Pre-policy evaluation period was January 1 to June 30, 2014 while post-policy period was January 1 to June 30, 2015. Continuously enrolled Florida Medicaid plan members were matched on sociodemographic and health characteristics to their counterparts enrolled in a Michigan Medicaid plan. Outcome measures were number of 30-day adjusted traditional drug prescriptions per member per period and total drug plan costs per member per period for all drugs, and separately for generics, formulary brand and non-formulary brand drugs. Bivariate comparisons were conducted using t-test. Multivariable negative binomial regression and multivariable regression with generalized estimating equations were used to analyze pre-post changes in utilization and plan costs, respectively.

RESULTS: A higher proportion of brand drugs switched their status from non-formulary in the pre-period to formulary in the post-period in the Florida plan (79%) compared to the Michigan plan (1%). The final sample consisted of 9,182 members in each plan for a total of 18,364. Findings from the multivariable regression analyses validated the bivariate findings of changes in post-period utilization and plan costs. Overall drug, generic and non-formulary brand drug utilization declined by 9%, 13% and 97%, respectively, while formulary brand drug utilization increased by 50% among Florida Medicaid members in the post-policy period (P < 0.001). Overall, and formulary brand drug plan costs increased by 4% and 49%, respectively, while generic plan cost declined by 13% (P < 0.001). None of the utilization and plan cost changes among the Michigan Medicaid members over the same time period were statistically significant (P > 0.05).

CONCLUSIONS: Our findings highlight the unintended consequences of decreased drug utilization and increased plan costs that may result from state-mandated PDLs. Partnership between State Medicaid agencies and health plans are essential for ensuring access to appropriate medications while cost-effectively managing access to these medications.

SPONSORSHIP: Express Scripts.

U24 Reasons for Primary Medication Nonadherence in Specialty Pharmacy
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BACKGROUND: Primary medication non-adherence (PMN) has been recognized by Pharmacy Quality Alliance (PQA) as a high-priority measure for medication adherence. They define PMN as newly initiated medications not picked up from the pharmacy within 30 days of receipt of the prescription by the pharmacy. Rates of PMN reported in the literature vary widely from 1.94-75%; however, the definition used to assess PMN differed amongst these studies. Additionally, most studies were not designed to identify underlying reasons for PMN and very few evaluated PMN in specialty pharmacy. It’s theorized that because of the challenges unique to specialty medications including high cost, strict insurance requirements and specialized training needs, reasons for and rates of PMN may differ than those for non-specialty medications.

OBJECTIVE: To establish a quality management program with the purpose of identifying the frequency of and reasons for PMN in specialty pharmacy.

METHODS: A retrospective electronic health record review was performed from April 1, 2015 to March 31, 2016 to determine the rates and associated reasons for PMN with specialty medications managed by the University of Illinois Hospital and Health Sciences System Specialty Pharmacy Service (UI-SPS). The reasons for PMN were then further grouped into one of five categories: insurance- (e.g., denied claims); cost- (e.g. high out of pocket costs); clinical- (e.g., missing labs); patient- (e.g. patient refused to start); and coordination- (e.g. scheduling injection training) related factors.

RESULTS: The overall rate of PMN for all therapies was determined to be 18.6% using the PQA definition. A total of 87 records met the PQA criteria for PMN. The causes of PMN identified in the chart review in order of highest to lowest frequency included insurance- (33%), coordination- (32%), patient- (21%), clinical- (9%), and cost- (5%) related factors.

CONCLUSIONS: UI-SPS implemented a quality management program to identify the rates and reasons for PMN in specialty pharmacy. Specialty medications are often associated with high drug costs, complex administration, complicated diseases and stringent insurance criteria which may contribute to PMN. Because of this, it’s essential to identify the underlying reasons for PMN in order to address the issues and improve timely delivery of the life-changing therapeutic interventions.

SPONSORSHIP: None.

U25 Development of a Health System-Based Specialty Pharmacy Service for Uninsured and Underinsured Patients in a Women’s Health Fertility Clinic
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BACKGROUND: The University of Illinois Hospital and Health Sciences System (UIH) is a disproportionate share hospital serving patients who are underinsured or uninsured. UIH established a URAC accredited specialty pharmacy (SP) at the Wood Street Pharmacy that provides
comprehensive medication services for patients with hepatitis C, immunologic disorders, sickle cell disease, and multiple sclerosis. The UIH Reproductive Endocrinology & Infertility Clinic serves patients who need assisted reproductive technology (ART), many of whom lack insurance coverage for their medications. Infertility is a disease with significant psychological and financial burden, and ART drug regimens are complex, expensive and require education highlighting drug administration, storage and precise timing of medication administration. A needs analysis revealed that 20% of infertility patients seen at UIH are either uninsured or underinsured and must pay cash for some or all of their prescriptions. Based on need, a specialized pharmacy service would benefit these underserved patients and provide medications at a reasonable price.

**OBJECTIVE:** To build a health system-based pharmacy service for uninsured or underinsured fertility patients that offers reasonable prices and other forms of medication assistance for ART medication regimens while providing pharmacy based medication education, high-touch patient care, timely medication access, and copay assistance.

**METHODS:** UIH SP worked with the Reproductive Endocrinology & Infertility Clinic to establish a pharmacy service for fertility patients at Wood Street Pharmacy. Elements of the program included online and in-person training of pharmacists and technicians, drug reference cards for fertility medications; establishment of a referral pool for prescriptions; ordering of medications, samples, and supplies; workflow modifications in the Wood Street Pharmacy; patient education counseling sessions and program enrollment; medication pickup or courier, 24/7 on-call pharmacist access; and patient follow-up.

**RESULTS:** In the first two months, fifteen uninsured or underinsured patients filled 40 ART prescriptions at UIH SP resulting in total revenue of $40,000. The average number of prescriptions per patient was 2, ranging from 1 to 9. Providers and patients were satisfied with the convenience of the service and prices offered to patients.

**CONCLUSIONS:** UIH is working with payers to be included in the contracted network for insured patients. Patient outcomes and satisfaction will be assessed and reported. Elements of this program could be adopted by health plans and PBMs across the country.

**SPONSORSHIP:** None.

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**U28 Cost Savings Analysis from a Fully Implemented Site of Service Management Program**

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**BACKGROUND:** Physician-administered medications have gained an increasing role in the management of many chronic diseases. These products are typically infused by a nurse and can be administered in several different sites including hospital outpatient facilities, physician offices, ambulatory infusion suites, and the patient’s own home. While most office-based practices and home infusion providers are subject to a standard fee schedule for reimbursement, hospital outpatient facilities are usually reimbursed based on the larger national average cost, which may result in more than 100% increase in cost. Shifting utilization to more cost-effective sites can result in significant savings to health plans without compromising quality of care. In response, a Site of Service (SOS) Management Program was developed to address this need.

**OBJECTIVE:** To assess the impact of a SOS program for a health plan after 12 months.

**METHODS:** The SOS program was implemented on July 1, 2015 and included infliximab and all intravenous immunoglobulin products. When a prior authorization (PA) request is approved for an eligible product, a SOS case is automatically generated. Once the patient’s insurance benefits are confirmed, a nurse case manager will conduct member and provider outreaches to provide information related to different sites of care and help coordinate care to the new SOS. Data from July 1, 2015 to June 30, 2016 was analyzed. Cost is calculated by multiplying the number of approved units (based on PA) by the ASP for the drug and the ASP index for the site based on historical claims data. The ASP index represents the cost per unit at a given site compared to the ASP. Savings is estimated using the difference between the cost at the original SOS compared to the new SOS.

**RESULTS:** Data for a regional health plan with approximately 2.5 million covered lives was represented in this analysis. Over a course of 12 months, 480 eligible cases were received and 60 cases were successfully shifted. Estimated annual savings is $2,182,500 with an average savings of $36,375 per shift.

**CONCLUSIONS:** This SOS program offers unique potential to produce significant cost savings to the health plan without compromising the quality of care. The process of this program is designed to minimize patient and network disruptions. Within the current scope of the program, an annualized savings opportunity of $0.07 per member per month (PMPM) was realized. Expanding the program to include additional insufiable drugs will allow for an opportunity to further increase the savings potential of this program.

**SPONSORSHIP:** Magellan Rx Management.

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**U26 Insights from Analysis of Formulary Coverage Trends for Generics with High Price Increases**

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**BACKGROUND:** Generic drugs provide valuable and affordable treatment option for many patients. Traditionally, generic drugs were covered at Tier 1 with low copay of $5-$10. However, recent triple digit price increases have led to change in access for generic drugs.

**OBJECTIVE:** To review and analyze the access trends for generic drugs in U.S. health plans.

**METHODS:** Systematic review of the literature was conducted to identify generic drugs with significant price increases. The coverage trends for the selected drugs for all health plans were obtained from CMS. For each plan the data was obtained for the drug name, tier status, deductible, and type of restrictions. The coverage trends were analyzed by drug name, state level and at a national level.

**RESULTS:** We identified five generic drugs whose price was increased by 500-5,000% during the last 24 months. We identified 829 coverage policies for the five generic drugs (doxycycline glycopyrrolate, pravastatin, lisinopril, pyrimethamine). Among these plans, only 30% covered these generic drugs at Tier 1. The other 24%, 19% and 23% of the plans covered the selected generic drugs at Tier 2, 3 and 4, respectively. Only 24% of the plans covered these drugs as a generic, others covered them as non-preferred brand (24%), preferred brand (18%) and preferred generic (28%). The patient copay and coinsurance vary significantly across plans and type of formulation. For example, for doxycycline oral, few plans (13%) still have low copay of $5-$10, while majority have coinsurance ranging from 25-47%. Similarly, injectable formulation of Glycopyrrolate has coinsurance of 33-47% (which can lead to a high patient cost share of $1,400 per month).

**CONCLUSIONS:** This is a first in-depth analysis of access trends for generics with high price increases. This study shows that patient access for some generic drugs has been restricted significantly.

**SPONSORSHIP:** None.
U31
Emerging Costs and Utilization Patterns by Metal Levels of Health Exchange Beneficiaries
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BACKGROUND: Examining prescription medication utilization and cost patterns are crucial to understanding the health status of exchange members.
OBJECTIVE: To examine the emerging patterns of costs and utilization of prescription medications among Health Exchange beneficiaries selecting various metal levels.
METHODS: A retrospective pooled cross-section analysis of prescription medications utilized by Health Exchange beneficiaries enrolled in plans whose benefits were covered by a large pharmacy benefit manager between January 1, 2014 and December 31, 2015. Members who remained in the same metal level (indicating the benefit plan selections by the beneficiaries, platinum being the highest followed by gold, silver and bronze) within a calendar year were included. Utilization was examined using 30-day adjusted prescriptions per-member-per-year (PMPY) and costs were computed using PMPY billed plan costs of the dispensed medications. PMPY was computed by dividing the measure by the sum of the total number of months the metal level members were eligible for benefits in a given year. Year-over-year trend was calculated by dividing the difference between the two years by the value in 2014.
RESULTS: The sample consisted of 3,956,058 and 6,003,926 total member months for all four metal levels in 2014 and 2015, respectively. Silver plans had the highest number of member months and platinum plans had the least in both years. The PMPY cost in 2015 was the highest for platinum ($2,191.16), then gold ($1,543.80), silver ($1,086.08) and bronze ($208.09) and similar to the pattern in 2014; the cost trend from 2014 to 2015 was highest for silver (20.5%), followed by gold (6.0%), bronze (4.5%) and platinum (4.4%). PMPY utilization in 2015 was highest for platinum (2.32), followed by gold (19.6), silver (18.0) and bronze (7.7), respectively. Utilization trend increased for silver (12.0%) and bronze (10.2%) plan members and decreased for gold (-3.4%) and platinum (-0.1%) plan members.
CONCLUSIONS: Increased cost and utilization of prescription medications at metal plan members poses a management challenge for plan sponsors. Given today's rapidly changing healthcare landscape with the implementation of Accountable Care Act, growing exchange population and healthcare cost burden, these early insights can help plan sponsors explore opportunities for utilization management and cost containment strategies in collaboration with pharmacy benefit managers.
SPONSORSHIP: Express Scripts.

U45
Dispensing Channel and Adherence to Specialty Drugs Among Medicare Part D Beneficiaries
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BACKGROUND: Adherence to specialty drugs is critical for treatment success. Studies on commercial health plans have found higher adherence among patients using the specialty drug channel. However, the effect of dispensing channel on adherence to specialty drugs is not well understood among Medicare beneficiaries.
OBJECTIVE: To assess the effect of dispensing channel on adherence to oral or self-administered cancer (CA), multiple sclerosis (MS) and rheumatoid arthritis (RA) specialty drugs among Medicare Part D beneficiaries.
METHODS: We analyzed 2010 Medicare Part D data. Specialty drugs were defined as drugs with a mean cost ≥ $600 per month. We identified the 13 top selling specialty drugs (by cost) for CA, MS and RA. Dispensing channels included retail (RT), specialty (SP), mail order (MO), long term care (LTC) and others (OT). Patients who were continuously enrolled in Part D for 2010 and had their first prescription before the end of June were included, and followed until the end of December. Adherence was measured by proportion of days covered (PDC). Patients with PDC ≥ 80% were considered adherent. Adherence rates were calculated after weighting for drug mix. Logistic regression (LR) analysis examined the effect of dispensing channel on adherence controlling for demographics, low income subsidy, disease burden, days' supply (DS) per claim and out of pocket cost per 30 DS.
RESULTS: Of 5,433 patients, 1,249 used specialty drugs for CA, 1,724 for MS and 2,460 for RA. Weighted adherence rates were 57.2% for SP, 63.5% for MO, 50.9% for RT, 47.6% for LTC and 48.3% for OT. Among CA patients, SP (49.0%) and MO (53.8%) had higher adherence rates than RT (44.1%). Similar findings were seen for RA patients (56.1% for SP, 59.1% for MO and 46.2% for RT). For MS patients, adherence was comparable between RT (62.6%) and SP (64.8%) but was higher for MO. Multivariable LR analysis indicated that among RA patients, SP users were more likely to be adherent than RT users (OR = 1.46, P = 0.0079). However, there was no significant association between dispensing channel and adherence among CA or MS patients (P = 0.8398).
CONCLUSIONS: Effect of dispensing channel on adherence varied by therapeutic class. Specialty pharmacy was associated with higher adherence to RA drugs but not for CA and MS drugs.
SPONSORSHIP: None.

V01-Y98
External Causes of Morbidity and Mortality (e.g., Accidents, Intentional Self-Harm, Surgical Care Complications)
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BACKGROUND: Accidental falls are the leading cause of fatal and non-fatal injuries among older adults, costing the U.S. health system $34 billion annually. A common risk factor for falls is fear of falling due to physical deconditioning as people limit daily activities due to the fear.
OBJECTIVE: To quantify the association between sleep medication use, fall-related worries, and daily activity limitations due to those worries.
METHODS: A case-control study was performed using the 2011 nationally representative National Health and Aging Trends Study (NHATS) study. Respondents were asked “In the last month, how often did you take medication to help you sleep?” They were classified into 5 groups based on their answer: never, rarely (once a week or less), some nights (2-4 nights/week), most nights (5-6 nights/week), and every night. Survey weighted multiple logistic regression was applied to quantify the association of sleep medication use with the outcomes of falls-related worries and limitations of daily life due to worries. Confounders were adjusted for based on a causal model. Analyses were conducted using Stata 14 with alpha = 0.05.
RESULTS: Fall worries were reported by 27.4% of the participants and were more prevalent in older age groups, female, Hispanics, divorced/widowed/single, and those with lower education levels (P < 0.01). Amongst individuals who reported fall worries, 42.2% said that the worries limited daily activities Compared to those who did not use any sleep medication, those with every night use and most night use had increased odds of fall worries [OR: 1.45, (95% CI: 1.20-1.74) and OR: 1.70, (95% CI: 1.21-2.39), respectively]. Those with rare and some nights use of sleep medications were at elevated odds of fall worries, however the ORs were non-significant [OR: 1.20, (95% CI: 0.95-1.53) and OR: 1.07, (95% CI: 0.83-1.30), respectively]. Every night sleep medication users were more likely to be limited by their fear of falls compared to non-users with an OR: 1.34 (95% CI: 1.01-1.77).

CONCLUSIONS: Use of sleep medications was associated with increased fall worries and daily limitations due to worries. With increasing societal sleep medication use, patient-specific pharmacist recommendations in interdisciplinary fall risk reviews are necessary. Future studies include evaluation of clinic-based, pharmacists-led fall reduction programs.

SPONSORSHIP: This study was supported by an MSTAR Grant under award number T32MH019934.
Survey of Patient Knowledge and Satisfaction with Pharmacists Providing Telephonic Care Management of Anticoagulation Therapy as Part of a Risk-Sharing Accountable Care Organization

BACKGROUND: Pharmacists have demonstrated significant impact in patients’ understanding and acceptance of long term oral anticoagulation (OAC) therapy, which is critical for effective management. Montefiore Care Management (CMO) is part of an integrated health-care delivery system and one of the country’s most successful Pioneer Accountable Care Organizations. Over its 20-year history, pharmacists have been embedded in integrated care management teams that coordinate care for high risk populations. Since 2013, clinical care management pharmacists have been collaborating with the Montefiore Medical House Call (MHC) program to telephonically manage warfarin in a unique population of homebound patients in the Bronx, NY.

OBJECTIVE: To evaluate patient knowledge and satisfaction with telephonic OAC management services provided by CMO clinical pharmacists to a vulnerable population of older, lower-socio-economic, homebound patients taking warfarin.

METHODS: A cross-sectional observational design was used. A pharmacy resident independent of the MHC program telephonically interviewed patients using a survey that evaluated their understanding of their therapies as well as recall and satisfaction with pharmacists’ OAC management and in-home phlebotomy services.

RESULTS: 41 out of 78 patients completed surveys. The average age was 79.0 ± 9.5 years (61% > 80 years old); 24.4% were male. 78% correctly recalled the OAC pharmacist’s name. 50% recognized that these professionals were pharmacists (other responses: 20% RN, 22% don’t know; 5% admin; 2% PA). 78% of patients had INR at goal, and of these, 97% knew they were at goal. All patients who were not at goal correctly identified that their INRs were low (17.1%) or high (4.9%). Results showed that 88% were “very” to “extremely satisfied” with in-home phlebotomy services. Interestingly, while only 97% were either “satisfied” or “very satisfied” with quality of information provided, 100% were “very” or “extremely satisfied” with pharmacist-managed services.

CONCLUSIONS: The surveyed patients in the Montefiore MHC program demonstrated high levels of OAC knowledge and satisfaction with pharmacists’ services. This survey acknowledges the value of telephonic OAC management provided by CMO’s integrated care management pharmacists to a vulnerable, homebound population. The majority were able to correctly identify the names of CMO clinical pharmacists, and half accurately recognized that their clinicians were pharmacists, which is a notable distinction and a positive testament to their interpersonal relationship.

Sponsorship: Sponsored by Montefiore Care Management and Pfizer, Medical Affairs.

Increasing Medication Adherence and Receipt for Commercially Delivered Packages

BACKGROUND: Chronic diseases and pain management require adherence to prescribed medications to decrease disease progression, prevent relapse, maintain or improve quality of life and decrease utilization of health care resources. Two identified factors that contribute to a better medication possession ratio (MPR) are using commercial delivery and 90-day fills. Commercial delivery directly to a recipient’s home assists those working, living in rural areas, dealing with mobility or transportation issues. Fills for 90 days provides convenience and a longer MPR. Limited information is available to evaluate the volume of nondelivered packages and using e-mail notification to increase awareness of a potential delivery.

METHODS: A retrospective cohort design was utilized using the population of warfarin patients managed by CMO clinical pharmacists as part of the MHC program. The time frame for TTR evaluation was from August 15, 2015 through January 15, 2016. Epic’s TTR reports were generated for this time frame for both individual patients and for the overall population. For the same time frame, pharmacists manually calculated TTRs for both individual patients and for the overall population. Both Epic and manual TTR calculations utilized the Rosendaal method.

RESULTS: N = 78, 99% > 80 years. Average TTR for overall population was 61% (Epic) and 71% (manual); P = 0.017, chi-square. Percent population with TTR above 60 was 53% (Epic) and 71% (manual); P = 0.006, 2 sample t-test. Percent population with TTR above 70 was 38% (Epic) and 60% (manual); P = 0.008, chi-square.

CONCLUSIONS: There were significant differences between the TTR report generated by Epic versus manual calculation for the same patients, time frame and TTR calculation methodology. The discrepancy could have significant impact on administrative and clinical decision making. If relying on the Epic TTR report, the clinic services could be considered to be substandard and more patients could be considered to be unstable on warfarin therapy. One needs to exercise caution when examining Epic’s TTR report for decision making.

Sponsorship: Sponsored by Montefiore Care Management and Pfizer, Medical Affairs.
OBJECTIVE: To measure the number of commercially delivered packages that do not reach the recipient and identify ways to increase the recipient awareness of a package status.

METHODS: Eleven medical centers (MCs) in Veterans Integrated Service Network (VISN) 10 kept weekly logs of packages that were not received by the recipient. This included packages sent by commercial delivery and then returned ripped with or without usable medication due to mechanical processing, undeliverable due to a bad address, or lack of a delivery receipt signature. Additional data was collected on calls from the intended recipient, who had not received an expected package in the specified time frame. Third the number of patient e-mail addresses for those receiving a medication package.

RESULTS: MCs used commercial delivery for approximately 2,466,000 packages (6 months). Packages returned without delivery or incomplete tracking were 8,359 (0.17%). On average 3 medications were in each package (range 1-14). This suggests 25,077 medications were not received by the recipient. Phone call reports for nonreceipt of an expected package were 289 (3.6%). Patients with an available e-mail remained at 86,950 (23%).

CONCLUSIONS: Recipients did not always report when a package was not delivered. Without promoting the benefits of receiving an e-mail notification for a package being sent, the count of e-mail addresses did not increase. The next steps will be to increase e-mail address capture and notification on sent packages, develop a handout explaining how to track a package, and what to do if a package is not delivered.

SPONSORSHIP: None.

Z08 Development and Validation of a Discrete Event Simulation Model to Evaluate the Long-Term Use of Electronic Cigarettes on the U.S. Population

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BACKGROUND: Cigarette smoking is associated with lung cancer, cardiovascular disease, and chronic respiratory conditions. Quitting smoking is difficult and is often accompanied by variety of withdrawal symptoms, and eventual relapse. As a novel combustion-less nicotine delivery system, electronic cigarette (e-cig) is rapidly gaining popularity as a tool to help in smoking cessation and abstinence. Centers for Disease Control and Prevention (CDC) recently reported that around 4 million Americans are e-cig users, and around 1.8 million are middle and high school students. The increasing use of e-cig among minors and young adults is concerning because it may serve as a gateway to use of conventional tobacco products for non-smokers and past smokers.

OBJECTIVE: To construct and validate a Discrete Event Simulation population model to simulate e-cig use behavior, and to estimate the long term e-cig use prevalence in different groups of the U.S. population over the period of 15 years.

METHODS: The model population was generated from the National Health Interview Survey data and categorized into current cigarette smokers, recent former, late former, and never smokers. The e-cig use probabilities associated with different smoking demographics were derived from a national e-cig use survey data, while the probabilities associated with different events in the model were used from a comprehensive literature review of e-cig studies done on the U.S. population. Model structure was built using published information on e-cig use behavior, and by seeking expert opinion. The prevalence over time period of 15 years was estimated for overall and sub groups of model population. Sensitivity analyses were performed to test the effects of various scenarios.

RESULTS: At the end of 15 years, projected e-cig use was found to increase from about 3% to 19%, however the conventional cigarette use was found to reduce from 40% to 25%. Demographically, highest prevalence was found in people of age groups of < 21 years (6.5%), females (9.7%), whites (9%) and with less than high school level education (7.5%). Prevalence of e-cig use was found to be most sensitive to change in e-cig related policies (such as tax increase, prohibition of under age e-cig use), and the timing of implementation of the policies.

CONCLUSIONS: Our research provides empirical evidence that may be used by relevant organizations to regulate marketing and sales of e-cigs in various sections of the population, and may guide policy makers to introduce relevant policies at specific time points.

SPONSORSHIP: Funding provided by Regulatory Health Science Fellowship, Virginia Commonwealth University.
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