Meeting Abstracts

Academy of Managed Care Pharmacy
Nexus 2015

Orlando, Florida
October 26-29, 2015
Abstract Submission Process

The 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). Of the abstracts accepted for publication, most are presented as posters, so interested AMCP meeting attendees can review findings and query authors. The main poster presentation is Tuesday, October 27, 2015; posters are also displayed on Wednesday, October 28, 2015.

The AMCP Nexus 2015 in Orlando, Florida, is expected to attract more than 3,500 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:** describe models that predict the effect of various benefit design or clinical decisions on a population. For example, an economic model could be used to predict the budget impact of a new pharmaceutical product on a health care system.

**Solving Problems in Managed Care:** describe the specific steps taken to 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. These abstracts describe a course of events; they do not test a hypothesis, but they may include data.

The content of poster abstracts submitted for consideration should not have been published previously as an abstract or article or presented in another forum.

**Abstract Submissions Timeline:** This table gives an approximate timeline for abstract submission.

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**Abstract Authorship:** Abstracts are classified by the status of the first author.

**Student/Resident/Fellow:** Abstracts may be submitted by students enrolled in a Doctor of Pharmacy degree program or a pharmacy-related graduate program (MS or PhD), pharmacy residents, and pharmacists completing postdoctoral fellowships. Students, residents, and fellows who have results and conclusions are strongly encouraged to submit their abstracts for review and publication.

**Professional Abstracts:** These abstracts are submitted by nonstudents.

**Nonreviewed Student Abstracts:** Students, residents, and fellows are eligible to submit “work in progress” poster abstracts that do not undergo peer review. Results and conclusions are not required. These abstracts are not published in JMCP, and they are not indexed in PubMed.

At least 1 author of each accepted poster (preferably the primary author) must register for and attend the meeting to present the poster during the time designated for poster presentations.

**Abstract Review Process**

Fourteen reviewers and 6 JMCP editorial reviewers were involved in the review process for the 2015 Orlando 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
- Bias
- Originality
- Quality
- 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.

The reviewers and JMCP editorial reviewers of the abstracts for the 2015 Orlando meeting were as follows:

**Reviewers**

- Christopher Bell, MS, GlaxoSmithKline
- Jongwa Chang, PhD, Samford University
- Abimbola Farinde, PharmD, BCPS, Texas Southern University, Department of Pharmacy
- Donald Klepser, PhD, MBA, University of Nebraska Medical Center College of Pharmacy
- Shellie Keast, PharmD, PhD, University of Oklahoma College of Pharmacy
- Alexandra Lin, PharmD, Brown University College of Pharmacy
- Gregory Slow, PharmD, PhD, Massachusetts General Hospital
- Uche Anadu Ndelo, PharmD, BCPS, Texas Southern University, Department of Pharmacy Practice
- Terry Richardson, PharmD, BCACP, Express-Scripts
- Cynthia Sanoski, PharmD, Jefferson School of Pharmacy
- Andy Szczotka, PharmD, Emdeon
- Patty Taddei-Allen, PharmD, WellDyne

**JMCP Editorial Reviewers**

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- Laura E. Happe, PharmD, MPH, Humana
- Robert Ohsfeldt, PhD, Texas A&M Health Science Center
- Karen L. Rascati, PhD, The University of Texas College of Pharmacy
- Craig Stern, RPh, PharmD, Pro Pharma Pharmaceutical Consultants

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OUR HEART IS ALWAYS IN OUR WORK BECAUSE OUR PATIENTS ARE ALWAYS ON OUR MIND.

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G06 Real-World Analysis to Assess the Difference in Long-term Medication Adherence and Persistence with Fingolimod Compared to Injectable Disease-Modifying Therapies in Patients with Multiple Sclerosis
### 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.

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**PLATINUM**

Saurabh (Rob) Aggarwal, BS, MS, PhD; [U32] Comprehensive Review of Managed Care Formulary Access Trends for Top 100 Selling Drugs

James Gagnon, PharmD; [U55] A Medication Prior Authorization Pilot Program in Primary Care Practices Increases Efficiency and Patient Care Outcomes

Andrew Howe, PharmD, BA; [N02] An Analysis of Real-World Outcomes with FSH Versus FSH+hMG in IVF: Results from a Large U.S. Medical and Pharmacy Claims Database

Douglas Mager, MA; [U45] Impact of Plan Sponsor Cost Sharing on Utilization of Specialty Medications

Daniel Ng, PharmD, MBA; [N01] Impact of Overactive Bladder Step-Therapy Policies on Medication Utilization and Expenditures Among Treated Members

Julie Olson, DNP, MS, RN, CQIA, CBE; [U16] Implementation of CMS-Recommended MED Point of Sale Edit in a Medicare Part D Population

Hoa Pham, PharmD; [M04] Cost Sharing and Abandonment Rates of Anti-inflammatory Biologics: Potential Opportunity for Biosimilars

Aaron Smith-McLallen; [U19] A Randomized Clinical Trial of Medication Therapy Management in a Commercial Population

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**GOLD**

Carrie Armstrong, PharmD, MBA; [I33] Occurrence of Gastrointestinal Bleed with Anticoagulant Use: A Comparison of Outcomes Between Apixaban and Rivaroxaban

Jennifer Baird, PharmD Candidate; [C09] Palbociclib Utilization and Costs Among 18 Million Insured Americans: Managed Care Pharmacy Opportunities

Kevin Bowen, MD, MBA; [I25] Cumulative Incidence and Incremental Claims Cost of Coronary Heart Disease Events in a Commercially Insured Cohort Stratified by Risk

Karen Carroll, PharmD; [K07] Evaluation and Surveillance of Patient Adherence to Sofosbuvir Regimens for the Treatment of Hepatitis C Within a PPO Health Plan

Zoe Clancy, PharmD; [L18] Long-term Efficacy in Apremilast: Results from the ESTEEM Trials

Bobby Clark, PhD, MSPharm, MHA, MS, MA; [U01] Patients Who Utilized Retail Healthcare Clinics Have Fewer Emergency Department Visits and Incur Lower Overall Healthcare Cost

Ankur Dashputre, MS; [G18] Cost-Effectiveness of Alemtuzumab Versus Subcutaneous Interferon Beta-1a in Relapsing-Remitting Multiple Sclerosis

Steve Deitelzweig, MD; [I16] All-Cause and Bleeding-Related Hospitalizations in Non-valvular Atrial Fibrillation Patients Initiating Oral Anticoagulant Therapy

Victoria Erxleben, PharmD; [U21] Prevalence and Cost of Unsafe Opioid Use in a Medicare Advantage Population


Reethi Iyengar, PhD, MBA, MHM; [U09] Medication Adherence and Biometric Outcomes Among Patients with Diabetes and Dyslipidemia: Before and After Testing

Stephen Johnston; [M09] The Association Between Anti-cyclic Citrullinated Peptide/Rheumatoid Factor Positivity and Healthcare Costs Among Patients with Rheumatoid Arthritis

Russell Knoth, PhD; [R01] The Budget Impact of Adopting Netupitant/Palonosetron for the Prevention of Chemotherapy-Induced Nausea and Vomiting in a U.S. Health Plan

Alexander Miguel, PharmD, CGP; [U31] Examining Alternate Standardized Scripts to Improve Comprehensive Medication Review Participation Rate

Philip Mease, MD; [M07] Patient-Reported Outcomes in Psoriatic Arthritis Patients with Dactylitis and Enthesitis: Results from the Corrona Registry

Michael Migden, MD; [C04] Comorbidities, Healthcare Utilization, and Costs of Advanced Basal Cell Carcinoma Among Commercially Insured Patients


Indira Pulliadath, MBA, MS; [B07] Evaluating Outcomes with Sofosbuvir and Sofosbuvir Plus Ledipasvir Using an Integrated Data Approach

Teresa Roane, PharmD; [U18] The Impact of a Telephonic Outreach Program on Medication Adherence in Medicare Advantage Prescription Drug Plan Members

Derek Tang, PhD, BPharm; [M10] Adherence to Quality Standards for Time to Initiation of Disease-Modifying Anti-rheumatic Drugs Among
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**ABSTRACTS**

**M04** Cost Sharing and Abandonment Rates of Anti-inflammatory Biologics: Potential Opportunity for Biosimilars

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**BACKGROUND:** As lower-cost biosimilar biologic agents become available in the United States, their use may reduce patient out-of-pocket costs. Two previous studies found that rates of abandonment (failure to pick up a filled prescription at the pharmacy) were higher among health plan members initiating treatment with specialty drugs at high cost-sharing amounts; however, these studies used a single pharmacy benefits manager (PBM). To inform benefit design for biosimilars, more information about the relationship between out-of-pocket costs and adherence is needed.

**OBJECTIVE:** To explore the association between abandonment rates and patient cost-sharing for anti-inflammatory biologics using claims from multiple commercial health plans.

**METHODS:** In this observational study, we used an administrative claims database for >30 U.S. commercial health plans (9.2 million members) to identify pharmacy claims for selected anti-inflammatory biologic agents from 2011-2014. Abandonment was defined as a pharmacy claim reversal with no evidence of a medical or pharmacy claim for any drug in the same therapeutic class within the subsequent 14 days. We calculated abandonment rates among all patients (patients with ongoing or newly initiated therapy) and patients new to therapy (defined as no claims for an anti-inflammatory biologic in the previous six months) for all agents combined and for individual agents by copayment level (11 categories spanning $0 to ≥ $1,000).

**RESULTS:** 5,036 patients had 60,462 claims for anti-inflammatory biologics. The rate of abandonment for all agents combined was 0.5%, with higher rates occurring at copayment levels ≥$200 (P for trend <0.01) and the highest rate (16.3%) at copayment ≥$5750. Abandonment rates for the four highest-volume drugs were 0.6% for adalimumab, 0.6% for certolizumab pegol, 0.5% for etanercept, and 0.4% for golimumab and were higher at higher copayment levels for adalimumab, etanercept, and golimumab (P<0.01) but not for certolizumab pegol. In patients new to therapy (1,646 claims), the abandonment rate for all agents was 1.5%. Higher rates occurred at higher copayment levels for all agents combined (P<0.01) and for adalimumab (P<0.05) and etanercept (P<0.05).

**CONCLUSIONS:** In this insured population, high copayment levels were associated with higher rates of abandonment of anti-inflammatory biologics. Payers considering copayment designs for biosimilars may benefit from understanding the association between patient adherence and cost-sharing differentials for biologics.

**SPONSORSHIP:** This study was sponsored by Hospira.

**U32** Comprehensive Review of Managed Care Formulary Access Trends for Top 100 Selling Drugs

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**BACKGROUND:** In the United States, access and utilization of pharmaceutical drugs is managed by health plans using formulary tier coverage, restrictions, co-pays and deductibles. Due to several new changes introduced by the Affordable Care Act, there is a need to understand how various health plans annually change the access and the utilization controls for pharmaceuticals.

**OBJECTIVE:** The objective of this study is to review formulary coverage, utilization controls and cost sharing for top 100 selling drugs in the United States.
METHODS: The data for formulary tier status, prior authorization, quantity limits, co-pays and deductibles for top 100 selling drugs in Medicare Part D plans was obtained from CMS. This data covers ~116 million from top five states (i.e., FL, IL, NY, TX and CA). The access trends were analyzed overall and for individual drugs. The trends for 2015 were also compared to 2014 to understand changes in access year over year (YoY).

RESULTS: 6,144 coverage policies were identified for top 100 selling drugs in the selected five states. Overall, in 2015, 43% of the coverage was as a preferred brand, 27% at specialty tier and 25% as a non-preferred brand. Compared to 2014, in 2015, there was an absolute increase in specialty tier (+2%), decrease in preferred tier (-3.37%) and increase in non-preferred tier (+1.16%) coverage. In terms of Tier status, in 2015 the percentage of plans which covered the drugs at Tier 2, 3, 4 and 5 were 4.93%, 42.83%, 23.02%, and 29.22% respectively. Compared to 2014, the absolute percentage of plans with coverage at Tier 3 decreased (-2.31%) and Tier 5 increased significantly (+7.57%). In terms of utilization controls, compared to 2014, in 2015, there was a significant increase in prior authorizations (+3.99%), increase in quantity limits (+1.15%), slight increase in step therapy (+0.28%) and decrease in plans with no restrictions (-5.43%). Case studies of branded products further demonstrate decrease in access for drugs indicated for oncology, MS and HCV.

CONCLUSIONS: The managed care coverage trends review shows an overall decrease in access for commonly prescribed branded drugs. This study suggests need for policy measures to improve access for drugs for patients.

SPONSORSHIP: None.

U55 A Medication Prior Authorization Pilot Program in Primary Care Practices Increases Efficiency and Patient Care Outcomes

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PROBLEM DESCRIPTION: The medication prior authorization (PA) process has increasingly become a core activity of physicians and practice staff. Pharmacists and certified pharmacy technicians (CPhTs) are capable of assisting with this, allowing practice resources to be redeployed to support patient care.

GOAL: The purpose of the program is to (a) alleviate physician and practice administrative burden and (b) improve quality of care.

PROGRAM DESCRIPTION: New England Quality Care Alliance is a physician network that implemented a medication PA pilot program in January 2015. The program utilizes CPhTs, under the direct supervision of a clinical pharmacist, to submit medication PAs on behalf of physicians. The CPhT is virtually integrated into the practice workflow. PA requests are triaged by practice staff to a CPhT via the electronic medical record. The CPhT submits the PA and communicates the outcome to the patient, physician and practice staff. If the PA is denied the physician is provided recommendations consisting of alternative agents and next steps.

OBSERVATIONS: (a) Decrease burden—Dedicated practice time for PAs has been reduced, resulting in a 51% return on investment. On average, 1 CPhT can support 30 physicians and their staff. Each physician saves an estimated 40 hours per year and their staff more than 80 hours per year. To date the program has been accepted by 75% of physicians it has been offered to. (b) Improve care—Previously, self-report of practices noted that it routinely took 3-7 days to submit a PA. Now, the average time for a CPhT to submit a PA is 30 minutes. Within 24 hours of assignment to CPhT, 96% of PAs are submitted and 60% completely resolved. Additionally, an alternative recommendation was provided to the physician for 70% of the denied PAs with an 88% acceptance rate.

FINDINGS/RECOMMENDATIONS: CPhTs are a cost effective resource for managing the medication PA process allowing for physicians and practice staff to redirect their time to other patient-care activities. The program has improved efficiency of the PA process resulting in patients receiving the appropriate mediation sooner. Prior authorization support in the primary care setting is a unique opportunity to expand CPhT and pharmacist services that improve patient care in a cost efficient manner.

SPONSORSHIP: New England Quality Care Alliance.
A00-B99 Certain Infectious and Parasitic Diseases (e.g., HIV, Hepatitis C)

A01 Pulmonary Nontuberculous Mycobacterial Infections: Healthcare Resource Utilization and Costs in Medicare Patients at a U.S. Health Plan

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BACKGROUND: Pulmonary nontuberculous mycobacterial (PNTM) infections are difficult to diagnose, since their symptoms (e.g., cough, dyspnea, hemoptysis and fatigue) are common in other respiratory comorbidities. These overlapping symptoms may mask the infection, delaying diagnosis. PNTM infections are increasing among patients >65 years old and can exacerbate deterioration of lung function, compounding respiratory problems for some patients with serious comorbidities. PNTM infections are challenging to diagnose and treat, which can lead to prolonged treatment with multiple antibiotics as well as increased resource utilization and costs.

OBJECTIVE: Pre- and post-diagnosis resource utilization and costs for patients with PNTM infection and matched controls were examined.

METHODS: Using Medicare medical and pharmacy claims between January 1, 2007, and May 31, 2014, patients with PNTM infection (defined by ≥2 separate medical claims for PNTM infection [ICD-9-CM 031.0]) (n = 738) and matched controls (n = 5,166) were identified, first diagnosis served as index date. Both groups had ≥18 months of continuous enrollment pre- and post-index. Patients with PNTM infection were further split by those treated with ATS/IDSA guidelines-based antibiotics (n = 214) and those not treated (n = 524). Resource utilization calculations were completed for each group of patients on 8 categories (e.g., Inpatient Stays, Outpatient Visits). Healthcare costs were computed using the allowed amount and were reported in 2013 dollars for all medical, pharmacy, and total (medical + pharmacy) costs.

RESULTS: Pre- and post-diagnosis resource utilization was higher across all service categories for patients with PNTM infection than for matched controls (P < 0.001). Costs were also significantly higher for the PNTM group in all 3 categories pre- and post-diagnosis (P < 0.0001). Patients with PNTM infection treated post-diagnosis had fewer and shorter inpatient stays (P < 0.005, P < 0.001), fewer ED visits (P < 0.05), and, as would be expected, more pharmacy fills than untreated NTM patients (P < 0.001). Total and medical costs were significantly lower (P < 0.01), but no difference was seen in pharmacy costs.

CONCLUSIONS: Resource utilization and cost patterns for patients with PNTM infection were significantly higher than their matched controls both pre- and post-diagnosis. However, those treated according to ATS/IDSA guidelines showed lower utilization and costs than untreated patients. Based on these findings, healthcare plans should consider mechanisms to identify and appropriately treat this population.

SPONSORSHIP: Insmed.

B01 Impact of Tier 6 in Medicare Part D on Zoster Vaccine Uptake Among Medicare Beneficiaries in a Managed Care Organization

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BACKGROUND: A new 6-tier Medicare Part D formulary was introduced to cover the cost of zoster vaccines in 2011. In January 2012, Kaiser Permanente Southern California (KPSC) adopted Tier 6 ($0 patient copay).

OBJECTIVE: To assess the impact of this adoption on zoster vaccination rate (ZVR).

METHODS: We examined ZVR in an open cohort of Medicare Part D beneficiaries ≥65 years during January 1, 2008-June 30, 2014, compared to commercial health plan members ≥65 and those 60-64 years old. Demographics, vaccination records, and insurance and benefit type were ascertained by KPSC electronic medical record databases. Person-time based ZVR was calculated for each observation interval (calendar month or year) during the study period. Changes in annual ZVR in one year pre-(2011) and post-(2012) Tier 6 adoption were compared between Medicare Part D cohort and the two comparison cohorts in a difference-in-difference analysis (DID). Linear spline Poisson regression models were fitted to compare monthly ZVR trend in Medicare Part D cohort vs. the two comparison cohorts, with a pre-specified change point at month January 2012 to indicate Tier 6 adoption.

RESULTS: There was no apparent difference in monthly ZVR trend among the three cohorts prior to Tier 6 adoption. On average, ZVR increased in all cohorts post January 2012. DID showed that ZVR increase from 2011 to 2012 was marginally higher in Medicare Part D cohort than the two comparison cohorts (both differences in rate ratio [RR] 0.04, P > 0.05). In non-Hispanic white members, difference of RR was 0.09 (P = 0.02) and 0.08 (P = 0.03) comparing Medicare Part D cohort vs. commercial plan ≥65 and 60-64 years old cohorts, respectively. Secular trend analysis did not show significant increase in overall and race stratified ZVR attributable to Tier 6 adoption in Medicare Part D cohort.

CONCLUSIONS: Impact of Tier 6 on ZVR in elderly Medicare beneficiaries was not substantial in KPSC, perhaps due to a low copay ($20 to $40 for Part D members) pre-tier 6. Further research is needed to explore the numerical relationship between vaccination and amount of copay.

SPONSORSHIP: GlaxoSmithKline Biologics SA funded this study (GSK study identifier: HO-13-14182) and all costs related to the development of this abstract and all related publications.

B02 Long-term Cost Per Sustained Virologic Response in Patients with Genotype 1 Chronic Hepatitis C Virus and Human Immunodeficiency Virus Coinfection Treated with Ombitasvir/Paritaprevir/Ritonavir, Dasabuvir + Ribavirin and Other HCV Regimens in the United States

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BACKGROUND: Hepatitis C virus (HCV) is one of the leading causes of liver-related morbidity and mortality among human immunodeficiency virus (HIV)-infected patients. Novel HCV regimens have demonstrated high efficacy in these patients. While the costs of these regimens have been debated, long-term (i.e., lifetime) cost per sustained virologic response (SVR) has not yet been studied.

OBJECTIVE: To estimate the long-term cost per SVR for ombitasvir/paritaprevir/ritonavir, dasabuvir+ribavirin (3D±R), sofosbuvir plus peg-interferon and ribavirin (SOF+PR), SOF+R and sofosbuvir plus ledipasvir (SOF+LDV), in patients with genotype 1 (GT1) HCV and HIV coinfection in the United States (U.S.).

METHODS: A natural history model of HCV with Markov transitions driven by the additional annual HIV therapy costs. Total costs of HCV included direct medical costs by health state (including costs of HIV treatment), costs of HCV regimen and managing adverse events (AEs). Transition probabilities and medical costs (in 2014 prices) were obtained from published literature. HCV regimen costs were based on wholesale acquisition costs from the December 2014 Red Book. Distribution of patients by fibrosis stage at baseline, incidence of AEs and SVR were based on published trials. Selection of comparators was based on SVR data availability. SVR rates for 3D±R (TURQUOISE I), SOF+PR (P7977-1910), SOF+R (PHOTON-1 and PHOTON-2) were available in the overall GT1 coinfected population as well as the naïve non-cirrhotic population; SVR (PHOTON-1 and PHOTON-2) were available in the overall GT1 coinfected population, 3D±R has a relatively low long-term cost per SVR compared to other HCV regimens.

RESULTS: In the overall GT1 HCV and HIV coinfected population, 3D±R had the lowest long-term cost per SVR ($468,744), followed by SOF+LDV ($468,035) and SOF+R ($485,424) and SOF+PR ($480,033) and SOF+R ($623,127). In the treatment-naive non-cirrhotic coinfected population, SOF+LDV (ERADICATE) were available in the naïve non-cirrhotic population only. Long-term cost per SVR for a regimen was calculated by dividing the total cost of HCV over a patient’s lifetime by the mean SVR rate for that regimen.

CONCLUSIONS: In the overall U.S. GT1 HCV and HIV coinfected population, 3D±R has a relatively low long-term cost per SVR compared to other HCV regimens.

SPONSORSHIP: The design, analysis, and financial support of this study were provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the study.
**RESULTS:** In total, 1,439 members initiated HCV treatment with SOF and 551 had at least one lab test post-treatment. Patients were 63% male, mean age of 55 years, 74% MAPD; 90% on 12-week treatment, 36% on a treatment containing interferon, 63% genotype (GT) 1, 26% GT2, 8% GT3 and 3% unknown. The lab test used to assess SVR12 was on average almost 5 weeks post-treatment. The estimated SVR12 rate for 12 and 24 week treatments overall was 78.2% and 69.6%, respectively. The 12-week treatment SVR was marginally higher for COM vs. Medicare (80.3%, 77.3%; P = 0.46) but higher for Medicare in 24-week treatment (56.3%, 73.0%; P = 0.17). The SVR rates for GT1 COM patients on 12-week SOF + peginterferon(P) + ribavirin(R), SOF + simprevir (SIM), and SOF + SIM + R were 86.3% (n = 32), 80.3% (n = 41) and 50.0% (n = 8), respectively. For GT1 Medicare patients the SVR 12 rates for SOF + PR, SOF + SIM, and SOF + SIM + R were 73.8% (n = 126), 76.0% (n = 100) and 84.6% (n = 13), respectively.

**CONCLUSIONS:** Overall SVR12 rates of SOF-based regimens in the real world are lower than in clinical trials. While the mean time to post-treatment SVR in this real world study was 11.1 weeks, this is very close to the optimal 12 weeks post-treatment measure.

**SPONSORSHIP:** The financial support for the study was provided by AbbVie.

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**B05 The Cost of Specialty HCV Populations with Private or Public Insurance**

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**BACKGROUND:** People infected with hepatitis C virus (HCV) who also have human immunodeficiency virus (HIV) coinfection, history of liver transplant, or renal impairment comprise “specialty” patient populations which are difficult to treat and cure for HCV. While these conditions affect only a relatively small portion of people infected with HCV, they may account for substantial costs to the healthcare system overall.

**OBJECTIVE:** This study quantifies the prevalence and cost of specialty HCV populations with employer-sponsored or Medicare insurance in the U.S.

**METHODS:** A real-world analysis of specialty HCV patients in 2013 Truven Health MarketScan, representative of Employer Sponsored Insurance (ESI) covered lives, and the 2012 Medicare 5% Sample databases using diagnosis and procedures codes in administrative claims was conducted. Annual average medical spending for this cohort was summarized by payer into inpatient, outpatient, and physician service categories. Spending was derived from allowed amounts which include those paid by insurance and patient cost-sharing. Prescription drug spending was not considered.

**RESULTS:** The specialty cohort of HCV patients comprise over 7% of all HCV patients covered by ESI, and about 25% of all Medicare-covered HCV patients. However, these patients accounted for 31% (ESI) and 53% (Medicare) of total medical costs. Among the specialty HCV patients with ESI, the average annual medical costs per patient are $30,101 for the HIV coinfected, $126,708 for patients with a history of liver transplant, and $150,342 for patients with renal impairment. The average cost for specialty HCV patients with ESI coverage is $86,179 in 2013, over four times the $20,627 annual cost of the typical ESI HCV patient. Average costs to Medicare per specialty HCV patient in 2012 are $39,914 for HIV coinfection, $48,403 for history of liver transplant, and $82,936 for renal impairment. The average annual cost of a specialty HCV patient in Medicare is $66,449, more than double the $31,431 cost of a typical Medicare HCV patient.

**CONCLUSIONS:** In spite of their relatively low prevalence, specialty HCV populations account for a large portion of overall HCV-related medical spending by employers and Medicare. The annual employer cost per specialty HCV patient is greater than Medicare’s; while some of these differences can be attributed to higher reimbursement levels of ESI, this issue deserves further investigation.

**SPONSORSHIP:** The design, analysis, and financial support of this study were provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the study.

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**B06 The Distribution of Pharmacy, Medical, and Total Costs in Patients with HCV**

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**BACKGROUND:** As health care costs rise for conditions such as hepatitis C virus (HCV), many payers have increased cost-sharing on specialty medications. If health care costs are skewed, with the bulk of these being medical costs incurred by a relatively small group of individuals who have disproportionately high cost-sharing burdens, then potential interventions (such as premium support) targeted to this group could have a significant impact on cost containment. An understanding of the share of treatment costs incurred by the most expensive patients, and the drivers of these costs, can inform the implementation of potential cost-saving interventions.

**OBJECTIVE:** To examine the distribution of pharmacy, medical, and total treatment costs for HCV patients in the United States.

**METHODS:** A real-world study was performed with the Optum Touchstone database. This cohort study (N = 50,763 patient-year observations) consisted of commercially-insured patients aged 18-64 years, with at least one inpatient medical claim or one ambulatory visit with a diagnosis of HCV from 2004-2014 Q1. HCV patients were ranked by their total annual costs (i.e., medical plus pharmacy) and grouped into deciles of total cost and of out-of-pocket (OOP) cost. Bivariate analyses were conducted to assess the distribution of pharmacy, medical, and total costs by decile, and mean values and standard error of the mean (SEM) were evaluated.

**RESULTS:** The cohort, with a mean age of 50 years, is comprised of 60% males. The mean total annual cost for this cohort is $16,879 (SEM 433), with $15,321 (SEM 361) medical costs and $1,558 (SEM 154) pharmacy costs. The upper cost deciles have substantially greater mean total and medical expenditures, but less prominent pharmacy costs. From the first to tenth decile, total costs increased from $15 to $122,159; medical costs from $15 to $108,066; and pharmacy costs from $0 to $14,093. The mean total expenditures in the tenth decile is 7,902 times that of the first decile. Medical costs accounted for 88% of the total costs in the top decile. Replicating the analysis by decile of OOP costs indicated that higher OOP costs are associated with higher total and medical costs.

**CONCLUSIONS:** Total and medical expenditures for HCV patients have a highly skewed distribution, with a few patients representing a disproportionate share of these costs. Patients who bear the greatest burden for their health care have much higher medical expenditures, suggesting cost-sharing disproportionately impacts the highest need patients.

**SPONSORSHIP:** The design, analysis, and financial support of this study were provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the study.
Evaluating Outcomes with Sofosbuvir and Sofosbuvir Plus Ledipasvir Using an Integrated Data Approach

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BACKGROUND: Sofosbuvir and sofosbuvir plus ledipasvir are two new treatments for Hepatitis C that were approved by the U.S. Food and Drug Administration (FDA) over the past two years. The clinical trials showed high efficacy rates, however real-world effectiveness data for these new drugs has been limited. Aetna traditionally receives an estimated 50% of laboratory results through an automated data feed. Aetna has implemented a Precertification program that requires submission of “Early Viral Response Results” (EVR) after four weeks of treatment in order for patients to continue treatment. We decided to use an integrated data approach for evaluating outcomes in this population, combining pharmacy claims data, laboratory results data and data from Aetna’s Precertification program.

OBJECTIVE: The primary objective was to evaluate sustained virologic response (SVR) associated with sofosbuvir combinations and sofosbuvir plus ledipasvir treatments for Hepatitis C. The secondary objective was to evaluate the predictive ability of EVR for SVR.

METHODS: Adults with a prescription of sofosbuvir or sofosbuvir plus ledipasvir were identified from Aetna’s claims database. Patients’ Hepatitis C Virus RNA measurements and genotype were extracted from the lab data using leading LOINC (Logical Observation Identifiers Names and Codes). Data cleaning was done and an algorithm was employed to interpret the results of the lab data. Treatment durations were assigned based on their genotype and per recommended guidelines per the FDA and the American Association for the Study of Liver Diseases and Infectious Disease. The SVR was defined as treatment duration plus 12 weeks and was determined using laboratory results data. For evaluating EVR rates, data from the Precertification program was used.

RESULTS: Our study showed that 506 out of 513 patients (98.6%) achieved a SVR. The sofosbuvir plus ledipasvir group (N=71) showed 100% SVR rate. The SVR rate for sofosbuvir without ledipasvir regimens (N=442) ranged from 95.8% to 99.0%. The positive predictive value of EVR for SVR was 99.0% and the negative predictive value was 100%.

CONCLUSIONS: Our study found that sofosbuvir treatment regimens without ledipasvir as well as sofosbuvir plus Ledipasvir regimen resulted in high SVR rates. Our study results also demonstrated that EVR had a good predictive ability for SVR showing a both high positive predictive value as well as a high negative predictive value.

SPONSORSHIP: This study was fully funded by Aetna.

Effectiveness of Sofosbuvir Regimens for Hepatitis C in a Real-World Setting

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BACKGROUND: The efficacy of sofosbuvir for treatment of Hepatitis C virus (HCV) has been demonstrated in clinical trials. However, few studies have examined its performance in real-world settings.

OBJECTIVE: This study evaluates response and relapse rates among HCV patients receiving sofosbuvir-based regimens using a combination of administrative claims and clinical data from provider medical records.

METHODS: This observational cohort study identified HCV patients who initiated sofosbuvir treatment between December 1, 2013 and April 30, 2014 in a large managed care database from 14 U.S. commercial health insurance plans. Patients aged 18 years or older and with ≥1 RNA viral load test after commencing treatment were included. Three regimens were evaluated—sofosbuvir+ribavirin (SOF+RBV,
Among the 2.7 million Americans with chronic HCV, diagnosed and treated like insured patients, this would add $4.88 billion. If the undiagnosed were diagnosed and treated like insured patients, this would add another $11.83 billion.

CONCLUSIONS: As baby boomers with HCV enter Medicare, the program may face substantial cost burdens. Proactively treating HCV patients before they suffer expensive long-term complications can help mitigate this burden to the U.S. government.

SPONSORSHIP: The design, analysis, and financial support of this study were provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the study.

B12 Awareness of Hepatitis C Status in HCV-Infected U.S. Adults, 2003-2012

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BACKGROUND: Recent advances in treatment for hepatitis C virus (HCV) infection heighten the need for policies that improve detection of HCV, particularly for subpopulations most at risk.

OBJECTIVE: As a first step toward understanding unmet need for screening, this study examines HCV status awareness across racial, risk, and income groups in the U.S.

METHODS: Data from five combined waves (2003-2012) of the National Health and Nutrition Examination Survey (NHANES), a nationally representative survey of the housed, non-institutionalized, civilian U.S. population, were used for descriptive analyses. All NHANES respondents age ≥ 18 years were tested for presence of HCV antibodies and/or RNA, depending on year of data collection. Presence of either antibodies or RNA is considered a positive test for HCV infection. Follow-up interviews of HCV-infected respondents ascertained prior awareness of HCV infection status. Population percentages and P-values were weighted to adjust for sampling design.

RESULTS: 172 of 480 NHANES respondents who tested positive for HCV antibodies or RNA during 2003-2012 participated in the follow-up survey. Of these, 97 (59%) reported that they were already aware of their HCV status when informed of their positive HCV test in NHANES. Rates of prior HCV status awareness varied considerably; 70% of adults born in 1945-1965 reported prior awareness, for example, compared to 27% of adults not in major risk groups (P = 0.001). People living above 2× Federal poverty level were more likely (72%) than those below 2× FPL (48%) to have been aware of their HCV status (P = 0.019).

CONCLUSIONS: HCV screening practices before 2010 appear to have identified just over half of total HCV cases in the non-institutionalized U.S. population. Furthermore, large disparities exist in awareness of HCV status, particularly among marginalized and seemingly low-risk groups. With new therapies promising higher certainty of cure for people with HCV development of effective screening policies is of great importance.

SPONSORSHIP: The design, analysis, and financial support of this study were provided by AbbVie. AbbVie participated in the interpretation of data, review, and approval of the study.
**B13 Estimating the Budget Impact of Daclatasvir for the Treatment of Chronic Hepatitis C Virus for Genotype 3 Patients in a U.S. Health Plan**

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**BACKGROUND:** The treatment landscape for hepatitis C virus (HCV) is evolving rapidly. An open label phase III trial evaluated the efficacy and safety of daclatasvir (DCV) in combination with sofosbuvir (SOF) for subjects with HCV genotype (GT) 3. However, the budget impact of DCV for the treatment of chronic HCV in GT 3 patients has yet to be determined.

**OBJECTIVE:** Estimate the impact of adopting a DCV-containing regimen for a hypothetical U.S. health plan cohort of HCV GT 3 patients through a budget impact model.

**METHODS:** A budget impact model was developed to compare the costs of a sofosbuvir plus ribavirin (SOF + RBV) regimen to the costs of adopting a DCV-containing regimen (DCV + SOF) in a 1 million-member hypothetical U.S. health plan over a 1 year time horizon. Estimates of HCV GT 3 rates and percentages of patients treated were derived from the literature. An estimated price for DCV was used based on the current availability of other combination regimens. Regimen pharmacy costs were estimated using standard prescribing dosages, WAC pricing, and simple reimbursement and dispensing assumptions. Utility costs for testing, physician visits, and adverse event (AE) management were derived from the literature. Initial market share was assumed to be 100% for SOF + RBV. After 1 year, uptake of DCV + SOF was calculated at +40% with the remaining 60% for SOF + RBV. The incremental annual total budget impact was calculated as well as the incremental pharmacy budget impact. Per member per month (PMPM) costs were also reported for the total budget and pharmacy budget. Sensitivity analysis was conducted to assess the impact of varying prevalence and market share.

**RESULTS:** 53 patients with HCV GT 3 were identified in the hypothetical model scenario. The annual total plan budget with SOF + RBV prior to the adoption of DCV + SOF regimens was estimated to be $9,744,710. After the adoption of a DCV-containing regimen, costs were estimated to be $9,067,787 resulting in a reduction of $676,924 or 6.95%. This translated to $0.81 PMPM costs prior to adoption, and $0.76 post adoption of DCV + SOF. Sensitivity analyses suggested that a ±30% change in prevalence would result in a PMPM reduction of $0.04-$0.07 at 1 year for the pharmacy budget, and a ±30% change in market share would result in a reduction of $0.04-$0.07 for the pharmacy budget.

**CONCLUSIONS:** Budget impact model results indicate that adopting a DCV-containing regimen for patients with HCV GT3 has the potential to reduce total and pharmacy budgets.

**SPONSORSHIP:** None.

**B15 Impact of Adherence to HIV/AIDS Antiretroviral Therapy and Utilization of Opportunistic Infection Prophylaxis**

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**BACKGROUND:** Treatment options for human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) can be costly and require frequent monitoring and specialized care. Adherence to antiretroviral therapy (ART) is crucial to prevent replication of HIV and ART drug resistance. The minimum adherence rate to ART to suppress viral replication has been reported to be at least 95%. Additional pharmacological therapy is not typically needed to prevent opportunistic infections (OI) when a patient’s viral load is suppressed. Primary prophylaxis for opportunistic infections (OIP) is utilized when the number CD4 cells decrease below thresholds as defined by AIDSinfo.nih.gov. The most common OIs are Pneumocystis pneumonia (PCP), toxoplasmosis, and Mycobacterium avium complex (MAC).

**OBJECTIVE:** To evaluate the difference in utilization of OIP between members who are adherent and non-adherent to ART.

**METHODS:** A retrospective analysis using pharmacy paid claims data obtained within the preceding 6 months was conducted. Paid claims data for members age 18 and older receiving ART, defined as FDA-labeled medications indicated for treatment of HIV/AIDS, was evaluated across members enrolled in a prescription plan administered by the pharmacy benefit manager. Adherence to ART was assessed using proportion of days covered (PDC). OIP was defined as one or more claims for medication used for primary prophylaxis of at least one of the following: MAC, PCP, and toxoplasmosis. Proportion of ART compliant (PDC ≥ 0.95) members on one or more OIP was compared non-compliant members using chi-square analysis. Proportions of members compliant at PDC values of 0.90 and 0.80 were also analyzed using chi-square.

**RESULTS:** Out of 410 members using PDC ≥ 0.95, 57% were compliant with 13% on OIP, and 43% were non-compliant with 20% on OIP (P > 0.05). Using PDC ≥ 0.90, 61% of members were compliant with 13% on OIP, and 39% were non-compliant with 21% on OIP (P < 0.05). Using PDC ≥ 0.8, 68% were compliant with 13% on OIP, and 32% were non-compliant with 22% on OIP (P < 0.05).

**CONCLUSIONS:** OIP claims do not differ between compliant and non-compliant members when PDC ≥ 0.95. Using PDC ≥ 0.9 and 0.9 did show significant difference between compliant and non-compliant members. Since the use of OIP is based on CD4 count, and CD4 count is affected by the patient’s viral load, it is expected that patients with low adherence to ART would be on OI prophylaxis more so than those adherent. With the use of newer agents, the generally accepted PDC ≥ 0.95 may not need be as high as a marker of disease management. Further study in PDC rates and clinical outcomes is warranted.

**SPONSORSHIP:** None.
RESULTS: Base case analysis showed that ISAV cost $7,377 less per patient than VORI for the treatment of IA in the hospital setting. In both incremental cost per death averted and incremental cost per additional clinical responder, ISAV was dominant. Results were robust; in deterministic sensitivity analysis, only when initial LOS, mortality, or clinical response was assumed to be worse for ISAV while remaining unchanged for VORI was ISAV no longer dominant. In probabilistic sensitivity analysis, ISAV had a lower cost per patient than VORI in 80.1% of 5,000 replications.

CONCLUSIONS: Results show that ISAV may be more cost-effective than VORI for the treatment of invasive aspergillosis among hospitalized patients.

SPONSORSHIP: Astellas Pharma Global Development, Northbrook, IL.

The Impact of Specialty Pharmacy Integration and Guideline-Based Formulary Management on the Use of Palivizumab in a Commercially Insured Population

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BACKGROUND: Similar to many injectable and infused specialty products, palivizumab can be administered through both the pharmacy and medical benefit. Reimbursement and utilization management controls vary greatly between benefits making coordination a key component to a specialty pharmacy strategy (SPS). In 2014, the American Academy of Pediatrics updated treatment recommendations on the use of palivizumab in the treatment of RSV.

OBJECTIVE: Describe the impact of utilizing guideline based formulary management and specialty pharmacy integration strategies on the use of palivizumab under the medical and pharmacy benefit in a commercially insured population.

METHODS: Palivizumab was part of an integrated SPS utilized by a health plan and pharmacy benefits manager. Outpatient use of palivizumab therapy was restricted to the pharmacy benefit beginning in 2011. Additionally, palivizumab therapy was restricted using prior authorization (PA) criteria based on current practice guidelines. Administrative claims data from a health plan of 160,000 commercially insured patients was analyzed for periods 2012-2013 (S1), 2013-2014 (S2), 2014-2015 (S3). Pharmacy claims were used to evaluate the utilization of palivizumab. PA and appeals requests for palivizumab therapy were analyzed and costs savings were calculated comparing S3 utilization to prior seasons.

RESULTS: Utilization of palivizumab therapy under the pharmacy benefit was 65, 100, and 26 claims for S1, S2, and S3, respectively. The number of PAs submitted and approval rate was as follows. 26 (88%) in S1, 27 (81%) S2, and 23 (77%) in S3. There were no appeals submitted for S3. The cost savings from the implementation of updated PA criteria for S3 was estimated to be between $96,352 (S1 vs. S3) and $157,452 (S2 vs. S3).

CONCLUSIONS: The results of the study show a decrease in the number of authorizations approved and utilization after implementation of the new guideline based criteria. No appeals were submitted during S3, suggesting the denied claims were deemed clinically appropriate. There is recognized variance in RSV seasons, but the decrease in the total number of PAs submitted may suggest providers followed the updated guidelines and did not request coverage for therapy based on the previous recommendations. An integrated SPS allows for the ability to evaluate for appropriateness prior to product administration. Clinically appropriate PA criteria reduced the utilization of palivizumab and potentially saved the health plan $96,352 to $157,452 in the 2014-2015 season when compared to the two prior RSV seasons.

SPONSORSHIP: None.

Economic Characteristics of Patients Initiating Chemotherapy in a Novel Cancer Care Quality Program

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BACKGROUND: The HIRE-Oncology dataset is a clinically rich data source derived from the Anthem Cancer Care Quality Program, a novel program designed to align reimbursement with evidence-based, cost-effective treatment, integrated with administrative claims data.

OBJECTIVE: To assess 12-month baseline direct costs by cancer stage among chemotherapy naive breast, colorectal, and lung cancer patients.

METHODS: This retrospective study identified breast, lung, and colorectal cancer patients in the HIRE-oncology dataset for whom a request to utilize chemotherapy and/or supportive care medication (pre-certification) was submitted by their oncologist between June 1, 2014 and January 31, 2015 (Intake Period). The earliest observed pre-certification date was marked as index and 12-months pre-index health plan enrollment and no prior claim associated with chemotherapy was required. Healthcare mean annual costs were calculated as the total all-cause medical and pharmacy costs in the 12 months prior to the pre-certification.

RESULTS: The study included 653, 141, and 318 breast, colorectal, and lung cancer patients, with average (SD) ages of 54 (10), 56 (10), and 63 (9) years, respectively. Breast cancer patients were most likely to be stage II (44%). The majority of colorectal and lung cancer patients were male (59% & 55%) and at stage IV at index (57% & 69%). Mean healthcare costs among breast cancer patients ranged from $30,704 to $42,775 across stages I-IV, with outpatient services accounting for the majority of costs (82%-66%) and inpatient costs increasing with stage (I = 14% to IV = 29%). Mean healthcare costs among colorectal cancer patients ranged from $50,197 to $58,862 across stages II-IV, with inpatient services accounting for 63%-76% and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages. Among lung cancer patients, the mean healthcare costs ranged from $31,987 to $54,210 across stages I-IV, with inpatient costs representing the majority share at each stage (63%-76%) and outpatient costs accounting for 21%-33% across stages.
SPONSORSHIP: This study was internally funded by HealthCore, a wholly owned subsidiary of Anthem.

C04 Comorbidities, Healthcare Utilization, and Costs of Advanced Basal Cell Carcinoma Among Commercially Insured Patients

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BACKGROUND: Basal cell carcinoma (BCC) is the most common skin cancer in the U.S. and can be effectively treated. However, some patients progress to advanced BCC (aBCC), including locally advanced BCC (labcC) and metastatic BCC (mBCC), for which the disease burden is not fully understood.

OBJECTIVE: To compare comorbidities, healthcare utilization, and costs between patients with aBCC and those with non-aBCC.

METHODS: Commercially-insured adult patients were selected if they had ≥2 claims with a BCC diagnosis (ICD-9: 173.x1) separated by ≥30 days on or after October 1, 2011 (BCC-specific ICD-9 codes release date). Patients were classified into the aBCC (mBCC and labC) and non-aBCC cohorts using an algorithm based on metastasis diagnosis, use of radiation therapy, and medical oncologist/other specialist visits. For aBCC patients, the index date was defined as the first aBCC qualifying diagnosis or event. Non-aBCC patients were assigned the same index dates as aBCC patients and matched 1:1 to aBCC patients on age, gender, and region. Patients in both cohorts were continuously enrolled in a health plan for ≥6 months before (baseline) and ≥12 months after the index date (study period) and had ≥1 BCC diagnosis during baseline. Charlson comorbidity index (CCI), individual physical and mental comorbidities, healthcare resource use and costs were measured during the study period and compared between the two cohorts using Wilcoxon signed-rank tests for continuous variables and McNemar's tests for categorical variables.

RESULTS: A total of 847 matched pairs of aBCC (labcC: 826, mBCC: 21) and non-aBCC patients were selected, with mean age of 73 years and 57% male. During the study period, aBCC patients had significantly higher CCI (1.8 vs. 1.5) and rate of obsessive-compulsive and related disorders (2.1% vs. 0.8%) compared to non-aBCC patients (both P<0.05). aBCC patients had significantly higher numbers of outpatient (38.3 vs. 22.4), dermatologist (4.0 vs. 2.2), and medical oncologist/other specialist visits (14.5 vs. 8.0) during baseline. Charlson comorbidity index (CCI), individual physical and mental comorbidities, healthcare resource use and costs were measured during the study period and compared between the two cohorts using Wilcoxon signed-rank tests for continuous variables and McNemar's tests for categorical variables.

CONCLUSIONS: aBCC patients had significantly higher resource utilization and costs compared to non-aBCC patients. The differences were largely driven by BCC treatment costs.

SPONSORSHIP: Bristol-Myers Squibb.
Bristol-Myers Squibb. MEL, including AE- and persistence-associated costs. Further analysis will evaluate economic burden of low persistence suggest that these AEs impact patients' ability to nausea, fatigue, and depression. Higher AE rates among patients with CONCLUSIONS: Adjuvant high-dose IFN for MEL is associated with nausea, fatigue, and depression. Higher AE rates among patients with low persistence suggest that these AEs impact patients' ability to remain on therapy. Further analysis will evaluate economic burden of MEL, including AE- and persistence-associated costs.

SPONSORSHIP: Bristol-Myers Squibb.

C09 Palbociclib Utilization and Costs Among 18 Million Insured Americans: Managed Care Pharmacy Opportunities

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BACKGROUND: On February 3, 2015 palbociclib, a kinase inhibitor, was approved for the treatment of postmenopausal women with estrogen positive and human growth factor receptor 2 negative advanced breast cancer in combination with letrozole as initial endocrine based therapy for their metastatic disease. With a wholesale acquisition price of $128,037 per year and wide scale forecasted uptake, it is important to understand palbociclib cost trends and utilization due to the limited trial data.

OBJECTIVE: To evaluate palbociclib utilization patterns and costs immediately following approval in order to optimize utilization management (UM) programs.

METHODS: Prescription claims data from 18.6 million average members per month, 17.5 million commercial and 1.1 million Medicare, were queried for palbociclib claims. Members were followed from their first palbociclib claim (index date) through June 19, 2015. Persistence was defined as a palbociclib supply on June 19, 2015 for members continuously enrolled. Letrozole utilization was defined as any letrozole claim from index date through June 19, 2015. Palbociclib dose reduction was defined as a claim for a lower palbociclib capsule strength after the index claim. Total paid was paid plan plus member share.

RESULTS: In the first 136 days of palbociclib availability, 382 members had a palbociclib claim (21 per million) at a cost of $9,224,861 or $0.11 per member per month (PMPM). Medicare had 89 members (82 per million) at a cost of $2,098,357 or $0.43 PMPM and Commercial had 293 members (17 per million) at a cost of $7,126,503 or $0.09 PMPM. Average days follow-up from index palbociclib claim was 59 days with a range of 1-130 days. Palbociclib days supply was an average of 67 days, range 28-168 days, median 56 days. Palbociclib persistence was found in 303 (79.5%) and dose reduction occurred in 69 (18.1%) members. Letrozole utilization was found in 342 (89.5%) members.

CONCLUSIONS: In less than 6 months after launch, palbociclib has quickly resulted in substantial cost to both Commercial and Medicare pharmacy benefits with a disproportionately 5 fold higher utilization and cost occurring within Medicare. Of concern are the 1 in 5 members no longer persistent at on average 2 months follow-up, the dose reduction occurring in 1 in 6 members, and 1 in 10 members with no evidence of letrozole use. Payers should develop care management and UM programs to ensure appropriate palbociclib use and prevent unnecessary costs. Potential product strategies include a split fill program, PA criteria and outcomes based contracting with manufacturers.

SPONSORSHIP: Prime Therapeutics, Eagan, MN.

C10 Real-World Treatment Patterns of Everolimus for Advanced Breast Cancer: A Multi-country Chart Review Study

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BACKGROUND: BOLERO-2 demonstrated the efficacy of everolimus (EVE) + exemestane among postmenopausal women with hormone receptor positive (HR+) human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer (aBC) after failure of a non-steroidal aromatase inhibitor (NSAI).

OBJECTIVE: This study aims to describe real-world EVE treatment patterns in this population based on a multi-country chart review.

METHODS: The retrospective chart review study collects information on patients with HR+/HER2- aBC over 20 sites in 6 countries (Canada, the Netherlands, France, Italy, Russia and Argentina). The current analysis used interim data on the patients receiving EVE+endocrine therapy (ET) from 3 countries (Canada, the Netherlands, and Argentina). Stratified sampling by line of therapy was used to ensure representation of different lines. Patient characteristics and treatment patterns with EVE were described.

RESULTS: In the interim analysis, 15 patients received EVE+ET (3 in 1st, 6 in 2nd, and 6 in 3rd/4th lines) with a median follow up of 13.6 months. The median age was 66.0 years. 14 patients (93%) had recurrent breast cancer, and 3 (20%) had visceral metastasis. All patients received EVE + exemestane. Prior to EVE, 10 (67%) received ET, and 2 (13%) received chemotherapy (CT). Physicians most frequently cited treatment efficacy as the top reason for prescribing EVE (67%). 13 (87%) started on 10 mg EVE daily; the rest on 5 mg daily. 4 (27%) had ≥ 1 dose reduction, of which, 3 due to intolerance. The median average daily dose was 10 mg. At the end of follow up, 2 (13%) remained on EVE+ET, 1 (7%) died, and 12 discontinued due to progression (9/12), intolerance (2/12), or other medical reasons (1/12). Among EVE discontinuers, 6 (50%) switched to CT, 3 (25%) to ET, and 3 (25%) to best supportive care. The median time from EVE discontinuation to CT/ET initiation was 11 days.

CONCLUSIONS: All patients received EVE with exemestane as labeled. Treatment efficacy was the most selected reason for prescribing EVE. Most patients started at full dose. Dose reduction and discontinuation due to tolerability were not prevalent. EVE+ET could be an option for patients seeking a more efficacious treatment with manageable tolerability.

SPONSORSHIP: This study was funded by Novartis Pharmaceuticals.

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BACKGROUND: Clinical practice guidelines are increasingly used throughout the world to improve the quality of care for patients by providing evidence-based recommendations. Cancer treatment guidelines are created by various groups at the local, national, or global levels, and may consider factors such as resource availability and robustness of evidence. While there is data reporting practitioner adherence to specific guideline recommendations, little is known about which guidelines the practitioner is utilizing.

OBJECTIVE: The primary objective of this study is to evaluate the impact of cost factors on the level of utilization of local, regional, and global breast cancer treatment guidelines to direct oncology practice in the United States.

METHODS: In April 2015, an IRB approved web-based survey was disseminated to physicians practicing in the U.S. via a third-party vendor. Respondents qualified if they have administered cancer-related treatment to breast cancer patients for 3 or more years.

RESULTS: A total of 33 oncologists were qualified and completed the survey. When asked to rate the impact on treatment decisions, local guidelines had a significant, large, medium, and low impact according to 3 (9%) 15 (45%), 8 (24%), and 6 (18%) oncologists, respectively; national guidelines according to 11 (33%), 15 (45%), 6 (18%), and 1 (3%) oncologists, respectively. Global guidelines had the least impact with 15 (45%) indicating low impact. Cost of therapy had a medium impact with 13 (39%) oncologists, significant with 5 (15%), large with 9 (27%), and low with 5 (15%). Eighty-five percent indicated they use ASCO, 33% use peer reviewed literature/consensus statements, 61% use NCCN, 52% use clinical trial/investigational therapy, 33% use NCI, 33% use local guidelines, and 12% use other guidelines. While ASCO guidelines had the highest utilization, only 43% of oncologists stated that they followed at least 75% of the recommendations. In contrast, 61% stated that they followed at least 75% of the NCCN recommendations. In comparing guideline preferences in general and if there were no restrictions due to financial considerations, there were only slight differences. The largest difference was in the number of oncologists referencing ASCO (28 [85%] in general vs. 19 [58%] if no restrictions).

CONCLUSIONS: This study provides insight on which breast cancer guidelines are used as well as impact of cost on their preferences. Factors such as national regulations on pharmaceutical availability and reimbursement practices may have an impact on the practitioner’s choice in breast cancer treatment guidelines.

SPONSORSHIP: None.

The Importance of Duration of Treatment and Therapy Discontinuation Rates in Third-Line Relapsed/Refractory Multiple Myeloma Patients Treated in U.S. Community Oncology Practices

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BACKGROUND: The standard of care for third-line relapsed/refractory multiple myeloma (RRMM) patients is not well established. Expanding choices in treatments necessitate a holistic assessment of therapy value. While clinical efficacy (progression-free survival) remains a key driver in treatment choice, duration of treatment (DOT) and rate of adverse events (AEs) are important components of value frameworks as they impose significant economic/humanistic costs.

OBJECTIVE: To assess DOT and experience of AEs among patients with RRMM starting third-line treatment in community oncology practices.

METHODS: RRMM patients diagnosed between January 2007-August 2014 with at least 2 lines of treatment following induction were selected from 20 large community oncology practices. Patient and disease characteristics, treatment information and physician-reported reason for treatment discontinuation and report of any grade AEs were captured from electronic medical records. Drug combinations were aggregated into mutually exclusive treatment regimens if they contained bortezomib (BTZ), lenalidomide (LEN), pomalidomide (POM) or carfilzomib (CFZ). DOT was captured from the date of therapy initiation to discontinuation due to any reason. Regimens used as maintenance (per physician designation) were excluded from analysis.

RESULTS: There were 391 patients meeting inclusion criteria, with mean age at diagnosis being 68 years, 46.9% being ISS III and 35.5% classified as IgG. Median follow-up was 36.1 months and median lines of therapy was 4 (range 3-9). Third line median DOT (months) by aggregated treatment regimen were: BTZ = 3.7; BTZ + immunomodulatory drug (IMiD) = 3.4; LEN = 3.1; POM = 2.4; and CFZ = 1.4. The rate of discontinuation due to disease progression was: BTZ = 35.9%; BTZ + IMiD = 28.8%; LEN = 44.3%; POM = 29.4%; CFZ = 48.6%. Rate of discontinuation due to toxicity was: BTZ = 20.3%; BTZ + IMiD = 15.3%; LEN = 22.7%; POM = 23.5%; CFZ = 27.7%. Asthenia/fatigue, diarrhea and neuropathy were the most frequently reported AEs in 3rd line.

CONCLUSIONS: Real-world observed DOT was generally much shorter compared to that reported in the clinical trials. There was significant variability in the rate of discontinuation due to progression and AEs in part due to the underlying clinical heterogeneity of patients. From the payer perspective, these findings highlight the importance of incorporating not only clinical benefit (such as progression-free survival) but also real-world time on therapy and toxicity to determine costs and subsequently therapeutic value.

SPONSORSHIP: This research was funded by Novartis Pharmaceuticals.

Modeling the Budget Impact of Panobinostat for the Treatment of Relapsed/Refractory Multiple Myeloma from the Perspective of a U.S. Health Plan

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BACKGROUND: Panobinostat was approved by the U.S. FDA as a new treatment option for relapsed/refractory multiple myeloma (RRMM) patients who have received at least two prior regimens, including bortezomib (BTZ) and an immunomodulatory (IMiD) drug. Panobinostat in combination with BTZ and dexamethasone (dex) was shown to significantly improve progression-free survival (PFS) compared to bortezomib and dex alone (10.6 months vs. 5.8 months) in these patients.

OBJECTIVE: To estimate the incremental budget impact of adding panobinostat to a commercial plan and Medicare plan formulary.

METHODS: An economic model was constructed from the perspective of 1 million-member commercial and Medicare plan with a 1-year time horizon. The target population was specific to the approved panobinostat indication. Comparator regimens were those with a labeled indication or recommended by national guidelines for
use in RRMM and included: BTZ+dex; lenalidomide (LEN)+dex; LEN+BTZ+dex; carfilzomib (CFZ); CFZ+LEN+dex; and POM+dex; Costs included drug cost, administration, adverse event (AE) prophylaxis and monitoring, and grade 3/4 AEs. Duration of treatment (DOT) was standardized to a 1-year time horizon across regimens by calculating the duration of treatment needed to achieve 12 months of PFS using the ratio of the median DOT to median PFS to allow fair comparisons across treatment regimens and facilitate 1-year budget impact analysis. The panobinostat+horzob+ Dex regimen was assumed to gain 10% market share from comparator regimens. Results included incremental total cost and incremental cost per-member-per-month (PMPM). One-way sensitivity analysis was conducted to model the impact of varying each parameter ±10%.

RESULTS: The model estimates that the introduction of panobinostat will be cost neutral or cost saving from the perspective of commercial plans (-$38,078) and Medicare plans (-$280,697), equating to less than $0.001 increase in PMPM. One-way sensitivity analyses showed that the model results were dependent on the DOT and PFS parameters but robust to variation in others, with the incremental budget impact remaining cost-saving under all conditions.

CONCLUSIONS: The approval of panobinostat represents a clinically efficacious new treatment option for patients with RRMM previously treated with bortezomib and an IMiD. Due to the relatively small population size and high cost of current treatment regimens, adding panobinostat to the formulary is expected to be cost neutral.

Sponsorship: This research was funded by Novartis Pharmaceuticals.

C14 Utilization Patterns and Adherence to TKIs and PCR Testing in Patients with CML in a Regional Health Plan

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Magellan Rx Management

BACKGROUND: Health plans are seeking new management strategies to improve cost-effective quality of care in oncology. Chronic myelogenous leukemia (CML) is an oncology category that normally requires chronic treatment with oral tyrosine kinase inhibitors (TKIs); the proper choice of medication is often dependent on response to prior medications which are monitored regularly using polymerase chain reaction (PCR) testing. Poor adherence and lack of monitoring may lead to an increase in inappropriate drug utilization, waste, and poor response to therapy.

OBJECTIVE: To describe utilization patterns and adherence to TKIs and PCR testing within a regional health plan.

METHODS: Using one regional health plan’s medical and pharmacy database (approx. 700,000 lives), patients with a diagnosis code of CML who were receiving a TKI between January 1, 2013 and August 15, 2014 were identified. Total spend, TKI claims, adherence (using proportion of days covered [PDC] method), PCR and mutational analysis claims were identified for each member. Results were analyzed using descriptive statistics.

RESULTS: A total of 70 unique patients with CML receiving a TKI were identified representing $148,828 and $6,361,625 in medical and pharmacy benefit spend, respectively. Of the 1,036 TKI claims identified, 52%, 25%, 22%, and 2% were for imatinib, dasatinib, nilotinib, and ponatinib, respectively. The mean TKI PDC was 75%; however only 56% of all patients maintained a PDC of at least 85%. Average medical benefit spend was 29% higher for patients with a PDC < 85% compared to patients with a PDC ≥ 85%. Only 17% and 61% of patients were compliant to receiving PCR testing every 3 or 6 months, respectively. 11 members had switched TKIs during the study time period, but only 2 had a medical claim signifying that a mutational analysis was performed.

CONCLUSIONS: Medical and pharmacy claims data from a regional health plan demonstrate that nearly half of CML patients failed to achieve a TKI PDC ≥ 85%. Furthermore, a large proportion of CML patients are not adhering to the NCCN guideline recommendations as it relates to monitoring. Improved medication adherence and more frequent testing are necessary to assess TKI response and optimize TKI selection. A clinical program that aims to improve monitoring and adherence through patient and provider outreach is one opportunity for managed care organizations to improve quality of care in CML patients.

Sponsorship: This research was conducted by Magellan Rx Management, Newport, RI, without external funding.

C15 Assessment of Pharmacists’ Views on Biosimilar Naming Conventions

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Xcenda

BACKGROUND: On March 6, 2015, Zarxio, the first biosimilar in the United States, was approved by the U.S. Food and Drug Administration (FDA) As we gain more clarity on how this important market is going to develop, a key standing question relates to the nonproprietary naming of biosimilars, and how different stakeholders are preparing for the introduction of these new products.

OBJECTIVE: To ascertain pharmacists’ awareness of and comfort level with biosimilars, and determine the impact of identical or different non-proprietary names on pharmacists’ confidence in substituting interchangeable biologics.

METHODS: The Academy of Managed Care Pharmacy (AMCP), the American Pharmacists Association (APhA) and the American Society of Health-System Pharmacists (ASHP) fielded a survey to their membership or a partial segment of their membership. The survey consisted of two sections: (a) current processes for reporting biologics being dispensed and (b) familiarity and preferences regarding biosimilars.

RESULTS: A substantial majority (70.1%) of respondents reported regularly using National Drug Codes (NDCs) as the identifier for biologics and biosimilars. Xcenda was approved by the U.S. as a biosimilar, but only 2 had a medical claim signifying that a mutational analysis was performed.

CONCLUSIONS: Medical and pharmacy claims data from a regional health plan demonstrate that nearly half of CML patients failed to achieve a TKI PDC ≥ 85%. Furthermore, a large proportion of CML patients are not adhering to the NCCN guideline recommendations as it relates to monitoring. Improved medication adherence and more frequent testing are necessary to assess TKI response and optimize TKI selection. A clinical program that aims to improve monitoring and adherence through patient and provider outreach is one opportunity for managed care organizations to improve quality of care in CML patients.

Sponsorship: This research was conducted by Magellan Rx Management, Newport, RI, without external funding.
**SPONSORSHIP:** The study instrument was developed in collaboration with AMCP and Xcenda. Analysis and write-up of study was conducted by Xcenda without any external funding.

**D01** Thromboembolic Events and Associated Costs in Hydroxyurea-Treated Patients with Polycythemia Vera

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**BACKGROUND:** Polycythemia vera (PV) is a rare myeloproliferative neoplasm, associated with an increased risk of thromboembolic events (TE). Treatment goals include reducing this risk, with hydroxyurea (HU) being the most common first-line cytoreductive agent.

**OBJECTIVE:** To describe the occurrence of thrombotic events (TE) and associated costs among adults with PV who are treated with HU in the U.S.

**METHODS:** Adults (aged ≥ 18 years) with PV (ICD-9 code 238.4x) who initiated HU (index event) between 2005 and 2012 were identified in the Truven Health MarketScan Research Databases. Patients were required to have continuous enrollment for 6 months pre- and 12 months post-index. TE rate and all-cause healthcare resource utilization and costs were described during the 12-month follow-up period.

**RESULTS:** Among the 1,322 HU-treated PV patients, the mean age was 66.0 years (SD = 13.3), 48.7% were female, the average baseline Deyo Charlson Comorbidity Index Score was 0.65 (SD = 1.16), and 14.0% of HU patients had a TE in the year prior to HU initiation. Among the HU-treated patients, 16.3% had a TE in the year following HU initiation, 44.9% of whom had a history of TEs. Mean baseline Deyo Charlson comorbidity index score was higher for patients with TE than those without (1.13 vs. 0.73, P < 0.001). Mean post-index total annual costs were higher for patients who had a TE compared to patients who did not have one ($45,039 vs. $16,438, P < 0.001). This increase was seen within each healthcare cost component (inpatient: $18,952 vs. $4,794, P < 0.001; ER: $495 vs. $285, P = 0.012; outpatient pharmacy: $5,244 vs. $3,598, P = 0.017; outpatient office: $1,953 vs. $1,446, P < 0.001; outpatient lab: $1,660 vs. $993, P < 0.001; outpatient radiology: $2,413 vs. $858, P < 0.001; other outpatient: $14,324 vs. $4,465, P < 0.001). Patients with TE were more likely to have an ER visit or inpatient stay than those without a TE during the follow-up period (ER: 48.2% vs. 26.3%, P < 0.001; Inpatient: 50.9% vs. 18.4%, P < 0.001).

**CONCLUSIONS:** Despite treatment with HU, a considerable number of patients experienced TEs. While the overall healthcare costs for PV patients were substantial, having thromboembolic events was associated with an approximately three-fold increase in healthcare costs and increased healthcare resource utilization.

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

**D02** Real-World Dosing and Patient Characteristics of rFIXFc in Hemophilia B Patients

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**BACKGROUND:** Regular replacement of coagulation factor IX (FIX) to prevent bleeding is the standard of care in hemophilia B and requires frequent intravenous infusions (≥ 2 times per week). Recombinant factor IXFc fusion protein (rFIXFc) has been on the market for one year and real-world data describing prophylactic dosing regimens of recombinant FIX (rFIX) are limited.

**OBJECTIVE:** To analyze real-world rFIXFc patient characteristics and treatment interval patterns in patients with hemophilia B based on specialty pharmacy dispensing records.

**METHODS:** A retrospective analysis was conducted using aggregate Specialty Pharmacy Provider (SPP) records from May 2014 through March 2015. SPP data included 63 different attributes for each prescription, including trade name, national drug code, quantity shipped, prescribed infusion dose, days supplied, and dose frequency. Patients were considered eligible for the analysis if they received at least one shipment of rFIXFc for a prophylactic treatment regimen. Patients were excluded from the analysis if they were receiving episodically, for immune tolerance induction, or pharmacy records did not specify a prescribed infusion dose frequency. Patients were categorized according to their age and dosing interval.

**RESULTS:** The analysis included 313 hemophilia B patients, regardless of severity, that received at least one shipment of rFIXFc with a median age of 23 (range: 1-77) and median weight of 70 kg (range: 8-168 kg). 3.4% percent of dispensing records were for patients less than 6 years of age, 32.3% were between 6 and 17 years of age, and 64.3% were 18 years or greater. Ninety-three percent of all patients had a dosing frequency of once weekly or longer. Of the patients receiving rFIXFc that had previous rFIX dispensing records, the most common rFIX dosing frequency was twice per week. The majority of patients previously on prophylaxis regimen with a rFIX dosing frequency of two times per week had a decreased number of prophylactic infusions per week on rFIXFc; 77.8% of patients reduced infusion frequency to once weekly, 11.1% of patients reduced infusion frequency to every 10 days.

**CONCLUSIONS:** Current SPP dispensing records demonstrate that rFIXFc is being used in a broad patient population based on age range. Patients with hemophilia B in the U.S. may experience reductions in FIX infusion frequency when they switch to rFIXFc, with conversion to an infusion frequency once weekly as the most common treatment regimen.

**SPONSORSHIP:** Biogen.

**D03** The Use of Pain Medication in Patients Diagnosed with Hemophilia

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**BACKGROUND:** More than 50% of hemophilia patients have painful joints that cause disability and impair quality of life. Many of these patients have chronic pain that is often the result of joint degeneration or other long-term complications of bleeding disorders. Little is known about the type of medications hemophilia patients are taking for their pain. This is important to consider because there is an epidemic of opioid abuse in the United States (U.S.) today. When pain is treated with opioids, there is a potential for opioid dependence, misuse and abuse.

**OBJECTIVE:** To assess the types of pain medications hemophilia patients are utilizing to treat their pain in the United States.

**METHODS:** We collected and analyzed over 722 records for hemophilia patients between January 2013-May 2015 from a unique database of U.S. physician-patient interactions (RealHealthData). All patients diagnosed with hemophilia, regardless of severity, and with presence of pain or pain medications noted in their record were included in the analysis. Using descriptive statistics, we analyzed these records to assess medications patients are taking including: opioids, non-steroidal anti-inflammatory drugs (NSAIDs) and over-the-counter medications (OTCs).
RESULTS: A total of 627 hemophilia patients were included in the analysis. The average age was 32 years (± 5.6 SD), the majority of patients (94%) were prescribed an episodic factor treatment regimens. Of the 627 records included, 212 (34%) patients were prescribed opioids. The most common opioids prescribed were: hydrocodone (15.1%), oxycodone (9.7%), morphine (4.1%), codeine (3%). Of the 35 (5.5%) records for prescribed NSAIDs, the most common NSAIDs were diclofenac (31%), meloxicam (31%) and celecoxib (31%). Of the 167 (5.5%) who reported using OTC medications, the most common medications included: ibuprofen (45%) and acetaminophen (43%).

CONCLUSIONS: Monitoring and treating chronic pain is a common aspect of hemophilia patient management. Of the patients with a presence of pain or pain medication, approximately one-third of patients are prescribed opioids. Prescribed NSAIDs and OTCs are being used less frequently. Their chronic use of any of these medications may contribute to additional side effects and tolerability issues. Therefore, further research is required to determine the potential implications of pain management medication use in the hemophilia patient population.

SPONSORSHIP: Biogen.

D05 Systematic Review of Erythropoietin-Stimulating Agents and Iron Supplementation Usage in Anemia Management Post Implementation of the Prospective Payment System

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BACKGROUND: The prospective payment system (PPS) of 2011 has brought about cost saving measures in ESRD patients. Compounded with changing FDA guidelines regarding erythropoiesis-stimulating agents (ESA) and uncertainty in optimal IV iron usage, anemia management has been a dynamic process.

OBJECTIVE: To examine changes in anemia management related to ESA and iron supplementation for dialysis patients post introduction of the PPS. Anemia management measures such as transfusions and hemoglobin (Hgb) levels were also collected and reviewed.

METHODS: This systematic review involved a comprehensive search of the literature utilizing the following electronic databases: NLM, Science Direct, and Web of Science. To examine potential trends post PPS, date range chosen was January 1, 2011 to June 1, 2013. Search terms used were “PPS” and either “iron” or “ESA.” Abbreviations were expanded in the search. Study inclusion criteria were based on the degree of relation to ESRD patients undergoing dialysis treatment through Medicare. Exclusion criteria included review or editorial articles and studies outside of the U.S.

RESULTS: The majority of the studies suggest a decrease in ESA use post PPS. Studies included the use of epoetin or darbepoetin and showed a decrease in ESA usage ranging from a reduction of 38% to 4.6%. Iron supplementation in contrast has increased post PPS. Transfusion values were absent in more than half of the studies, but for those with data there was a consistent trend of increased transfusions post PPS. In addition, reported Hgb levels dropped accordingly which was due to the FDA’s suggested reduction in Hgb level with ESA use. To find meaningful correlations between the studies reviewed, each study was categorized based on each respective sample population from varying facilities. Viewing this subset of studies together, the national trend can be strengthened from the multiple studies of different time periods after PPS. Out of this subset of studies, all but one confirmed the trend of higher iron use and lower ESA usage. The remaining studies were categorized by different facility types, but nonetheless reiterated a similar trend.

CONCLUSIONS: The PPS has had a major role in dictating the course of anemia management in ESRD patients. The evidence for specifically quantifying transfusion and Hgb levels post PPS implementation was limited, but still demonstrated a common theme of increased transfusion and decreased Hgb levels. Anemia management within managed care settings will further be developed to reduce potential transfusions through better control of Hgb levels.

SPONSORSHIP: None.

D06 Budget Impact Analysis of Ibrutinib for Patients with Previously Treated Chronic Lymphocytic Leukemia

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BACKGROUND: In the U.S. in 2015, there will be an estimated 14,620 incident cases and 4,650 deaths due to chronic lymphocytic leukemia (CLL). Even though survival in CLL is estimated to be around 10 years after failing initial therapy, limited therapeutic options are available. Ibrutinib was recently approved for CLL and recommended by the NCCN (Category 1) for patients who have received at least one prior therapy.

OBJECTIVE: This analysis examined the estimated budget impact of ibrutinib in a hypothetical 1-million member U.S. health plan over 1 year.

METHODS: An Excel-based budget-impact model was developed. Comparators included FDA-approved and Category 2A NCCN-recommended regimens for previously-treated CLL. Dosing, administration, mean duration of therapy (DOT), and adverse event (AE) rates 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. AE costs were based on AHRO H-CUP data and published literature. The estimated treatment-eligible population was based on epidemiologic data and a large, claims database analysis. The market share was estimated for each treatment with and without ibrutinib. 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 119 previously-treated CLL patients for a 1-million member health plan. The 1-year incremental budget impact of adopting ibrutinib for previously-treated CLL patients was $225 PTMPM, or $0.027 PMPM. The model results were most sensitive to ibrutinib DOT, followed by ibrutinib market share, and treated population ≥ 65 years.

CONCLUSIONS: The model results indicate that the budget impact of ibrutinib 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 ibrutinib in this orphan disease with high unmet need.

SPONSORSHIP: This research was funded by Janssen Scientific Affairs.

D08 Beyond the Label: Real-World Dosing Variability of rFVIII-Fc Using U.S. Specialty Pharmacy Dispensing Data

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BACKGROUND: With the introduction of extended half-life (EHL) rFVIII-Fc for hemophilia A patients, there has been much debate (1-4) regarding the transition of on-label dosing recommendations to
real-world dosing of individuals. Current recommended product label dosing for prophylaxis with rFVIII-Fc is every 4 days, with a starting dose of 50 IU/kg, and adjusted to 25-65 IU/kg at 3-5 day intervals based on patient response (5). An analysis of real-world dosing variability from what is recommended on the product label is explored.

**OBJECTIVE:** (a) To estimate real-world dosing regimens of patients on rFVIII-Fc, and (b) To understand the proportion of patients who remain on the product label starting dose (50 IU/kg).

**METHODS:** Retrospective analysis using national U.S. specialty pharmacy dispensing databases from January 1, 2013 to April 25, 2015 of individuals with Hemophilia A (ICD-9 code 286.0) prescribed rFVIII-Fc. Included patients had ≥ 30 days of prescription and weight (kg) data available. Using the most recent prescription claim, the median dose and percentage of patients above the recommended rFVIII-Fc product label starting dose of 50 IU/kg were reported by regimen frequency. First and last fill were also analysed to understand dosing optimization patterns.

**RESULTS:** Sixty-nine patients prescribed rFVIII-Fc were included in this analysis. The most frequent regimens prescribed were 2×/week (33%) or every 4 days (33%); with the rest at 1×/week (10%), 3×/week (6%), every 3 days (7%), and every 5 days (9%). Across all 69 patients, the median monthly dose on first prescription was 384 IU/kg/30 days; the last prescription claim increased to a median dose of 401 IU/kg/30 days. The percentage of patients above the product label starting dose of 50 IU/kg was 20.8% for 2×/week, 60.0% for every 3 days, 39.1% for every 4 days and 66.7% for every 5 days.

**CONCLUSIONS:** While the availability of EHL products provides hemophilia A patients an option for less frequent infusions, our findings demonstrate that EHL regimens and dose ranges can be highly variable, with many patients requiring FVIII-Fc treatment above the targeted 50 IU/kg dose. This analysis provides initial real-world data for EHL therapy and may be helpful in decision makers’ understanding of the utilization of EHL rFVIII-Fc in hemophilia A.

**SPONSORSHIP:** Baxalta U.S.

**D09 Real-World Analysis of Costs for Hemophilia B Individuals Who Switched from rFIX to rFIX-Fc Using U.S. Specialty Pharmacy Dispensing Data**

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**Baxalta**

**BACKGROUND:** Until recently, the hemophilia B community has only had standard Factor IX (rFIX) products as treatment choices. With the availability of extended half-life rFIX-Fc, there has been much debate (1-4) regarding clinical and cost expectations, balanced with optimizing use in patients. To level the debate, an understanding of real-world prescription costs of patients who switch to rFIX-Fc products is warranted.

**OBJECTIVE:** (a) To characterize patients who switch from rFIX to rFIX-Fc, and (b) to understand their change in factor costs.

**METHODS:** Retrospective analysis using national U.S. specialty pharmacy dispensing databases from January 1, 2013 to April 25, 2015 of hemophilia B (ICD-9 code 286.1) individuals who switched from rFIX to rFIX-Fc. Descriptive statistics were used to summarize patient characteristics. Patients who had ≥90 days of prescription coverage on each product were included. Utilization was averaged on a monthly basis pre and post switch for individuals who remained on a similar regimen post-switch. Cohorts were characterized as prophylaxis to prophylaxis (P to P) or on-demand to on-demand (OD to OD). Costs were calculated by multiplying the units utilized by the U.S. wholesale acquisition price for each product (RedBook) and the percent change in cost from rFIX to EHL-rFIX was compared.

**RESULTS:** Sixteen switchers were included in the study. Switchers were 62.5% severe, 12.5% moderate, 6.25% mild, and 18.75% were of unknown severity. The P to P cohort comprised the majority of patients at 87.5% (n=14) while OD to OD were smaller at 11% (n=2). The median ages for these cohorts were similar: P to P median age was 15 (range: 5-51) and OD to OD was 14 (range: 13-19). Median prescription costs increased in the P to P cohort by 40% (range: -56% to +181%), while OD to OD increased by 173% (range: 1% to 348%).

**CONCLUSIONS:** While the availability of rFIX-Fc provides hemophilia B patients an option with less frequent infusions, our findings demonstrate that for those who initially switched from prophylaxis to prophylaxis or from on-demand to on-demand regimens, costs increased for the majority of patients. This analysis provides initial real-world cost data that may be helpful in decision makers’ evaluation of switching hemophilia B patients to rFIX-Fc.

**SPONSORSHIP:** Baxalta U.S.

**D10 Patient Outcomes Collected During Home Infusion of IVIg to Improve Care and Cost Utilization for a Single Managed Care System**

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**Axelacare Health Solutions**

**BACKGROUND:** The ability to control costs and prove effectiveness of expensive specialty infused therapies is hampered by the lack of objective clinical outcomes data and low frequency of visits to specialists who can appropriately assess and optimize therapy.

**OBJECTIVE:** Data collected from CareExchange for IVIg patients across several disease states were analyzed for one managed care system. Cost of therapy, savings based on clinician therapy management, and potential savings were analyzed retrospectively.

**METHODS:** CareExchange was developed to capture and integrate pharmacy, infusion nursing, and patient outcomes data surrounding IVIg therapy for Neurology (Chronic Inflammatory Demyelinating Polynévropathy (CIDP), Peripheral Neuropathy (PN), Myasthenia Gravis (MG), and others) and Immunology patients (Primary Immunodeficiencies (PIDD)). We analyzed Patient Reported Outcomes Measures (PROMs), physical and nurse assessments, cost utilization, nursing notes, and any clinical provided by the treating physician during the course of IVIg therapy patients receiving IVIg with sufficient CareExchange data to analyze for a single managed care system. These 16 patients included 9 CIDP, 2 PIDD, 3 MG, 1 Idiopathic PN, and 1 Inflammatory and Toxic Neuropathy.

**RESULTS:** We found 5 patients with good physician attention to CareExchange data and management and optimization of IVIg therapy. Of those 5, 2 were considered non-responders and subsequently taken off IVIg, 2 were responders and IVIg was titrated down and stopped, and 1 had their IVIg optimized and is currently IVIg dependent. Of the remaining 11, 6 showed the need for dose titration, 3 were moved to other services, and 2 showed no signs of IVIg benefit, but were still receiving IVIg. We estimated the annualized drug spend across the analyzed population of $1.6MM, or approximately $100k/patient.

**CONCLUSIONS:** Using CareExchange and other clinical tools, we were able to appropriately review the clinical findings which resulted in physician interventions, demonstration of improved patient outcomes, and aided the treating physician in determining the optimal and appropriate use of IVIg therapy. With the use of CareExchange,
we found that there was an estimated CareExchange savings of $430k (21%) from the estimated $2.03MM or $127k/year/patient, and the potential for an additional $600k (30%) savings with full implementation of CareExchange for this group.

SPONSORSHIP: AxelaCare Health Solutions.

E01 HbA1c Reduction, Medication Adherence, Treatment Patterns, and Costs in Patients with Type 2 Diabetes Mellitus Initiating Second-Line Antihyperglycemic Therapy After Metformin Monotherapy

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BACKGROUND: Type 2 diabetes mellitus (T2DM) treatment guidelines recommend the addition of one or more antihyperglycemic agent (AHA) classes such as sulphonylureas (SU), thiazolidinediones (TZD), dipeptidyl peptidase-4 (DPP-IV) inhibitors, glucagon-like peptide-1 (GLP-1) agonist, or insulin after failure to control HbA1c with metformin alone. HbA1c reduction, adherence, and costs associated with these AHAs, as well as patients’ characteristics are important aspects in selecting an appropriate second-line agent.

OBJECTIVE: The objectives of this analysis are to characterize patients initiating a second-line AHA, and to describe HbA1c reduction, medication adherence, treatment patterns, and costs in patients treated with these agents.

METHODS: Linked EMR-administrative claims data were used to identify patients ≥ 18 years diagnosed with T2DM, initiating second-line AHAs (SU, TZD, DPP-IV, GLP-1, or insulin) at least 60 days after metformin therapy during January 1, 2006 and December 31, 2012. Patients were followed from second-line therapy initiation date to the earliest of discontinuation, switch, augmentation, health plan disenrollment, or the end of one year. Medication adherence was measured using proportion of days covered (PDC). Reduction of HbA1c was calculated as the difference between the average HbA1c during the follow-up period and the last observed baseline HbA1c.

RESULTS: Of 3,908 eligible patients, 1,841 (47%) initiated SU, 1,149 (29%) DPP-IV, 361 (9%) TZD, 316 (8%) GLP-1, and 241 (6%) insulin as second-line therapy, with average age 53.8 years, 48.3% female, and 64.5% white. The insulin cohort had the highest baseline Charlson Comorbidity Index score (2.5; other cohorts: 1.7-1.9), and the highest baseline HbA1c (9.1; other cohorts: 7.3-8.2%), and was associated with the largest reduction in HbA1c (2.2%; other cohorts: 0.7-0.9%). The insulin and DPP-IV cohorts had the lowest (33%) and highest (59%) PDCs, respectively, and the highest (56%) and lowest (27.6%) proportions of discontinuation, respectively. The insulin cohort had the highest mean monthly follow-up diabetes-related costs ($540; other cohorts: $111-374) and all-cause costs ($3,467; other cohorts: $1,138-$1,611).

CONCLUSIONS: The results of this descriptive study suggested that insulin was given to the most severe T2DM patients as a second-line antihyperglycemic therapy, and was associated with the greatest reduction in HbA1c. However, insulin also had the lowest adherence, highest discontinuation rates, and highest follow-up costs. To validate the above findings, future studies would need to control for baseline heterogeneity across cohorts.

SPONSORSHIP: Boehringer Ingelheim.

E02 Effect of a Patient Decision Aid for Type 2 Diabetes on Patient Knowledge, Decisional Conflict, and Self-efficacy

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BACKGROUND: Patient decision aids (PDA) are evidence-based tools designed to support shared-decision making. The American Diabetes Association recommends that when considering T2DM medication intensification, providers should use a patient-centric approach assuring patient understanding of options and considering patient preferences. Aligning patient preferences with treatment may improve adherence and outcomes. However, patients are often unaware they have a choice, leading to ineffective or delayed decisions.

OBJECTIVE: To determine the impact of a newly developed PDA on knowledge of T2DM treatment options, difficulty in choosing among options (decisional conflict) and self-confidence in decision-making ability, including shared decision-making participation. The PDA delivers content online regarding medication choices, clarifies patient values related to options, and enables treatment preference expression.

METHODS: A randomized trial was conducted in which patients treated in U.S. primary care or endocrinology clinics from April 2014-March 2015 either used the PDA or received usual care (UC) to support medication decision-making. Included were English-speaking adults with T2DM advised by their physician to consider addition of medication to metformin-containing regimens to improve glycemic control. Main outcome measures were patient knowledge about medication options, the Decisional Conflict Scale (DCS) and the Decisional Self-Efficacy Scale (DSES). Twenty-seven clinics participated. Of 363 patients screened, 225 met criteria and agreed to participate. Of these, 114 were randomized to use the PDA, and 111 received UC.

RESULTS: Overall, patients had a mean [SD] age of 52 [±12] years, had been diagnosed with T2DM for 6 [6] years and 102 [45%] were male. In intent-to-treat analysis, compared to UC, PDA users had significantly larger knowledge gains (11.0 [12.8] vs. 1.6 [8.9]; P < 0.0001) and improvements in both decisional conflict (-2.2 [2.0] vs. -7.5 [16.6]; P < 0.0001) and self-efficacy (3.7 [16.7] vs. -3.9 [19.2]; P < 0.0001) within 6 weeks of enrollment. The mean DCS score among PDA users at final follow-up was <25 (2.3 [14.3]), the threshold below which correlates with effective decision implementation.

CONCLUSIONS: This PDA supports patient-centric care and improves knowledge, reduces decisional conflict and improves self-efficacy. This readily accessible online PDA is designed to be easily incorporated into clinical practice, which may be important as payers transition to fee-for-value compensation. This PDA can help providers better communicate treatment options to T2DM patients and promote shared decision making.

SPONSORSHIP: This research was sponsored by Janssen Scientific Affairs.

E06 Development of the Quality Population Analyzer: Tool for Health Systems (QualityPATH)

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BACKGROUND: In the United States approximately 21 million Americans have diagnosed diabetes at a cost of $245 billion per year. Additionally, over 50% of the lifetime medical costs are attributable to treating diabetic complications in type 2 diabetes (T2D) patients. Quality measure reporting is used to improve healthcare
quality in a variety of ways and are informing payment models and driving care delivery.

**GOAL:** The objective of this project was to develop a software analyzer tool that allows organizations to review T2D data from a quality metrics perspective.

**PROGRAM DESCRIPTION:** The software tool was designed to identify gaps in care based on retrospective pharmacy and medical claims analysis. Reference data from a large commercial managed care population (Optum Clininformatics Data Mart database) was incorporated to allow users to quickly compare plan demographics, antihyperglycemic agent utilization, resource utilization, and adherence to quality measures. At the beginning of the development process we engaged advisors in payer organizations to provide guidance on the content and functionality. Usability, functionality, and quality assurance testing was completed throughout the process with numerous internal and external users providing direct feedback.

**OBSERVATIONS:** QualityPATH uses an organization’s pharmacy and/or medical claims to evaluate their T2D practice patterns and compares it to the reference population. There were 482,779 subjects included in the reference population and the mean age was 54.4 years. Approximately 80% had a Diabetes Complications Severity Index score of 0 and 78% had no hospitalization. The most prevalent comorbidities were hyperlipidemia (72%), hypertension (69%), cardiovascular disease (14%), and neuropathy (11%). Over 60% of the population was treated with a noninsulin antihyperglycemic agent and 41% were classified as adherent (PDC > 80%). In addition to providing customized population-level data, the analyzer has the functionality to provide patient- and provider-level reports to identify opportunities to develop interventions that promote quality improvement, increased adherence to quality measures, and potentially decrease healthcare resource utilization.

**FINDINGS/RECOMMENDATIONS:** The open-source, user-friendly tool provides descriptive and actionable measures at the patient, provider, and health plan levels. QualityPATH offers meaningful insights to pharmacy, medical, and quality improvement directors and may assist organizations in identifying the following areas for quality improvement opportunities.

**SPONSORSHIP:** This project was sponsored by Janssen Scientific Affairs.

**E08** Treatment Intensification for Patients with Type 2 Diabetes Mellitus with Poor Glycemic Control

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**BACKGROUND:** The European Association for the Study of Diabetes and the American Diabetes Association (EASD/ADA) treatment guidelines call for initial metformin therapy for most patients with type 2 diabetes mellitus (T2DM), followed by treatment intensification if there is failure to reach glycosylated hemoglobin (HbA1c) goals in 3 months. Many patients do not receive treatment intensification in a timely manner, despite such recommendations.

**OBJECTIVE:** Using a large U.S. insurance claims database, a retrospective cohort study was conducted to identify the time to and patient characteristics associated with treatment intensification in a U.S. real-world population.

**METHODS:** Patients aged ≥18 years with a T2DM diagnosis and on metformin therapy were identified. Treatment failure was defined as the first HbA1c≥8% (index date) after at least 3 months of metformin therapy between January 1, 2009 and December 31, 2012. Patients were required to have continuous enrollment for ≥12 months before (baseline) and after the index date, no diagnosis of type 1 diabetes or secondary or gestational diabetes, and no prescription for any injectable antidiabetes medications (insulin, GLP-1 RA, or amylin). Treatment intensification was defined as patients filling a prescription for injectable or additional oral antidiabetes drugs (OADs). Cox modeling was performed to identify factors associated with time to treatment intensification.

**RESULTS:** Of the 11,525 patients meeting inclusion criteria, mean age at index date was 57 years and 40% were female, and mean index HbA1c was 9.1%. 37%, 11%, and 52% of patients intensified within 6 months, between 6-12 months, or not intensified during the 12-months follow-up period, respectively. Time to treatment intensification was significantly longer among patients taking combination therapy compared to those taking metformin monotherapy within 3 months before the index date (HR=0.78 and 0.68 for metformin...
with 1 OAD and metformin with 2+ OADs, respectively, \( P < 0.0001 \), after adjusting for other demographic and clinical characteristics. Higher index HbA1c (HR = 1.18 and 1.41 for ≥ 9-10% and ≥ 10% relative to ≥ 8-9%, respectively, \( P < 0.0001 \)), number of outpatient visits (HR = 1.005 per additional visit, \( P = 0.002 \)), and lipid-lowering medication use (HR = 1.09, \( P = 0.009 \)) at baseline are significantly associated with earlier intensification.

**CONCLUSIONS:** Less than half of T2DM patients with treatment failure received intensification with injectable or additional OADs within 12 months in a real-world U.S. population. Factors associated with treatment intensification can be used to improve clinical care of these patients.

**SPONSORSHIP:** AstraZeneca.

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**E10** Estimating the Pharmacy Budget Impact of Adding Technosphere Insulin Inhalation Powder to Treatment Regimens for Patients with Type 2 Diabetes Mellitus

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**BACKGROUND:** Technosphere insulin (TI) inhalation powder is a new, fast-acting inhaled insulin for the treatment of adult patients with diabetes. The use of TI offers an important option for diabetes treatment intensification, particularly for patients with high barriers to initiation and adherence to insulin.

**OBJECTIVE:** To estimate the budget impact of adding TI for treating type 2 diabetes mellitus (T2DM) versus alternative therapies from a U.S. payer’s perspective.

**METHODS:** A 3-year pharmacy budget impact model was developed for a hypothetical U.S. health plan with 1 million members to estimate the cost of adding TI versus alternative treatments (injectable rapid-acting insulins [RAIs], premixed insulins, GLP-1 receptor agonists). Epidemiology and treatment pattern data were derived from published literature and analysis of payer administrative claims database. The model focused on acquisition costs, which were based on the wholesale acquisition cost (WAC), dosage, and co-payment in 2014. Costs of previous-line treatments and dispensing fees were considered identical; rebates and pt adherence were considered 0% and 100%, respectively. Medical costs associated with safety and efficacy profiles were not considered. Sensitivity analyses were also conducted for the proportion of patients using TI, the proportion of poorly controlled patients, the units/day of TI, and the WAC of TI. Three pt populations were identified as eligible to be treated with TI and included in the modeling: (a) T2DM patients poorly controlled with ≥ 2 oral antidiabetes drugs (OADs) (29.7% of patients; 73.3% poorly controlled); (b) T2DM patients poorly controlled with basal insulin + OADs (18.9% of patients; 75% poorly controlled); and (c) T2DM patients poorly controlled with basal insulin + RAI (3.3% of patients; 84.5% poorly controlled). Patients with contraindications to TI (asthma, COPD, other lung conditions, and smokers) were excluded.

**RESULTS:** Among plan members, 24,234 patients were eligible for TI treatment. Assuming 0.52% of the eligible population add-on TI over 3 years (0.06% in Year 1, 0.35% in Year 2, and 0.52% in Year 3), taking equal pt proportions from the comparator treatments, the estimated budget impact was $72,463, $221,518, and $316,720 in Year 1, Year 2, and Year 3, respectively, totaling $610,701 over 3 years. This corresponded to a budget impact per member per month of $0.01, $0.02, and $0.03 in Year 1, Year 2, and Year 3, respectively. Results were robust across the sensitivity analyses.

**CONCLUSIONS:** This budget impact model suggests that using TI in T2DM patients who need to add a RAI to OADs or injectable insulin will only have a marginal budget impact to U.S. health care payers.

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

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**E11** The Impact of Hypoglycemia on Health Care Use and Costs in Type 2 Diabetes Mellitus Elderly Patients Newly Initiated on Basal Insulin

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**BACKGROUND:** A quarter of adults aged ≥ 65 years are diagnosed with diabetes in the U.S. Due to the progressive nature of type 2 diabetes
mellitus (T2DM), effective glycemic management may require basal insulin. Hypoglycemia is an adverse event commonly associated with basal insulin, and may negatively impact clinical outcomes, and health care use and cost.

OBJECTIVE: This retrospective cohort study assessed health care use and costs in T2DM elderly patients who experienced hypoglycemia soon after starting basal insulin.

METHODS: T2DM patients (aged ≥65 years) who started basal insulin (defined as having no insulin prescription ≥ 12 months before starting insulin glargine, insulin detemir, or NPH insulin) between January 2008 and August 2012 were identified in the IMPACT claims database. Hypoglycemic events were based on health care encounters with ICD-9-CM diagnosis codes for hypoglycemia within the first 6 months of basal insulin use. Data were assessed for patients with a 12-month baseline and ≥ 6-month follow-up period after insulin initiation. Statistical significance of differences in characteristics between patients with hypoglycemia and those without was evaluated with Chi-square for categorical variables and student t-test for continuous variables. Health care costs were adjusted for baseline characteristics with the generalized linear model.

RESULTS: Of the 12,213 patients identified, 787 (6.4%) had hypoglycemia in the first 6 months. These patients more likely experienced hypoglycemia at baseline (27.2% vs. 6.7%, P<0.001), had a small difference of age (mean: 72.2 vs. 71.2 years, P<0.001), had more severe comorbidities (Charlson Comorbidity Index: 2.89 vs. 2.04, P<0.001), and had more all-cause hospitalizations (51.8% vs. 37.7%, P<0.001) than those without hypoglycemia. During follow-up, patients with hypoglycemia versus those without, had a greater average quarterly incremental health care use (all-cause hospitalizations: 0.34 vs. 0.17, all-cause emergency department [ED] visits: 0.50 vs. 0.25, diabetes-related hospitalizations: 0.26 vs. 0.11, diabetes-related ED visits: 0.31 vs. 0.11, all P<0.001). Average quarterly incremental costs were greater for patients with hypoglycemia versus those without (all-cause: $8,913 vs. $6,205, diabetes-related: $3,586 vs $1,974, both P<0.001). For the subset of 9,277 patients with ≥12-month follow-up, annual health care costs were greater for patients with hypoglycemia versus those without (all-cause: $34,422 vs. $24,791, diabetes-related: $14,355 vs. $8,146, both P<0.001).

CONCLUSIONS: Hypoglycemia was seen in 6.4% of T2DM elderly patients within 6 months of basal insulin initiation and was associated with greater health care resource use and costs.

SPONSORSHIP: Study funding and editorial support was provided by Sanofi US.

E12 Comparison of Long-term Adherence and Persistence Between Adults with Type 2 Diabetes Initiating Saxagliptin or Linagliptin

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BACKGROUND: Saxagliptin (SAXA) and linagliptin (LINA) are two dipeptidyl peptidase-4 enzyme inhibitors (DPP-4i), a class of oral antidiabetic medication used to treat type 2 diabetes mellitus (T2D).

OBJECTIVE: To compare adherence and persistence between T2D patients in the U.S. initiating SAXA or LINA in the 1 year and 2 years following initiation.

METHODS: This observational, retrospective cohort study was conducted in the MarketScan Commercial and Medicare Supplemental Databases. Adults with T2D who initiated SAXA or LINA between January 1, 2008 and January 31, 2012 were identified. Patients were required to meet the following criteria: continuous enrollment in the 1 year prior to initiation with no claims for a DPP-4i medication, continuous enrollment in the 1 year following initiation, and no diagnoses for type 1 diabetes or gestational diabetes. A subset of patients had 2 years of continuous enrollment following initiation. Adherence was measured as proportion of days covered (PDC) and PDC≥0.80 was considered adherent. Persistence was measured as the time from initiation to discontinuation, defined as the end of days’ supply prior to a 60-day gap without medication. Multivariable logistic regression models were fit to compare odds of being adherent between the two cohorts and multivariable Cox proportional hazards models were fit to compare hazards of discontinuation.

RESULTS: There were 21,599 SAXA initiators and 5,786 LINA initiators identified (mean ages 55 and 57 years; 53% and 54% male, respectively). Of those, 12,215 SAXA initiators and 1,974 LINA initiators had 2 years of follow-up. A significantly larger proportion of SAXA initiators were adherent to initiated drug over the 1-year (45.9% vs. 42.4%, P<0.001) and 2-year period (36.2% vs. 33.1%, P=0.008) following initiation and a significantly smaller proportion discontinued therapy (1-year: 46.8% vs. 50.9%, P<0.001; 2-year: 66.2% vs. 70.9%, P<0.001). Correspondingly, in models controlling for patient characteristics, SAXA patients had significantly greater odds of being adherent over the 1-year follow-up (adjusted odds ratio [AOR] = 1.21, 95% confidence interval [CI] 1.14-1.29, P<0.001) and had significantly lower hazards of discontinuation (adjusted hazard ratio [AHR] = 0.89, 95% CI 0.85-0.93, P<0.001). Results were consistent over the 2 years following initiation (AOR of being adherent = 1.18, 95% CI 1.06-1.31, P=0.002; AHR of discontinuation = 0.88, 95% CI 0.83-0.93, P<0.001).

CONCLUSIONS: Among adults with T2D in the U.S. who initiated a DPP-4i, initiation of SAXA was associated with better adherence and persistence compared with initiation of LINA.

SPONSORSHIP: This study was funded by AstraZeneca.
**RESULTS:** Hemoglobin A1c (HbA1c) and estimated glomerular filtration rate (eGFR) for patients visiting an endocrinologist during baseline was higher for the SGLT-2i cohort, the most common comorbidities were dyslipidemia (84.1%), hypertension (78.1%), and microvascular complications (22.1%). Rates were similar for GLP-1RAs (82.1%, 77.7%, and 23.8%) and DPP-4is (79.0%, 76.8%, and 20.5%), but lower for SUs (74.2%, 74.2%, and 22.1%). Rates were similar for GLP-1RAs (82.1%, 77.7%, and 23.8%) and hypertension (78.1%), and microvascular complications (22.1%). Rates were lower for SGLT-2is (79.0%, 76.8%, and 20.5%), but higher for DPP-4is (84.1%). The percentage of patients with HbA1c ≥ 8% before initiation was 50.9% for SGLT-2is, which was less than that of GLP-1RAs at 54.4% but greater than that of other classes: range 27.3% for metformin to 45.7% for DPP-4is. In the SGLT-2i cohort, 91.7% of patients had eGFR values ≥ 60; 97.7% had eGFR values ≥ 45.

**CONCLUSIONS:** SGLT-2is are prescribed to patients who tend to have prior treatment experience with approximately 2 antidiabetes medication classes and nearly all have eGFR values indicative of appropriate use in the context of renal impairment.

**SPONSORSHIP:** AstraZeneca.

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**E15 Is Lower Cost Share Related to a Higher Likelihood of Continued Home Glucose Testing?**

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**BACKGROUND:** Blood glucose testing is a key component of self-monitoring of blood glucose (SMBG) among diabetic patients with insulin regimen. However, the level of missed opportunities for testing strip use among insulin-using patients is rarely quantified. One reason for the missed opportunities may be out-of-pocket costs for testing strips, which is an added financial burden for diabetic patients who are typically on multiple medications, each subject to cost sharing.

**OBJECTIVE:** This study evaluates the relationship between cost sharing and subsequent diabetic testing strip use after index strip use.

**METHODS:** A retrospective observational study was conducted using medical and pharmacy claims data. Patient cost share was calculated as percentage of total annual testing strip costs. We compared likelihood of patients in the low cost share category (< 20%) to have ≥ 1 subsequent testing strip fill versus a high cost share group (≥ 20% of annual strip cost). We did this by fitting a log binomial model adjusting for age, gender and other variables. Estimates were interpreted as risk ratio (RR). Patient inclusion and exclusion criteria were adapted from HEDIS Comprehensive Diabetes Care guidelines. Diabetic patients on insulin medication and with ≥ 1 blood glucose testing strip prescription filled between January 1, 2010 and December 31, 2012 were included. Patients were required to have 1 year pre- and 1 year post-index continuous eligibility. The case group consisted of patients with low cost share (N = 6,953), whereas the comparison group included patients with high cost share (N = 7,012) for testing strips.

**RESULTS:** Median number of annual testing strip use for low cost share group was 600 strips versus 300 strips for the high cost share group (P < 0.001). A total of 17.3% patients had no subsequent fill for testing strips after the initial fill. Patients with lower cost share were 27% less likely to discontinue testing strip use (13.7% in lower cost share group as compared to 20.9% in high cost share group; RR: 0.73, 95% CI: 0.67-0.80, P < 0.001). Patients with more co-morbidities were less likely to discontinue testing strip use (RR: 0.95, 95% CI: 0.92-0.98, P = 0.001)

**CONCLUSIONS:** About 1 in 6 patients with initial fills of testing strip discontinued filling prescriptions for testing strips. Patients with lower cost share for testing strips were more likely to continue strip fills. The finding suggests that lowering cost-sharing for diabetic testing strips could facilitate continued use of testing strips.

**SPONSORSHIP:** Funding for the study was provided by Anthem.
E16 Use of Rapid-Acting Insulin Added to Oral Antidiabetes Drugs and Persistence Among Medicare Elderly Patients with Type 2 Diabetes Mellitus

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BACKGROUND: In clinical studies, the addition of a rapid-acting insulin (RAI) to oral antidiabetes drugs (OADs) has demonstrated benefit in terms of achieving glycemic control in patients with type 2 diabetes mellitus (T2DM). With an increasing shift towards personalized treatment of patients with T2DM, clinicians may add a RAI to OAD regimens.

OBJECTIVE: We examined the real-world utilization and persistence of RAI use among elderly patients with T2DM on OAD regimens.

METHODS: This study included patients aged ≥65 years with T2DM newly initiated on RAI added to OAD treatment between July 2007 and December 2011, who were continuously enrolled in Humana Medicare Advantage with Part D plans for 12 months. Among patients with ≥2 RAI prescriptions (RAIp) during 12-month follow-up, persistence was measured with 2 measures: Measure 1 (M1), having no 90-day gaps between RAIp during follow-up; and Measure 2 (M2), filling ≥1 RAIp every 3 months. Factors affecting RAI use and persistence were assessed with logistic regressions. All results are provided as adjusted odds ratio (AOR), 95% confidence intervals (95% CI).

RESULTS: Of 3,734 included patients, 1,400 (37.5%) had 1 RAIp during follow-up. Baseline risk factors for having 1 RAIp included: being on 1 OAD (AOR 0.72, 95% CI 0.58-0.91); being aged 70-79 years (70-74 years: 0.83, 0.70-1.00; and 75-79 years: 0.71, 0.58-0.87); living in the south (0.68, 0.53-0.88); and having non-diabetes-related complications (adapted Diabetes Complications Severity Index score 0: 0.82, 0.66-1.02). Patients with hemoglobin A1C values >8.0% (8.0-9.0%: 1.48, 1.05-2.07, and >9.0%: 1.94, 1.42-2.65), cognitive impairment (1.51, 1.23-1.85), and depression (1.25, 1.00-1.51) were more likely to have ≥1 RAIp. Among 2,334 (62.5%) patients with ≥2 RAIp during follow-up, 18.4% (M1) and 33.7% (M2) were persistent at 1 year. Those on 1 OAD (M1: 0.52, 0.38-0.71; and M2: 0.63, 0.48-0.81) and 2 OADs (M1: 0.69, 0.51-0.93) were less likely to persist than those on ≥3 OADs, as were those paying more for RAIp. Patients with prescriptions for basal insulin during follow-up were more likely to persist on RAI (M1: 1.32, 1.05-1.66; and M2: 1.33, 1.10-1.60).

CONCLUSIONS: In a retrospective database analysis of real-world practice among elderly patients with T2DM who were insulin-naive, a RAI was added to an OAD regimen. However, persistence with RAI was very poor, and alternative therapies might be needed for personalized treatment and optimum diabetes care. Our findings call for further research to understand the rationale for RAI use in elderly patients with T2DM, unmet needs, and comparative effectiveness.

SPONSORSHIP: Study funding and editorial support was provided by Sanofi US.

E18 Medication Adherence to and Treatment Patterns of Linagliptin and Sulfonylureas When Used as Second-Line after Metformin in Patients with Type 2 Diabetes Mellitus

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BACKGROUND: Medication adherence is an important aspect in the management of type 2 diabetes mellitus (T2DM). Early treatment regimen change indicates poor tolerability or efficacy. Limited knowledge exists on the adherence and treatment patterns of second-line therapy received after metformin use.

OBJECTIVE: The purpose of this study is to assess medication adherence and treatment patterns in patients with T2DM initiating linagliptin vs. sulfonylureas (SU) as second-line therapy after metformin monotherapy.

METHODS: All T2DM patients aged ≥18 years initiating either linagliptin or SU between May 1, 2011 and September 30, 2012 after at least 60 days on metformin monotherapy were identified in a large, nationwide insurance claims database. Patients were required to have 12 months continuous enrollment prior to the initiation of linagliptin or SU and were followed up to 12 months until the first treatment regimen change or disenrollment from health plan. Analyses were conducted on propensity score matched linagliptin and SU cohorts (1:1 ratio). Adherence was measured using proportion of days covered (PDC), with PDC≥80% considered adherent. Treatment regimen change was defined as the first occurrence of switch, discontinuation, or augmentation during the follow-up period. Logistic regression and cox proportional hazard model were both used to control for baseline characteristics.

E17 Rapid-Acting Insulin Persistence Among Elderly Patients with Type 2 Diabetes Mellitus New to Adding Rapid-Acting Insulin to Basal Insulin

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BACKGROUND: American Diabetes Association guidelines recommend adding a rapid-acting insulin (RAI) to basal insulin (BI) treatment in patients with type 2 diabetes mellitus (T2DM) and without adequate glycemic control in order to intensify treatment.

OBJECTIVE: Here we describe the real-world persistence of RAI use, and the associated clinical and demographic factors among elderly patients with T2DM on BI.

METHODS: The study population comprised elderly Medicare beneficiaries (aged ≥65 years) who initiated a RAI between July 2007 and December 2011, had continuous enrollment during the 6-month baseline and 12-month follow-up periods; and had ≥2 prescriptions for BI during baseline. Differences in RAI persistence (defined as 90-day gaps between RAI prescriptions) by patient characteristics were described. Factors affecting the persistence of RAI use were assessed with logistic regression. Results are provided as adjusted odds ratio (AOR), 95% confidence intervals (95% CI).

RESULTS: Of 4,979 patients, 21.1% (n = 1,052) had 1 RAI prescription during follow-up. Among those with ≥2 RAI prescriptions (n = 3,927) only 21% were persistent. Older patients (AOR 1.20, 95% CI 1.01-1.43), patients using ≥3 oral antidiabetes drugs (1.63, 1.16-2.28), patients having cognitive impairment (1.34, 1.03-1.73), and patients having hemoglobin A1C values >9.0% (1.58, 1.15-2.17) were more likely to persist. Patients with baseline emergency department visits (0.73, 0.59-0.91) and higher RAI out-of-pocket costs ($739: 0.53, 0.42-0.67; $40-74: 0.65, 0.52-0.81; and ≥$75: 0.56, 0.44-0.70) were less likely to persist. The mean (SD) A1C values were 8.64% (1.71) at baseline and 8.16% (1.50) during 1-year follow-up (n = 1,117).

CONCLUSIONS: Poor RAI persistence was observed among elderly patients with T2DM. Improving RAI persistence among elderly patients with T2DM could enhance treatment effectiveness.

SPONSORSHIP: Study funding and editorial support was provided by Sanofi US.
E19 A Cost-Consequences Analysis of Inpatient Use of Tolvaptan Among SIADH Patients with Hyponatremia

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BACKGROUND: Tolvaptan is a vasopressin-receptor antagonist used as an alternative to fluid restriction (FR) for the treatment of dilutional hyponatremia (HN) in hospitalized patients with syndrome of inappropriate diuretic hormone (SIADH). The efficacy of tolvaptan, compared to FR, as a treatment for HN was investigated in a prospective, multicenter, randomized, active-controlled, open-label trial (Gheorghiade et al., 2006).

OBJECTIVE: The objective of this cost-consequences study was to estimate the economic and health outcomes associated with tolvaptan, in comparison with FR.

METHODS: A decision-analytic model was developed from the perspective of a U.S. hospital system to estimate potential economic and health outcomes associated with tolvaptan compared to FR among hospitalized SIADH patients with HN. The model considers patients with severe (serum sodium [SS] levels <125 mEq/L) HN and patients with mild-to-moderate (SS levels ≥125 mEq/L) FR-resistant HN. Patients' response to treatment with tolvaptan, based on response rates among all hyponatremic patients reported in Gheorghiade et al. (2006), was assumed not to change with HN severity. FR-resistant patients with mild-moderate HN were assumed not to respond to treatment with continued FR. The model assumes patients' response to treatment (assessed in Gheorghiade et al., 2006) influences their health consequences: hospital length of stay, probability of an intensive care unit (ICU) admission, and probability of a 30-day all-cause hospital readmission. Health consequences data were obtained from published studies that compared patients with and without HN (Callahan et al., 2009; Deitelzweig et al., 2013).

RESULTS: Among hospitalized SIADH patients with severe HN, the model suggested that tolvaptan may yield total cost-savings of $223 per patient when compared to FR. Among hospitalized SIADH patients with mild-moderate FR-resistant HN, a total cost-savings of $966 per patient compared to continued FR. Tolvaptan drug costs were completely offset in both cases. Among hospitalized SIADH patients with severe HN, the model suggested reductions of 14.6% and 5.1% in the numbers of ICU admissions and 30-day readmissions, respectively. The model suggested reductions of 14% and 10% in the numbers of ICU admissions and 30-day readmissions, respectively, among hospitalized SIADH patients with mild-moderate FR-resistant HN.

CONCLUSIONS: As an effective treatment for HN among hospitalized CHF patients, tolvaptan, in comparison with FR, is expected to save hospitalization costs, regardless of HN severity.

SPONSORSHIP: This research was conducted by Evidera with funding from Boehringer Ingelheim.

E20 Impact of the 2013 ACC/AHA Cholesterol Guidelines on Statin and Non-statin Medication Utilization Using Pharmacy Paid Claims Data

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BACKGROUND: The landscape of cholesterol-lowering medication utilization is relatively unknown since the publication of the 2013 ACC/AHA blood cholesterol treatment guidelines. Focus shifted from treating to LDL goals towards using evidence-based medicine (EBM) principles by recommending the use of particular medications and doses dependent on patient parameters. There has been much controversy and confusion in the primary care field as a result of this paradigm shift.

OBJECTIVE: To identify changes in prescription utilization of statins and non-statin medications before and after updated guidelines were published.

METHODS: A retrospective analysis using pharmacy paid claims data from January 2013 to December 2014 was performed to identify statin and non-statin medication utilization. Proportions of statins and non-statin drugs were compared using chi-square analysis. Members enrolled in a prescription plan administered by the pharmacy benefit manager, at least 18 years of age, who had paid pharmacy claims for cholesterol medications as labeled by the FDA were included in the analysis.

RESULTS: Of the 13,853 paid claims that were eligible for analysis, 7,327 (52.9%) of the claims were from 2013 before publication of the guidelines, and 6,526 (47.1%) from 2014 after publication of the guidelines. Statin drugs represented 70.7% of claims in 2013 and 77.4% of claims in 2014 (P < 0.001). Non-statin drugs represented 28.2% of claims in 2013 and 22% of claims in 2014 (P < 0.001). Combination drugs represented 1.1% of claims in 2013 and 0.6% of claims in 2014 (P < 0.001). Further stratification of statin drugs revealed that there were significant changes in the utilization of high intensity statin drugs between 2013 and 2014 with 15% of total statins in 2013 belonging to the high intensity statin group and 19.4% of total statins in 2014 belonging to the high intensity statin group (P < 0.001). Utilization among moderate and low intensity statin groups did not change significantly from 2013 to 2014.

CONCLUSIONS: Statin and non-statin drug utilization changed significantly with an increase in statin usage and a decrease in non-statin usage. The association between statin usage and the year a claim was paid could represent a shift in prescribing practices due to the updated guidelines published in 2013. There are several limitations to the generalizability of this data, as the time to adapt to the updated guidelines was limited. A larger study covering a wider timespan is warranted to make inferences regarding trends. Despite controversy, it appears that many prescribers are subscribing to the 2013 ACC/AHA guidelines.

SPONSORSHIP: None.
E21 Analysis of Omega-3 Fatty Acid Dietary Supplements with Respect to Content: Are They Appropriate for Patients?

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BACKGROUND: The American Heart Association recommends 2-4 g/day of omega-3 fatty acids (OM3FA) for patients with elevated triglyceride (TG) levels. Patients may often take OM3FA dietary supplements (DS) instead of prescription (Rx) products (e.g., Vascepa, Lovaza), which are indicated in adults with very high TG levels (≥500 mg/dL). Some managed care plans require patients to fail on DS before covering Rx products. Although DS are widely available, their integrity and efficacy remain unverified. The contents of DS often require patients to take ≥10 capsules/day to attempt to reach a therapeutic dose equivalent to Rx OM3FA 4 g/day, negating any potential cost advantage.

OBJECTIVE: We tested the fatty acid content of leading DS (saturated fat, eicosapentaenoic acid [EPA], docosahexaenoic acid [DHA]). We tested OM3FA integrity by extent of oxidative damage and biological activity with respect to preventing low-density lipoprotein (LDL) oxidation.

METHODS: We tested 6 leading (by sales) DS as well as Rx products in a blinded fashion for fatty acid content using gas chromatography. Oxide levels were measured by spectroscopy and normalized to total content of OM3FA. Therapeutic levels of OM3FA isolated and concentrated from DS were tested for the ability to inhibit human LDL oxidation in vitro following Cu-induced initiation. As internal controls, we tested highly enriched (>99%) standards of OM3FA and pure OM3FA deliberately exposed to atmospheric oxygen for specific times.

RESULTS: DS contained more than 30 different fatty acids, including 10-14 different saturated fat species comprising up to 36% of the total fatty acid content. Levels of OM3FA also varied widely among the DS (33%-79%). DS peroxide levels were 5- to 10-fold greater than control levels observed with nonoxidized OM3FA. LDL oxidation was inhibited by >95% (P < 0.001) with nonoxidized forms of OM3FA but not with the mix of oxidized and nonoxidized OM3FA isolated from DS. Samples exposed to atmospheric oxygen had reduced antioxidant activity compared with nonoxidized OM3FA but were still superior to OM3FA from DS. By comparison, a Rx OM3FA did not have significant levels of oxidation.

CONCLUSIONS: Leading DS examined in this study contained more than 30 fatty acids, including significant levels of saturated fat in addition to desirable OM3FA. Consistent with previous reports, we observed elevated levels of peroxides, which interfered with OM3FA biological antioxidant activity. These data indicate that levels of saturated fat and oxidized OM3FA found in common supplements may interfere with their potential biological benefit.

SPONSORSHIP: None.

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

F02 Assessment of Pharmacy and Medical Utilization and Expenditures After the Addition of Prescriber Limitations to a State Medicaid’s Patient Review and Restriction Program

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BACKGROUND: Patient Review and Restriction Programs (PRRP) are used by state Medicaid programs to limit potential misuse of opioids and other controlled medications by limiting members to a single pharmacy. In July 2014, Oklahoma Medicaid (MOK) instituted a new component which limited the number of allowed prescribers of controlled medications for members in the PRRP.

OBJECTIVE: The objective of this research was to assess pharmacy and medical utilization and expenditures after the addition of prescriber limitations to a state PRRP.

METHODS: MOK members previously enrolled in a pharmacy-only PRRP were further limited to a maximum of three providers for prescribing of controlled substances including opioid narcotics and benzodiazepines. Per member per month (PMPM) utilization in the period before the addition of prescriber limitations (before July 2014) was compared to the period afterwards (after July 2014) for the entirety of calendar year 2014 with the Wilcoxon Signed Rank Test for nonparametric dependent means. Utilization was defined in terms of PMPM medical and pharmacy costs, opioid prescription counts, and opioid utilization.

RESULTS: Total PMPM opioid prescriptions were reduced by -0.27 (P < 0.01). Prescriptions for short-acting opioids (SAO) decreased by -0.29 PMPM (P < 0.01) while long-acting opioids (LAO) had a slight increase (0.02, P = 0.04). Maintenance medications remained stable (0.05, P = 0.71). The number of prescribers of opioids or benzodiazepines was reduced by -0.28 per month (P < 0.01). Review of members’ attempts to refill opioid prescriptions early (prior to 75% depletion) revealed a reduction of -0.03 PMPM (P = 0.04). Emergency department PMPM visits were unaffected (0.05, P = 1.0). Opioid PMPM costs were reduced -$15.79 (P = 0.03), with LAO only being reduced by -$4.19 (P = 0.4) and SAO being reduced by -$11.61 (P < 0.01). Benzodiazepine PMPM costs were reduced by a small but statistically significant amount (-$1.79, P < 0.01). PMPM medical costs decreased by -$350.05 (P < 0.01) after the prescriber limitation.

CONCLUSIONS: Overall opioid PMPM utilization was reduced due to decreased SAO utilization, however a small increase in LAO utilization was observed. Maintenance medications were unchanged indicating the limitation did not appear to affect chronic disease treatment. Additionally, the prescriber limitation appeared to have a positive effect on medical costs. Further research into the underlying changes to prescription and medical trends is necessary.

SPONSORSHIP: No funding was received for this research.

F03 Persistence and Healthcare Costs Among Opioid-Dependent Patients Treated with Buprenorphine/Naloxone Sublingual Film Continue to Differ from Buprenorphine or Buprenorphine/Naloxone Tablets: Retrospective Study of the Administrative Claims from a Medicaid Database

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BACKGROUND: Since 2010 buprenorphine/naloxone sublingual film has been available for the treatment of opioid dependence. Previous evidence suggested that the sublingual film formulation was associated with better persistence and lower healthcare resource use.

OBJECTIVE: The purpose of this study was to continue to evaluate the real world performance of the sublingual film formulation compared to the previous technology of tablet formulation.

METHODS: A retrospective cohort analysis was performed using medical claim records from January 2007 to December 2013 extracted from the MarketScan Medicaid database to compare patient persistence and...
healthcare costs associated with the treatment with buprenorphine/naloxone film, with buprenorphine or buprenorphine/naloxone tablets. Patients were split into two groups according to the index treatment: sublingual film (buprenorphine/naloxone) or tablet (buprenorphine alone or in combination with naloxone). Time to treatment discontinuation and annual healthcare costs were compared between the groups. To eliminate the impact of confounding factors the models included adjustment and matching on the baseline characteristics—sex, age, type of insurance and presence of comorbidities.

RESULTS: In the period September 2010-June 2014, the sublingual film and tablet groups included 4,668 and 2,610 patients followed over 14 months on average. Patient age in both groups was comparable at treatment initiation with a mean of 32 years. Patients treated with sublingual film were 10% less likely to discontinue treatment. Higher outpatient and pharmacy costs in the film group were offset by the lower cost of inpatient care (both psychiatric and non-psychiatric).

CONCLUSIONS: The sublingual film formulation of buprenorphine/naloxone continues to be associated with a reduced probability of early treatment discontinuation, lower occurrence of hospitalizations, and lower costs.

SPONSORSHIP: This study was sponsored by Reckitt Benckiser Pharmaceuticals, a subsidiary of Indivior.

F04 Persistence and Healthcare Costs Among Opioid-Dependent Patients Treated with Buprenorphine/Naloxone Sublingual Film Continue to Differ from Buprenorphine or Buprenorphine/Naloxone Tablets: Retrospective Study of Administrative Claims from Commercial U.S. Insurers

Khemiri A1, Aballea S1, Ruby J2, Zah V3, Kharitonova E1. 3450 Cawthra Rd., Administrative Claims from Commercial U.S. Insurers Naloxone Sublingual Film Continue to Differ from Buprenorphine F04

In the period September 2010-June 2014, the sublingual film and tablet groups included 4,668 and 2,610 patients followed over 14 months on average. Patient age in both groups was comparable at treatment initiation with a mean of 32 years. Patients treated with sublingual film were 10% less likely to discontinue treatment. Higher outpatient and pharmacy costs in the film group were offset by the lower cost of inpatient care (both psychiatric and non-psychiatric).

CONCLUSIONS: The sublingual film formulation of buprenorphine/naloxone continues to be associated with a reduced probability of early treatment discontinuation, lower occurrence of hospitalizations, and lower costs.

SPONSORSHIP: This study was sponsored by Reckitt Benckiser Pharmaceuticals, a subsidiary of Indivior.

F06 A Large-Scale Survey of Caregivers of Persons with Schizophrenia and/or Schizoaffective Disorder to Identify Unmet Needs

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BACKGROUND: Unpaid caregivers often bear the responsibility for meeting the medical and personal needs of individuals diagnosed with schizophrenia and/or schizoaffective disorder.

OBJECTIVE: To identify the demands associated with caregiving and the caregivers’ unmet needs.

METHODS: A cross-sectional web-based questionnaire was administered to caregivers recruited from ads placed in mental health advocacy organizations and the nationally syndicated Dear Abby newspaper column. Eligible caregivers provided assistance or arranged for assistance in the past 12 months. Validated question batteries and original items were included.

RESULTS: A total of 1,708 caregivers consented, 1,398 (81.9%) were eligible and 236 (16.9%) were excluded due to missing data (final n = 1,162). Most caregivers were female (81.9%). Mean caregiver age was 55.3 years (SD=13.3). More than half (59.3%) were the recipients’ parents or step-parents. Among the caregivers, 60.1% had daily contact with the recipient and 26.9% had multiple weekly contacts and 47.1% had been providing caregiving for 10 years or longer. Approximately two-thirds (67.8%) reported that caregiving imposed a financial burden on them. While 32.3% paid someone to assist them with caregiving, 45.1% of those without paid assistance (n = 760) would prefer to have had it. More than half were concerned about the recipient’s adherence to prescribed medication, (35.6% were “very” or “extremely” concerned and 18.1% were “somewhat” concerned). Further, 26.8% lacked confidence in the effectiveness of the medication and 35.5% were only partly confident. With regard to available supports and resources, 36.7% had no one else to provide caregiving when a substitute was needed, 33.7% had no one available to answer questions about caregiving and 24.9% had nobody to go to for medical advice. Help with legal or financial matters was absent for 46.4% and 49.7%, respectively. Advice regarding community services was not available to 37.4%.

CONCLUSIONS: Most caregiving involved daily responsibilities, sometimes spanning decades. Many caregivers lacked confidence in medications and the recipient’s ability to adhere to them. Access to key supports and resources frequently was lacking.

SPONSORSHIP: Janssen Scientific Affairs, Titusville, NJ, and the Tufts Clinical and Translational Science Institute (UL1TR001064), Boston, MA.
OBJECTIVE: Measure the effect of improved adherence to oral atypical antipsychotic medications on inpatient cost after accounting for adherence inaccuracies in claims data.

METHODS: We derived the statistical bias that occurs in adherence-utilization studies when adherence measurement is inaccurate and conducted a literature review to identify the key bias parameter: the correlation between true and claims-based adherence measures. Using data from Truven MarketScan Commercial and Medicaid databases (2007-2013), we applied our bias-correction methodology to a case study of patients diagnosed with bipolar disorder, major depressive disorder or schizophrenia who initiated atypical antipsychotic therapies. Adherence to oral atypicals was measured using PDC. We calculated the naive and bias-adjusted effect of adherence on inpatient costs controlling for patient demographics, comorbidities, and prior spending.

RESULTS: Among the 231,526 SM patients who initiated atypical therapy, a ten percentage point increase in PDC lowered annual inpatient costs for all patients by $42 (95% CI: -$65 to -$19) per person and for patients with schizophrenia in particular by $86 (95% CI: -$147 to -$23). After adjusting for bias due to mismeasurement, we found that this same increase in PDC decreased inpatient costs by $223 (95% CI: -$359 to -$106) and $458 (95% CI: -$815 to -$141) per person, respectively. Extrapolating these results to the entire U.S. population of patients with schizophrenia, the effect of a 10% increase in adherence is $0.3 billion using the naive approach and the $1.5 billion after adjusting for bias.

CONCLUSIONS: Payers may underestimate the effect of improved adherence on inpatient cost by a factor of 5 or more due to mismeasured adherence in claims data. Improving the accuracy of adherence data—through electronic pillboxes, smart caps, or ingestible sensors—could help provide clearer insight into the full value of improving adherence.

SPONSORSHIP: Otsuka America Pharmaceutical.
RESULTS: The 39,746 patients with schizophrenia meeting our inclusion criteria were divided into 6 adherence groups, as this grouping produced the best model fit. The 6 adherence trajectory groups were best described as: adherent (10%), discontinuation after 3 months (15%) and 6 months (24%), stop-start after 6 months (10%) and 3 months (30%), and discontinuation after one month (11%). Compared to patients in the adherent group, patients displaying a stop-start pattern after 3 months were more likely to have a history of drug abuse (OR: 1.56, 95% CI 1.34-1.78) and alcohol abuse (OR: 1.75, 95% CI: 1.55-1.95), have a higher Charlson comorbidity index (OR: 1.24, 95% CI: 1.16-1.42), and less likely to be 35-54 years of age (OR 0.48, CI 0.41-0.55).

CONCLUSIONS: Diagnosed schizophrenia patients’ adherence to antipsychotic therapy exhibits three broad patterns: adherent, discontinuing, and stop-start, but the timing of changes in adherence varied within the discontinuation and stop-start groups. Trajectory modeling could be used to identify patients likely to benefit from a variety of new adherence interventions including digital pill-boxes, ingestible sensors, provider messaging, and mobile pill reminders.

SPONSORSHIP: Otsuka America Pharmaceutical.

F12 Care Team Attitudes Towards LAI Use in Schizophrenia
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1Otsuka America Pharmaceutical; 2Health Analytics; 3Aetna

BACKGROUND: Clinical management of patients with schizophrenia (SZ) is often performed by a clinical team including prescribers (physicians, nurse practitioners [NP] or physician assistants [PA]) and non-prescribing healthcare professionals (social workers, therapists and case managers [influencers]). Care team members may have differing attitudes toward specific treatment approaches. Long acting injectable (LAI) antipsychotic medications were developed in part to address low adherence. However, there is uniform acceptance of these formulations.

OBJECTIVE: The purpose of this study was to measure prescriber and influencer attitudes toward LAIs and to analyze them as potential barriers to clinically appropriate LAI adoption.

METHODS: The sample included prescribers (n = 49) and non-prescribing influencers (n = 107). Survey respondents were asked about their knowledge, attitudes and beliefs regarding treatment with LAIs using a Likert scale (“strongly agree” to “strongly disagree”). Actual use of LAIs was also assessed. Chi-square analyses were performed to evaluate differences in belief valence as well as rate of endorsement items.

RESULTS: Prescribers who used LAIs were less likely to believe that side effects are more common with LAIs than oral antipsychotics (13% vs. 95%; P < 0.001), that LAIs limit patient autonomy (9% vs. 67%; P < 0.001), and that LAIs are coercive (0% vs. 68%; P < 0.001) than prescribers who did not use LAIs. They were also more likely to rank treatment with second generation LAIs as a first treatment choice for patients with multiple psychotic hospitalizations (30% vs. 4%; P < 0.001). All non-prescribing healthcare providers, whether or not their patients were routinely treated with LAIs, endorsed LAIs for their patients with at least one hospitalization. Almost a quarter of influencers whose patients were treated with LAIs felt they needed more time to discuss the pros and cons of LAI use with their patients, while prescribers indicated they had enough time to discuss LAI treatment.

CONCLUSIONS: Prescribers who reported using LAIs were less likely to endorse side effects, limited patient autonomy and the coerciveness of LAIs as barriers to LAI prescribing. They were more likely to prescribe an LAI for patients with multiple psychotic hospitalizations. Influencers were likely to view LAIs as an appropriate treatment. These data indicate that beliefs, regardless of their validity, about LAIs may affect prescribing patterns.

SPONSORSHIP: This study was sponsored by Otsuka America Pharmaceutical.

F13 Impact of Paliperidone Palmitate Versus Oral Atypical Antipsychotics on Healthcare Resource Use and Costs in Veterans with Schizophrenia
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BACKGROUND: Long-acting injectable antipsychotics such as paliperidone palmitate (PP) may improve adherence, thus reducing risk of relapse in patients with schizophrenia.

OBJECTIVE: Compare healthcare resource utilization and costs in veterans with schizophrenia treated with PP versus oral atypical antipsychotics (OAAs).

METHODS: A retrospective longitudinal study was conducted using electronic health record data from the Veterans Health Administration (VHA). Veterans with schizophrenia initiating PP or OAA between January 2010 and October 2014, with ≥ 12 months of enrollment prior to treatment initiation, ≥ 1 Global Assessment of Functioning (GAF) measurement at baseline, and ≥ 6 months of enrollment post-treatment initiation were included. To estimate the impact of treatment on outcomes, inverse probability treatment weighting (IPTW) was used to adjust for differences in baseline characteristics to reduce confounding and selection bias. Weighted regression models were used to estimate the incidence rate ratios (IRR) and cost differences (CD) for the impact of PP versus OAAs on healthcare resource utilization and costs. A non-parametric bootstrap procedure was used to calculate confidence intervals and P values for cost outcomes.

RESULTS: Among 10,290 eligible veterans, 2,285 and 8,005 were initiated on PP and OAAs, respectively. On average, the PP cohort was younger (50.2 vs. 53.7 years), more likely to be single (47% vs. 39%), and had a lower mean baseline GAF score (34.0 vs. 36.8) compared to OAA users, respectively. After applying IPTW weights, initiation with PP was associated with less frequent all-cause inpatient hospitalizations (IRR: 0.89, P < 0.001) and more frequent mental health intensive case management (MHICM) visits (IRR: 1.81, P < 0.001) during the 12-month follow-up period compared to OAAs. PP treatment was also associated with a significantly higher likelihood of increased income (odds ratio = 1.20, P = 0.027) and lower likelihood of homelessness (odds ratio = 0.82, P < 0.001). While mean annual pharmacy and outpatient costs were higher among PP users (CD = $3,552 pharmacy, $2,840 outpatient, P = 0.002), PP treatment was associated with significantly lower mean annual inpatient costs (CD = $14,543, P = 0.002), resulting in average annual total cost savings associated with PP (CD = -$8,151, P = 0.020) relative to OAAs.

CONCLUSIONS: PP treatment was associated with significantly lower total healthcare costs attributable to reduced inpatient admissions compared to OAAs. Higher MHICM participation among PP users may have also contributed to the differences observed relative to OAA users.

SPONSORSHIP: This study was supported by Janssen Scientific Affairs.
F14 Association Between Patterns of Long-Acting Injectable Antipsychotic Medication Use and All-Cause Hospitalizations Among Dual Medicare Medicaid Eligible Patients with Schizophrenia

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BACKGROUND: Patients with schizophrenia eligible for both Medicare and Medicaid (often referred to as dually eligible enrollees) are a particularly vulnerable group owing to disabilities and may experience barriers to access LAIs. Dually eligible patients with mental illness may experience difficulties accessing psycho-pharmacological medications, as coverage policies that are associated barriers to antipsychotics are common in Part D plans. Contemporary national data on the use of LAIs in dually eligible patients with schizophrenia are lacking. Little is known about long-term persistence to LAIs and the resulting impact on hospitalizations.

OBJECTIVE: To describe the patterns of long-acting injectable antipsychotic medication use (LAI) in patients with schizophrenia with dual Medicare and Medicaid coverage and to estimate the association between patterns of LAI use and all-cause hospitalizations.

METHODS: We employed a nested case-control design among 2010-2012 dually-eligible Medicare and Medicaid beneficiaries with schizophrenia (ICD-9 codes: 295.0, excluding 295.7). We required patients to have 18 months of continuous eligibility and ≥1 LAI claim. Cases were patients hospitalized for any cause during months 13-18 months of follow-up (n = 2,990). Each was matched to 10 controls using incidence density sampling (n = 29,990). LAI use in the 12 months preceding the index date (month/year of case’s hospitalization) was categorized as: (a) optimal, > 8 months; (b) sub-optimal, 4-7 months; (c) proximal-only, 1-3 months; and (d) LAI claim > 12 months preceding index date. Adjusted odds ratios (aOR) and 95% confidence intervals (CI) were derived from logistic regression models.

RESULTS: Among the study population, 22.1% of the cases and 41.5% of the controls had optimal LAI use. Among the cases, 55.9% were classified as either proximal or discontinued users. Adjusting for confounding by first controlling for sociodemographics and then for clinical variables including comorbidities, the risk of all-cause hospitalization in comparison with suboptimal users, patients with optimal LAI use had a 26% risk reduction (aOR=0.74; 95% CI 0.66-0.84), and patients with proximal-only use had a 40% increased risk (aOR=1.40; 95% CI: 1.23-1.59).

CONCLUSIONS: Optimal use of LAIs in dually-eligible patients is associated with a decreased risk of all-cause hospitalization. Our study provides national estimates of patterns of use of LAIs based on medical claims in dually-eligible beneficiaries. Efforts to improve adherence to LAI treatments are warranted.

SPONSORSHIP: This research was conducted as part of a contract to JEN Associates, with Janssen Scientific Affairs.

F15 Determining Physician and Patient Characteristics That Predict the Use of Atypical Antipsychotics in Children with Mental Health Disorders

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BACKGROUND: In 2011 the Department of Health and Human Services sent a letter to state Medicaid directors explaining the need for overseeing psychiatric prescriptions in children with mental health disorders. The NCQA proposed three quality measures for rating managed care organizations (MCOs) that involve use of atypical antipsychotics (APs) in children. In order to ensure appropriate utilization and effectively manage the use of APs in children, MCOs need to better understand the factors influencing medication treatment decisions for children.

OBJECTIVE: The objective of this study was to identify factors that influence physicians’ decisions to prescribe APs to children with psychoses.

METHODS: This study employed a cross-sectional survey of general practitioners (PCPs) and psychiatrists. A web-based patient simulation survey was administered using a commercial research vendor. Respondents were presented simulated patient profiles described by different levels of factors hypothesized to be important in treatment decision making. Physician treatment decisions were measured along with demographics and beliefs about available AP products.

RESULTS: An extension of a modified Poisson regression model showed that patient disease severity, age, WBC count, physician beliefs about evidence supporting AP use and current levels of AP use in their practices were significant predictors of AP use. Patients’ foster status, parental concern and BMI were not significant predictors. PCPs and psychiatrists differed with respect to the influence of beliefs in evidence for use, and patient WBC counts. Patients with moderate or severe psychosis were 1.1 times as likely to be recommended APs compared to mild severity. Four year olds and 10 year olds were 0.75 and 0.94 times as likely, respectively, to be recommended APs compared to 15 year olds. Up to 10% of physicians reported being unaware of evidence supporting AP use. More than 50% of patient profiles were also recommended multiple APs.

CONCLUSIONS: Physicians’ lack of knowledge of evidence supporting AP use in children is very concerning. Physicians are less likely to prescribe APs for younger children but need to treat this population when severity is high. MCOs should consider providing education programs to physicians regarding treatment guidelines, evidence for use of APs, importance of patients’ BMI levels and metabolic monitoring. Educating physicians on the evidence, providing or facilitating appropriate clinical use of APs and limiting unwanted AP polypharmacy may lead to lower costs for the patients and MCOs.

SPONSORSHIP: Reckner Healthcare provided support in the form of programming and fielding the study.

F17 Impacting the HEDIS AMM Measure and Patient Satisfaction with a Clinical Coaching Model in a Medicaid Population

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BACKGROUND: Depression affects 1 in 10 Americans and is the leading cause of disability worldwide. Medication is effective in treating depression, yet only half of patients receive appropriate treatment. The HEDIS Antidepressant Medication Management (AMM) measure aims to improve outcomes in depression by promoting medication adherence.

OBJECTIVE: To determine whether a patient-centric coaching model coupled with care coordination improves HEDIS AMM performance and patient satisfaction in a Medicaid population.

METHODS: Eligible patients were identified monthly through QSI reports and contacted telephonically by a pharmacist who provided
coaching and education. Using motivational interviewing, barriers were identified and resolved through health-literate appropriate education and care coordination. At the end of each encounter, a verbal commitment for adherence was requested of each patient. Follow-up coaching occurred throughout the duration of the measure. The average coaching session was 7 minutes long and translators were used for non-English calls. A week after the introductory call, the patient was surveyed on call quality and satisfaction.

RESULTS: 1,191 patients met criteria for acute and continuous AMM phases (January-July 1, 2015). Of these, 311 (26%) received a unique coaching session with one or more follow-up sessions. Emphasis was placed on the time-sensitive acute phase, resulting in an increase in adherence from 39% in February to 46.9% in June. Compared to the same model in 2014 without intervention, patients experienced a significant increase in adherence to their antidepressants (29.9% increase year-to-year, and a P value of 0.0000001). Continuation phase has also shown pronounced improvement, with adherence improving from 17.6% to 27.9% from January to June (with a target of over 35% by year’s end). Low health literacy or lack of knowledge about their disease state served as the primary barriers to adherence. The majority recalled speaking with the pharmacist (93%), felt that the pharmacist was easy to understand (100%) and was helpful (97%).

CONCLUSIONS: Personalized antidepressant coaching, aimed at education with barrier identification and resolution, positively influenced medication-taking behavior in a Medicaid population with low health literacy. Interactive patient education asking for a commitment to adherence and providing follow-up were influential elements of the coaching model. High patient satisfaction after the encounter demonstrated that this intervention was memorable, promoted trust, and motivated behavior change.

SPONSORSHIP: Molina Healthcare.

F18 Persistence on Desvenlafaxine As Compared to Other Antidepressants and Desvenlafaxine Switching Patterns in Patients with Major Depressive Disorders
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1Pharmerit International; 2Pfizer

BACKGROUND: Non-persistence is associated with prolonged depressive episodes, functional impairments, relapse, and higher healthcare costs.

OBJECTIVE: This study describes treatment persistence in major depressive disorder (MDD) for branded desvenlafaxine (brDSV) as compared to branded (escitalopram [brESC], venlafaxine [brVEN], duloxetine [brDUL]) and generic (VEN, ESC, citalopram [CIT], fluvoxamine [FLV], sertraline [SER], fluoxetine [FLO] and paroxetine [PAR]) MDD medications and explores brDSV switching patterns.

METHODS: MDD patients (ICD-9-CM codes 296.2, 296.3) with ≥2 prescription fills for brDSV, or other antidepressants (ADs; first fill = index date) and 12 months continuous enrollment pre-index were identified from the MarketScan Commercial Claims and Encounters Database (2009-2013). Treatment persistence (time to treatment discontinuation, defined as a prescription gap ≥45 days) and switch (initiating other AD within 45 days post-prescription supply end) were assessed using Kaplan-Meier curves. Treatment switch (starting other antidepressant within 45 days post-prescription supply end) was characterized for brDSV.

RESULTS: MDD patients prescribed brDSV (N = 14,379), brDUL (N = 29,244), brVEN (N = 2,508), brESC (N = 19,183), VEN (N = 34,433), ESC (N = 40,598), CIT (N = 44,880), FLV (N = 1,281), SER (N = 42,638), FLO (N = 32,732), PAR (N = 11,636) had mean age ranging from 43.7 [FLV]-48.9 [brDUL] years with between 62.9% (FLV)-73.8% [brDSV] female. Median time to discontinuation for brDSV was 40.7 [brDSV] female. Median time to discontinuation for brDUL was 40.7 (95% CI: 39.3-42.0) weeks which was significantly longer than both branded (28.9 [brDUL] years with between 62.9% [brDUL]-73.8% [brDSV] and nonbranded (33.4 [brDSV] AD groups. By 12 months 42.5% (41.7-43.4) of brDSV-prescribed patients were persistent, which was significantly higher than branded (31.6% [brDSV]-32.1) and generic (38.6% [brDSV]-38.8) AD groups. For brDUL, only 15.5% switched during the mean (maximum) follow up time of 10.32 (44.3) months. brDSV patients most frequently switched to generic serotonin and norepinephrine reuptake inhibitors (37.8%), atypical ADs (31.6%), and/or generic selective serotonin reuptake inhibitors (15.7%).

CONCLUSIONS: Within this cohort, MDD patients prescribed brDSV were more persistent than the majority patients prescribed branded or generic AD groups. Switching to other ADs after brDSV discontinuation was infrequent. Key limitations include reliance on prescription fills instead of actual medication taking, inferring indication for AD prescriptions based on ICD-9 codes, and limited follow-up time.

SPONSORSHIP: This study was sponsored by Pfizer.

F19 A Systematic Review of Claims-Based Methods for Measuring Adherence with Antidepressant Medication
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PROBLEM DESCRIPTION: Depression is a highly prevalent and costly illness within managed care systems, having a combined direct and indirect cost burden that exceeds that of diabetes and cancer. Response to drug therapy occurs predominantly among patients that are strictly adherent to antidepressant medication regimens. Medicare Part D star measures include adherence rates for medications for cholesterol, diabetes and hypertension, but not depression.

GOAL: To identify pharmacy claims-based methods for calculating adherence with antidepressant medication described in published studies, and to describe common measurement attributes and applications.

PROGRAM DESCRIPTION: A systematic literature review was conducted of relevant publications from 1996 to 2015. We identified 668 citations using keywords related to depression, adherence and medical claims. Additionally, references from published reviews were examined for relevant articles. Abstracts were screened for studies that evaluated adherence with antidepressant medication specifically, as measured using administrative pharmacy data. The search yielded 18 papers for inclusion in our review.

OBSERVATIONS: Researchers have used pharmacy claims data to measure adherence with antidepressant medication in differing ways. The most common approach uses the Antidepressant Medication Management (AMM) HEDIS measure, which evaluates adherence during both the first 12 weeks and 6 months of drug therapy. This approach was used as specified by HEDIS in five studies, while other studies modified the AMM measure to include different adherence thresholds (n = 3), to accommodate treatment augmentation (n = 1), or to restrict the types of antidepressant classes included (n = 1). Alternatively, the medication possession ratio (≥80%) was used in 3 studies, while medication gaps of 30 or more days were evaluated in 3 studies. All of the studies involved adherence measurement among patients with a new episode of depression, as documented by ICD-9 code or standardized instruments.
FINDINGS/RECOMMENDATIONS: Despite the pervasive use of antidepressants among patients in managed care systems, data are lacking to inform the measurement of adherence among chronic users of these medications, who represent the majority of patients for which these medications are prescribed. Our findings have relevance for measure developers and for those striving to improve quality of care in depression, considering the high burden of depression in the U.S. and the importance of treatment adherence among patients with chronic depression.

SPONSORSHIP: None.

F20 Using Student Pharmacists to Address Adherence to Antidepressants in a Medicaid Population

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PROBLEM DESCRIPTION: Medication nonadherence leads to poor self-care, premature mortality, and increased healthcare utilization. Specific skills are necessary to deliver patient-centered care which involves successful adherence interventions. While pharmacy students are exposed to didactic concepts of adherence and health literacy, few have the opportunity to apply them to practice in a real-world setting and receive feedback on the intervention outcome before graduation.

GOAL: To describe the training and skills provided to student pharmacists to impact adherence measures in a managed care setting.

PROGRAM DESCRIPTION: At time of hire, baseline knowledge of health literacy and adherence was assessed using four validated tools, followed by 40 hours of training and coaching. Training addressed disease state education, adherence coaching, health literacy, and techniques in motivational interviewing. Patients were identified for adherence intervention monthly and students contacted them by telephone. Approved scripts were used to guide the students in their conversations with patients, but allowed flexibility for personalized barrier identification and resolution. Preceptors provided ongoing coaching and evaluation of student work. A monthly meeting was held to provide education and present impact of interventions. Evaluation tests were re-administered one month from hire and the scores were compared to baseline scores.

OBSERVATIONS: The student scores improved with a 60% increase in health literacy knowledge, a 90% increase in medication adherence knowledge, a 80% increase in medication adherence attitudes, and an 100% increase in motivational interviewing utilization. In addition, students experienced self-reported improvement in their overall confidence in speaking with patients and other members of the healthcare team. Students developed a more dynamic understanding of health literacy issues and how to address them. Motivational interviewing habits were acquired enabling students to more easily identify and resolve barriers to adherence. The knowledge and skills gained also impacted patient outcomes. Compared to the prior year (without intervention), students positively impacted antidepressant adherence through education and adherence interventions.

FINDINGS/RECOMMENDATIONS: Pharmacists can impact medication adherence through patient-centric care. Pharmacy students who receive training opportunities in elements of adherence demonstrate improved competency and understanding of effective patient engagement. This also correlates to improved delivery of care and patient response.

SPONSORSHIP: Molina Healthcare.

F21 PRISM II: Improvement in Neurobehavioral and Physical Function Among Stroke Patients Treated for Pseudobulbar Affect with Dextromethorphan/Quinidine

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BACKGROUND: Pseudobulbar affect (PBA) is a disorder of emotional expression characterized by sudden, frequent, and uncontrollable laughing and/or crying outbursts, exaggerated or unrelated to mood. PBA occurs secondary to otherwise unrelated neurological conditions that damage brain pathways regulating emotional expression.

OBJECTIVE: PBA symptoms are reported to occur in 28%-53% of stroke survivors and may incrementally impact healthcare utilization and rehabilitation costs. PRISM II is an open-label multicenter study measuring safety and effectiveness of dextromethorphan/quinidine (DM/Q) for PBA in patients with dementia, traumatic brain injury (TBI) or stroke. This analysis, assesses neurobehavioral and physical function outcomes related to stroke following DM/Q treatment of PBA.

METHODS: Patients with PBA secondary to stroke and a Center for Neurologic Study-Lability Scale (CNS-LS) score ≥13 were administered the CNS-LS (primary outcome) and the Stroke Impact Scale (SIS) at baseline and Day 90 endpoint. The CNS-LS, a 7-item self-administered scale, [range: 7 (no symptoms) to 35 (maximum)] measures perceived PBA episode frequency and severity. The SIS, a 59-item interviewer-administered scale measures stroke-related physical and neurobehavioral outcomes in eight domains, a visual analog scale (VAS) also measures patient assessment of overall stroke recovery (range 0-100). Change from baseline to day 90 for both instruments was measured.

RESULTS: Of 113 patients enrolled, 103 were evaluable for effectiveness. Mean (SD; n) CNS-LS score improved from 20.7 (4.7; 103) at baseline to 13.1 (4.6; 100) at endpoint, P<0.001 vs. baseline. Baseline (n=64) SIS scores ranged from a low of 45.4 (34.4) for hand function to a high of 68.2 (21.6) for communication. Statistically significant improvement was seen on all domains vs. baseline with greatest improvement on neurobehavioral domains of Memory 8.3 (23.0); Emotion 11.0 (20.4); and Social Participation 12.4 (23.2). Improvement in physical domains ranged 4.2 (17.1) for strength to 6.0 (16.5) for mobility. Improvement in the stroke recovery assessment was significant: 8.1 (19.8) P<0.001.

CONCLUSIONS: Patients receiving DMQ for PBA following stroke experienced significant improvement from baseline in PBA symptom frequency as well as neurobehavioral and physical function outcomes related to stroke recovery. Further analysis evaluating the relationship between PBA symptom reduction and stroke recovery will help inform the impact on healthcare utilization.

SPONSORSHIP: Avanir Pharmaceuticals.

F22 PRISM II: Improvement in Neurobehavioral and Physical Function Among Traumatic Brain Injury Patients Treated for Pseudobulbar Affect with Dextromethorphan/Quinidine

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BACKGROUND: Pseudobulbar affect (PBA) is a disorder of emotional expression characterized by sudden, frequent, and uncontrollable laughing and/or crying outbursts, exaggerated or unrelated to mood. PBA occurs secondary to otherwise unrelated neurological conditions that damage brain pathways regulating emotional expression.
outbursts of laughing and/or crying that are exaggerated or unrelated to mood. PBA occurs secondary to a variety of neurological conditions that can damage brain pathways regulating emotional expression, and may impact healthcare utilization.

OBJECTIVE: PBA symptoms are common following traumatic brain injury (TBI), with 8%-23% of respondents reporting moderate to severe PBA symptoms in recent prevalence surveys. PRISM II is an open-label multicenter study investigating the safety and effectiveness of dextromethorphan/quinidine (D/MQ) in patients with a diagnosis of PBA and a history of dementia, stroke or TBI. In this analysis, changes in outcomes of neurobehavioral and physical function related to TBI were assessed.

METHODS: Patients with PBA secondary to TBI with a screening Center for Neurologic Study-Lability Scale (CNS-LS) of ≥13 were administered the CNS-LS (primary outcome) and the Neurobehavioral Functioning Inventory (NFI) at baseline and Day 90/endpoint. The CNS-LS is a 7-item self-administered scale [range: 7 (no symptoms)-35 maximum] measuring perceived PBA episode frequency and severity. The NFI is a 76-item self-administered scale validated in TBI patients measuring the frequency of physical and neurobehavioral functional symptoms in six domains (item response range: 1 “never” to 5 “always”). Higher scores represent greater symptom frequency; the aggression domain is highly correlated with severity. Score changes from baseline to Day 90 for both the CNS-LS and NFI were calculated.

RESULTS: Of 120 patients enrolled, 87 were evaluated for effectiveness. The mean (SD; sample size) CNS-LS score improved from 20.5 (4.4; n = 87) at baseline to 11.9 (4.4; n = 67) at endpoint (P < 0.001). All six NFI domains showed improvement during the study. Standardized NFI T-scores ranged from 51.1 (10.6) to 55.7 (10.9) at baseline (n = 64). Improvement in mean (SD) T-scores by domain were (n = 49): Depression -7.14 (10.99); Somatic -4.80 (9.37); Memory/attention -5.35 (9.73); Communication -5.61 (9.80); Aggression -5.71 (9.46); Motor -4.80 (3.31); P < 0.001 for each vs. baseline.

CONCLUSIONS: Patients with a history of TBI receiving DM/Q for PBA symptom reduction and neurobehavioral and physical function changes in outcomes of neurobehavioral and physical function related to TBI were assessed.

SPONSORSHIP: None.

F25 Effects of Memantine and One-on-One Caregiver Contact on Antipsychotic Medication Prescribed to Elderly Veterans with Dementia

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BACKGROUND: The reduction of antipsychotic medications for elderly patients diagnosed with dementia is an important goal for treatment because of the negative side effects and increased mortality risk associated with these drugs.

OBJECTIVE: This research examined the differences between these treatment protocols (cholinesterase inhibitor only and combination therapy) on antipsychotic drug dosage prescribed to 98 elderly male veteran outpatients with dementia. The theoretical foundations for this study are based on the neurochemical model, related to the cholinergic hypothesis of age-related cognitive decline, and cognitive behavioral therapy as a psychotherapeutic approach that seeks to reduce stress by altering problematic behavior and unhelpful thinking patterns.

METHODS: Using archival data of elderly veterans with a diagnosis of dementia, this study also examined whether differences in dosage were influenced by age and severity of dementia.

RESULTS: An ex post facto design was used to evaluate changes over time, and the differences of age and severity of dementia. A series of ANOVA statistics were conducted, and a significant reduction from baseline to post-test was not found. There were no differences between patients receiving the additional treatment and those receiving cholinesterase inhibitors only.

CONCLUSIONS: These finding have social change implications for bringing awareness to healthcare professionals about the appropriate use of antipsychotic medications, and recognizing the cautious use of antipsychotics medications in elderly dementia patients.

SPONSORSHIP: Magellan Rx Management.
The Impact of Direct Outreach Programs on Provider Prescribing Patterns in the Midwest

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BACKGROUND: Behavioral health (BH) disorders are common in the U.S., with an estimated 19% of adults and 13% of youth suffering from BH disorders yearly. Individuals with BH disorders can be frequent users of health services and can experience poorer health outcomes, if their physical and behavioral conditions are not treated effectively. An outreach program was created to use clinical algorithms to identify prescribing trends that are inconsistent with best practice guidelines. Interventions were conducted to engage providers with the goal of improving outcomes of the BH population.

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

METHODS: Targeted prescribers were identified based on pharmacy claims data whose prescribing practices were inconsistent with generally accepted and/or FDA-approved dosing for Abilify and Seroquel XR. Prescribers were targeted for interventions if a patient was prescribed Abilify at a daily dose greater than 1 per day, or prescribed Seroquel XR <50 mg. Intervention methods included face-to-face visits and mail. During interventions, prescribers were asked to consider dose consolidation, assess the appropriateness of dose consolidation, and assess the regimen’s impact on adherence. Pharmacy claims of identified patients were extracted 6 months pre and post intervention. The intervention date served as the index date. As a proxy for continuous eligibility, all patients without post intervention claims were excluded. We performed a cross-sectional analysis comparing pre and post data. Significance was calculated using the Wilcoxon signed rank test for paired data. A significance threshold of P < 0.05 was employed.

RESULTS: There were a total of 155 prescribers and 455 patients that met the inclusion criteria for direct intervention. The total pharmacy spend was $2,341,998 and $2,053,980 during the pre and post period, respectively, resulting in a 12% reduction ($P = 0.01). We observed a reduction in the average units per day (UPD) for members receiving Abilify, where the average UPD decreased from 1.9 to 1.8 ($P < 0.0001$). There was no significant difference in the claim counts of patients that received low doses of Seroquel XR.

CONCLUSIONS: Identifying and targeting prescribers based on historical pharmacy claims data and performing interventions have generated positive outcomes related to dose optimization. The observed reduction in total pharmacy spend, may be an artifact of patients being prescribed Abilify at a reduced frequency. Ongoing research is being completed to assess the impact of the intervention on total medical spend.

SPONSORSHIP: Magellan Rx Management.

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

An Investigation of the Prevalence of Alzheimer’s Disease, Diagnostic Screening Rates and Associated Healthcare Costs and Resource Utilization Among the Medicare Population

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BACKGROUND: Alzheimer’s disease (AD) is highly prevalent among the aging population and is associated with very high medical costs. Multiple pharmaceutical companies are currently conducting clinical trials to test the ability of drug candidates to slow disease progression in mild/moderate AD patients. Diagnosing early stage AD patients requires the ability to accurately screen for AD. Pharmaceutical companies are utilizing PET scans and CSF testing in their clinical trials to accurately identify early stage AD patients.

OBJECTIVE: To determine the prevalence and average cost of AD and AD Related Dementia (ADRD) patients in 2013 Medicare data and the rate of various AD screenings performed on these patients over the past 4 years.

METHODS: Medicare FFS beneficiaries aged 65+ consistently enrolled between 2010 and 2013 as part of the 5% random sample were analyzed. AD and ADRD were defined using pre-specified ICD-9 diagnosis codes. Costs associated with AD and ADRD patients in 2013 were assessed using the sum of the Medicare payment amounts divided by the number of months the patients were alive. Within AD and ADRD patients, rates of any type of screening were calculated, including PET scans, CSF as well as more traditional brain CT, MRI, or fMRI scans.

RESULTS: Within the 5% random Medicare sample, the prevalence rate of AD and ADRD were 5.5% and 11.2%, respectively. The prevalence of AD and ADRD differed slightly by sex (Male: 4.2% Female: 6.5% and Male: 8.9% Female: 12.9%, respectively), and increased with age within both gender categories. The rate of any form of diagnostic screening is relatively low within both AD and ADRD cohorts (AD: 33.2%, ADRD: 25.9%). The rate of PET scans and CSF testing for AD is less than 1% in both cohorts (AD: 0.9%, ADRD: 0.6%). The average monthly Medical cost is higher among AD and ADRD patients compared to patients with no ADRD ($6,791 vs. $5,768 vs. $2,660, respectively).

CONCLUSIONS: This descriptive analysis shows that a relatively low percentage of Medicare patients undergo screening to confirm an AD or ADRD diagnosis. If the drug candidates currently in development prove to be effective in slowing the progression of AD, more screening will be needed to identify appropriate early stage AD patients that could benefit from the new therapies. This change in diagnostic screening practices and treatment paradigm could have a significant impact on the cost of the AD and ADRD population to Medicare.

SPONSORSHIP: This research was conducted by Trinity Partners, Waltham, MA, without external funding.

Withdrawn
were mailed the survey and data collection occurred over a 6-week period. Survey results were analyzed descriptively, testing group differences using ANOVA for continuous variables and chi-square tests for categorical variables.

RESULTS: A total of 7,849 eligible caregivers were mailed the survey; 1,912 (25%) responded. Caregivers were 67.1 (± 11.8) years of age, 56.7% were female and 51.8% were spouses. On average, caregivers had been providing care for 105.8 (± 67.5) hours/week over 4.6 (± 4.0) years; 25% had in-home professional healthcare assistance. Caregivers reported the highest proportion of severe AD patients among those on no AD treatment (20.7%) and mixed treatment, which included memantine in combination with another AD treatment (17.4%). Of patients on any AD treatment (n = 1,409), most were using mixed treatment (45.7%), followed by non-memantine AD treatment (37.5%), memantine (11.1%), and memantine XR (5.7%). Total caregiver burden was significantly different between medication groups, with the highest reported for mixed treatment and lowest for non-memantine AD treatment (P < 0.05). Significant differences by AD medication use were observed in the burden domains of social and family life, loss of control over caregiver's life and role strain (P < 0.05). Among prior memantine IR users (n = 221), 142 (64.3%) reported less burden or hassle with memantine XR use.

CONCLUSIONS: When stratified by current AD medication use, caregivers of mixed treatment AD patients were caring for a higher proportion of severe AD patients and had the highest mean burden. Future research needs to better understand how caregiver burden impacts caregiver healthcare resource utilization and costs.

SPONSORSHIP: Funding was provided by Allergan to Comprehensive Health Insights for the conduct of this study.

G04 Healthcare Resource Utilization and Costs in Treatment-Naive Multiple Sclerosis Patients Initiating Delayed-Release Dimethyl Fumarate or Fingolimod

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BACKGROUND: Delayed-release dimethyl fumarate (DMF; also known as gastro-resistant DMT) is an oral disease-modifying therapy (DMT) approved by U.S. FDA for relapsing forms of multiple sclerosis (MS) in 2013. No real-world data have yet been published on healthcare resource utilization (HRU) or costs of DMF users.

OBJECTIVE: To examine the real-world HRU and costs among DMT treatment naive MS patients initiating DMF or fingolimod (FTY), the first oral DMT approved by FDA in 2010.

METHODS: This retrospective study used the MarketScan claims database from January 2012 to June 2014. DMT naive patients initiating DMF or FTY between January and June 2013 were identified. Treatment naive was defined as no claims for DMTs in 1 year prior to the index date. Proportions of patients with hospitalizations and urgent care (UC)/emergency room (ER) visits were compared for 1 year prior to and post the initiation date. Total annual healthcare costs and direct medical healthcare costs were examined. Difference in difference analysis was used to compare change in costs pre and post DMT initiation between DMF and FTY cohorts.

RESULTS: A total of 365 and 119 DMT naive patients initiated DMF (mean age ± standard deviation: 46.4 ± 9.7; female: 75.6%) and FTY (44.8 ± 9.6; 79.0%), respectively. In the year post-initiation date, the percentage of patients hospitalized was reduced by 8.2 (from 13.4% to 5.2%, P < 0.05) and 3.3 (from 10.9% to 7.6%, P = 0.30) in DMF and FTY cohorts, respectively, and percentage of patients with UC/ER visits decreased by 6.0 (from 30.1% to 24.1%, P < 0.01) in the DMF cohort and increased by 1.7 (from 31.1% to 32.8%, P = 0.11) in the FTY cohort. The total annual healthcare cost increased by $37,663 (from $24,664 to $62,327, P < 0.01) and $52,871 (from $19,776 to $72,647, P < 0.01) after the initiation of DMF and FTY, respectively. The cost increase in the DMF group was $15,208 (P < 0.01) lower than that of the FTY group; the age-gender-CCR-adjusted between-cohort difference remained similar ($15,800). The annual direct medical healthcare costs decreased in the DMF and FTY cohorts by $7,592 (from $18,978 to $11,386, P < 0.01) and $6,202 (from $15,763 to $9,561, P < 0.01), respectively; the unadjusted and adjusted differences in cost reduction were not significantly different between cohorts.
CONCLUSIONS: There was a significant decrease in hospitalization with DMF but not in FTY. DMF also showed a decrease in UC/ER compared to increase shown with FTY. Initiation of both oral DMTs was associated with a decrease in HRU and direct medical costs, and an increase in total healthcare costs (with DMF associated with a smaller increase than FTY).

SPONSORSHIP: This study was sponsored by Biogen.

G05 Adherence and Persistence to Oral MS Disease-Modifying Treatment in a Real-World Setting

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BACKGROUND: Oral disease-modifying treatments (DMTs) are indicated to reduce relapse rates and slow disease progression for relapsing-remitting multiple sclerosis (RRMS) patients when taken as prescribed. Non-adherence or non-persistence in the real-world setting can lead to greater risk for negative outcomes. Although previous research has demonstrated greater adherence and persistence to oral versus injectable DMTs, comparisons among oral DMTs are lacking.

OBJECTIVE: To compare adherence, persistence, and time to discontinuation among MS patients treated with an oral DMT: fingolimod (FTY), dimethyl fumarate (DMF), or teriflunomide (TFN).

METHODS: This retrospective study used MarketScan Commercial and Medicare Supplemental claim databases. MS patients with ≥1 claim for FTY, DMF, or TFN from April 1, 2013 to June 30, 2013 were identified. Index drug was defined as the first oral DMT within this period; no claims for index drug in prior 12 months. Baseline characteristics were described for patients in each group. Adherence measured by medication possession ratio (MPR) and proportion of days covered (PDC), persistence (30-day gap allowed), and time to discontinuation over a 12-month follow-up period were compared across treatment groups. Adjusted Cox regression models estimated the risk for discontinuation.

RESULTS: 1,498 patients were identified with an index oral DMT: FTY (n=185); DMF (n=1,160); and TFN (n=143). Patients were similar across baseline demographics, including region, prior DMT use, relapse history, and healthcare resource utilization. Statistically significant differences were observed across the treatment groups for age, sex, and co-morbidities. FTY patients had greater adherence at 12 months compared to other oral DMTs: MPR≥80% (FTY=88.7%; DMF=70.6%; TFN=72.7%; P<0.0001), and PDC≥80% (FTY=75.4%; DMF=60.3%; TFN=53.1%; P<0.0001). Persistence was also greater for FTY patients (74.4%) compared to DMF and TFN patients (55.9%, 49.7%, respectively; P<0.0001). Cox regression model adjusted for age, sex, region, prior DMT use, and relapse history found the risk for discontinuation to be 2 times greater for DMF (hazard ratio (HR)=2.36, 95% confidence interval (CI): 1.64-3.40), compared to FTY.

CONCLUSIONS: In a real-world setting, patients taking FTY had better adherence and persistence compared to other oral DMTs over 12 months. Coupled with clinical factors, medication adherence and persistence are important factors when determining coverage decisions for MS patients.

SPONSORSHIP: This study was sponsored by Novartis Pharmaceuticals.

G06 Real-World Analysis to Assess the Difference in Long-term Medication Adherence and Persistence with Fingolimod Compared to Injectable Disease-Modifying Therapies in Patients with Multiple Sclerosis

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BACKGROUND: The mainstay of treatment for patients with relapsing-remitting multiple sclerosis (RRMS) is the use of disease modifying therapies (DMTs). Adhering to DMTs can be a challenge for patients as many of these products require subcutaneous or intramuscular self-injection. Currently, there are limited data available regarding long-term adherence and persistence among these agents.

OBJECTIVE: To analyze the differences in long-term adherence and persistence for patients receiving fingolimod (FTY) versus injectable disease-modifying treatments (iDMT), specifically glatiramer acetate (GA) and intramuscular interferon beta-1a (IFN-β-1a).

METHODS: Medical and pharmacy claims data from four regional health plans were compiled for continuously enrolled adult patients with a diagnosis of multiple sclerosis (ICD-9: 340) within the identification period (January 1, 2011-December 31, 2011). MS patients with at least 1 claim for FTY, GA, or IFN-β-1a within both the identification period and 36-month follow-up period were included. Index date was defined as first claim during the identification period. Patients were required to have continuous enrollment in medical and pharmacy benefits during the 36-month follow-up period as well as the baseline period (12 months before index date). Adherence measured by proportion of days covered (PDC) and persistence (no gap >60 days) over a 36-month follow-up period were compared for FTY versus iDMTs.

RESULTS: A total of 98 FTY and 978 iDMT patients were identified. Age and gender were similar for both groups. The most common comorbidities were dyslipidemia and hypertension, and the top MS symptoms were pain and fatigue for FTY and iDMT patients. FTY patients were more likely to be adherent and persistent after 36 months than iDMT patients. The mean PDC was 62.6% for FTY and 51.5% for iDMTs (P<0.0001), and proportion of patients with PDC ≥80% was 51% for FTY and 15% for iDMT (P<0.0001). Persistence to the index drug was 19% for FTY and 4% for iDMTs (P<0.0001). A Cox regression model found the risk for discontinuation to be two times greater for iDMTs compared to FTY (hazard ratio 2.074; 95% confidence interval: 1.544-2.785).

CONCLUSIONS: In this real-world setting, FTY patients had greater long-term (36 months) adherence and persistence compared to patients on iDMTs. Selection of therapies for treatment of RRMS should give consideration to patient and disease specific factors which will impact adherence. Non-adherence to DMTs may lead to an increase in the risk of relapse and disability progression.

SPONSORSHIP: This research was funded by Novartis Pharmaceuticals.

G08 Real-World Comparison of Patient Adherence and Persistence to Fingolimod Versus Dimethyl Fumarate in Multiple Sclerosis

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BACKGROUND: Patients clinically diagnosed with relapsing-remitting multiple sclerosis (RRMS) are treated with disease-modifying therapies (DMTs). Clinicians report suboptimal adherence to DMTs leading to increased relapse rates and a decline in patient functional status. Data comparing one-year adherence and persistence between FTY and
DMF are limited. DMF adherence data beyond 6 months are particularly limited as DMF became available in March 2013. FTY and DMF were selected for comparison since these two DMTs have the greatest market share among oral DMTs as of April 2015.

**OBJECTIVE:** To analyze the differences in adherence and persistence in patients receiving fingolimod (FTY) and dimethyl fumarate (DMF) for treatment of multiple sclerosis (MS) since the availability of DMF in March 2013.

**METHODS:** This retrospective study was conducted using medical and pharmacy claims data from three regional health plans. Patients aged ≥18 years with a diagnosis of multiple sclerosis (ICD-9-CM 340) during the identification period (April 1, 2013–December 31, 2013) were included. MS patients with at least one claim for FTY or DMF within both the identification period and the 12-month follow-up period were identified. Index drug and date were defined as first claim during the identification period. Patients were required to have continuous enrollment in medical and pharmacy benefits during the 12-month follow-up period as well as the 6 months prior to the index date (baseline period). Adherence, which was measured by proportion of days covered (PDC), and persistence (defined as having no gap >60 days) over a 12-month follow-up period were compared for FTY versus DMF.

**RESULTS:** A total of 110 FTY and 123 DMF patients were identified. Both groups were similar at baseline for demographics, comorbidities, and MS symptoms. FTY patients were more likely to be adherent and persistent after 12 months than DMF patients. The mean PDC was 82.2% for FTY and 76.9% for DMF (P = 0.0408) and the proportion of patients with PDC ≥80% was 76.8% for FTY and 63.8% for DMF (P = 0.0361). Persistence to the index drug was 77% for FTY and 68% for DMF (P = 0.0451). A Cox regression model found the risk for discontinuation to be four times greater for DMF versus FTY (hazard ratio: 4.01, 95% confidence interval: 2.65-6.08).

**CONCLUSIONS:** In this real-world setting, FTY patients had greater adherence and persistence compared to patients on DMF. Use of therapies that demonstrate a favorable rate of adherence may result in improved clinical outcomes by reducing relapse rates and slowing disease progression.

**SPONSORSHIP:** This research was funded by Novartis Pharmaceuticals.
CONCLUSIONS: The model showed that 44 mcg scIFNβ1a was a cost-effective treatment strategy relative to imIFNβ1a using multiple composite clinical outcome measures.

SPONSORSHIP: EMD Serono, Rockland, MA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer, New York, NY.

G12 Cost-Offset Analysis of Interferon Beta Disease-Modifying Therapies in Relapsing-Remitting Multiple Sclerosis
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BACKGROUND: Interferon-beta (IFNβ) therapies often prescribed as first-line treatments for relapsing-remitting multiple sclerosis (RRMS) due to their favorable long-term efficacy and tolerability profiles and minimal monitoring requirements. Thus, it is important to evaluate the potential cost-offsets across disease activity-related endpoints that may be obtained from use of IFNβ therapies in RRMS.

OBJECTIVE: To compare direct medical costs for patients with RRMS treated with subcutaneous (sc) IFNβ1a 44 mcg three times weekly (TIW) versus other IFNβ therapies across endpoints comprising the “no evidence of disease activity” (NEDA) measure.

METHODS: A decision-analytic model was developed using comparative efficacy data sourced from a network meta-analysis (NMA) of IFNβ therapies: scIFNβ1a 44 mcg TIW, scIFNβ1b 250mcg every other day, intramuscular (im) IFNβ1a 30 mcg weekly, and pegylated (peg) IFNβ1a 125 mcg every two weeks. The number of patients experiencing NEDA-related endpoints (relapse, new MRI activity, or disability progression) for each therapy was determined using risk ratios derived from odds ratios (ORs) vs. placebo (pairwise analysis) or vs. other IFNβ therapies (NMA analysis). The model followed 1,000 patients with RRMS over 2 years. Costs were sourced from the literature. One-way sensitivity analyses (OWSAs) were performed to test the robustness of the results.

RESULTS: Only medical costs were assessed, thus observed cost-offsets meant fewer patients experienced NEDA-related endpoints. For scIFNβ1a 44 mcg vs. pegIFNβ1a, results from the pairwise analysis projected cost-offsets of $893,652 (relapse) and $252,219 (MRI); results from the NMA also projected cost-offsets of $84,826 (relapse) and $105,667 (MRI). For scIFNβ1a results from the pairwise analysis projected cost-offsets of $578,174 (relapse), $118,716 (disability), and $15,628 (disability), and $105,667 (MRI). For scIFNβ1a 44 mcg vs. imIFNβ1a, results from the pairwise analysis projected cost-offsets of $35,948 (disability). OWSAs confirmed substantial cost-offsets for the comparison examined.

CONCLUSIONS: The results of this decision-analytic model suggest that scIFNβ1a 44 mcg provides substantial cost-offsets versus other IFNβ treatments across NEDA-related endpoints.

SPONSORSHIP: EMD Serono, Rockland, MA (a subsidiary of Merck KGaA, Darmstadt, Germany).

G14 A Real-World Assessment of Multiple Sclerosis in Patients Treated with Subcutaneous Interferon Beta-1a: Relapse, Medical Costs, and Persistence
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BACKGROUND: It is important to assess the value of disease-modifying drugs in the treatment of patients with multiple sclerosis in a practical, real-world setting.

OBJECTIVE: To examine multiple sclerosis patients treated with subcutaneous interferon beta-1a (scIFNβ1a) and to describe relationships among treatment persistence, relapse timing relative to discontinuation, and medical costs.

METHODS: Patients (aged 18-63 years) with ≥1 MS claim (ICD-9-CM: 340.xx) and an initial scIFNβ1a claim (index event), with 12 months of continuous eligibility pre- and 24 months post-index, were identified in the IMS PharMetrics Plus database. Discontinuation was defined as ≥90 day gap in scIFNβ1a therapy. Relapse was defined as the first post-index MS-related inpatient stay, emergency room (ER) visit or MS outpatient visit with a corticosteroid claim ≥7 days. Relapse was categorized as before or after scIFNβ1a discontinuation. Medical costs (excluding disease-modifying drug (DMD) costs) per day (US$) pre- or post-discontinuation of scIFNβ1a are presented. Costs were evaluated with generalized linear regression models using gap, time of first relapse and the interaction as predictors. Prior costs, age, gender and time until relapse were evaluated as covariates.

RESULTS: 1,540 MS patients met the study criteria; 40% had a relapse and 50% (n = 770) discontinued scIFNβ1a during the follow-up period. Patients discontinuing scIFNβ1a averaged 250 (SD = 182) days of treatment and 33% relapsed, while those who did not discontinue averaged 726 (SD = 15) days of treatment and 25.2% relapsed (P < 0.01). Non-DMD medical cost per day was lowest for patients with no gap and no relapse ($24.71/day). Patients who discontinued scIFNβ1a and had their first relapse after discontinuation, had non-DMD medical costs of $39.04/day prior to discontinuation, and $52.29/day after discontinuation. Patients with no gap and a relapse while scIFNβ1a therapy was available had lower non-DMD medical costs ($38.88/day), than patients with a gap in scIFNβ1a that experienced a relapse while on treatment ($72.37/day). Models suggest that costs differ depending on gap status and timing of the relapse relative to scIFNβ1a discontinuation (P < 0.01).

CONCLUSIONS: These results suggest the value of maintaining scIFNβ1a treatment.

SPONSORSHIP: EMD Serono, Rockland, MA (a subsidiary of Merck KGaA, Darmstadt, Germany) and Pfizer, New York, NY.

G15 The Impact of Timing of Disease-Modifying Drug Treatment Initiation on Multiple Sclerosis Relapse Rates in Newly Diagnosed Patients
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BACKGROUND: Early treatment with disease-modifying drugs (DMDs) following a diagnosis of relapsing multiple sclerosis (MS) is recommended for most MS patients. DMD treatment has been proven to reduce the number of relapses and, in some cases, delay the progression of disability.

OBJECTIVE: To evaluate whether early or late disease-modifying drug (DMD) treatment initiation is associated with improved outcomes in multiple sclerosis (MS, i.e., rates of MS relapse).

METHODS: A retrospective analysis of a large U.S. electronic medical records (EMR) database was utilized to evaluate newly diagnosed MS patients from 2006-2014, where index date is the date of the first recorded diagnosis of MS (ICD-9 code 340.XX). Patients were required to have a minimum of 1 year of continuous baseline (pre-index) enrollment to help ensure that these are newly diagnosed cases, as well as
Cost-Effectiveness of Peginterferon Beta-1a in Relapsing-Remitting Multiple Sclerosis

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BACKGROUND: Multiple sclerosis (MS) is a chronic inflammatory disorder of the central nervous system, affecting 2.5 million people globally, and 400,000 people in the United States (U.S.). Since no cure exists for MS, the goal is to manage the disease using disease-modifying therapies (DMTs) which have shown to slow disease progression and prevent relapses. Relapse-remitting MS (RRMS) is the most common form of MS at the time of diagnosis. Peginterferon beta-1a (PEG), a recently approved DMT, has demonstrated good clinical outcomes including reduced relapse rates as compared to subcutaneous interferon beta-1a (IFN). Given the high costs of ALT, there is a need to conduct a cost effectiveness study to understand the overall value of this new DMT in the treatment of RRMS.

OBJECTIVE: To determine the cost-effectiveness of ALT compared to IFN in RRMS from a U.S. third-party payer perspective.

METHODS: A 2-year static decision model using MS Excel was utilized for the cost-effectiveness analysis. The model inputs included drug acquisition costs (Wholesale Acquisition Cost from Red Book), drug administration and monitoring costs (Package inserts and Medicare reimbursements), relapse rates and relapse rate reduction (CARE-MS II clinical trial), resource utilization for treatment of relapses in patients with EDSS 0-4 (published literature). All costs were adjusted to 2015 dollars using the medical care component of the Consumer Price Index published by the Bureau of Labor Statistics. Outcomes measured were 2-year total cost of therapy per patient, cost per relapse avoided and incremental cost-effectiveness ratios (ICER). Sensitivity analysis was conducted to test the model robustness.

RESULTS: The 2-year total cost of therapy per person was $161,717 compared to IFN ($144,371). However, the cost per relapse avoided for ALT was significantly lower ($137,048) compared to IFN ($313,850). The ICER for ALT compared to IFN was estimated at $24,092 per relapse avoided, which is well within the threshold of $50,000/outcome.

CONCLUSIONS: To our knowledge, this is the first cost-effectiveness study comparing ALT to IFN. ALT was found to be a cost-effective alternative compared to IFN in RRMS, but the model is being further refined to include adverse events associated with ALT like autoimmune thrombocytopenia and anti-glomerular basement membrane disease, which can affect the ICER for ALT.

SPONSORSHIP: None.
Role of Seizure Frequency and Severity in the Comparison of Economic Outcomes Associated with Monotherapy and Adjunctive Therapy Among Patients with Epilepsy

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BACKGROUND: Few real-world studies in epilepsy examining differences in economic outcomes take into account the potential effect of seizure frequency and/or severity.

OBJECTIVE: To compare the healthcare utilization and costs among patients with epilepsy treated either with monotherapy or adjunctive therapy, taking into account demographics and clinical characteristics (including seizure severity and frequency).

METHODS: Data from the 2011-2013 U.S. National Health and Wellness Survey, a nationally representative, self-administered, internet-based survey, were analyzed. Patients were grouped as monotherapy (1 antiepileptic drug [AED]) or adjunctive AED therapy (2 or more AEDs concurrently) users. Patients provided information on demographics and health characteristics (e.g., seizure severity [mild, moderate, severe] and frequency [seizures per year category]). Outcomes included healthcare utilization (number of physician visits, emergency room [ER] visits, and hospitalizations) and work productivity and activity impairment (WPAI: 6-item validated instrument assessing percentage of work and activity impairment). Mean annual direct and indirect costs in U.S. dollars were estimated using the 2012 Medical Expenditure Panel Survey and the U.S. Bureau of Labor Statistics with subject level NHWS data. Adjusting for patient characteristics, generalized linear models were used to compare differences in outcomes by treatment group.

RESULTS: Among 1,126 epilepsy patients (mean age = 46; 48% female), 744 were on monotherapy (66%), 286 on 2 AEDs (25%), 65 on 3 AEDs (6%), and 31 on 4+ AEDs (3%). In unadjusted comparisons, patients on 4+ AEDs vs. monotherapy had higher absenteeism (28% vs. 6%), presenteeism (54% vs. 23%), overall work impairment (59% vs. 26%), and more ER visits (2.8 vs. 0.8) and hospitalizations (2 vs. 0.4), each P <0.05. Additionally, patients on 4+ AEDs incurred higher direct costs ($88,522 vs. $29,546), indirect costs ($20,331 vs. $8,365), and total costs ($96,392 vs. $33,143), all P <0.05. However, after adjusting for patient characteristics, these differences were no longer significant; seizure severity and frequency were the two variables that most influenced the model.

CONCLUSIONS: Results suggest that seizure severity and frequency may more strongly influence economic outcomes than the number of concomitant AEDs taken by patients. Additional research could further explore this possibility.

SPONSORSHIP: Sunovion Pharmaceuticals provided funding for this analysis.

Exceeding Healthcare Utilization and Costs in Patients with Lennox-Gastaut Syndrome: A Real-World Observational Study in a U.S. Health Plan

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BACKGROUND: Lennox-Gastaut syndrome (LGS) is a pediatric seizure disorder which accounts for 1%-10% of all childhood epilepsies. Currently there are no specific ICD-9-CM codes available to identify LGS patients in healthcare claims or other databases. However, LGS algorithms developed for this purpose typically use diagnoses of generalized convulsive or non-convulsive epilepsy in combination with a developmental delay (e.g., Clements, 2013).

OBJECTIVE: The purpose of this study was to identify patients with LGS and compare them to patients characterized with generalized convulsive or non-convulsive epilepsy on epilepsy-related utilization and costs.

METHODS: This study was a retrospective observational cohort analysis using the OptumInsight claims database from the period January 1, 2010 to December 31, 2012. Patients were selected if they had at least one primary diagnosis of generalized convulsive or non-convulsive epilepsy and then subsequently stratified into one of two cohorts by the presence of the developmental delay (i.e., LGS vs. non-LGS). To adjust for differences in baseline characteristics and severity, a one-to-one propensity score matching technique was used. Patients were matched on demographic characteristics, comorbidities, and number of unique AEDs. Epilepsy-related healthcare utilization and costs were then compared between the two cohorts.

RESULTS: A total of 6,086 patients met study inclusion criteria, including 1,176 patients in the LGS cohort, and 4,910 in the non-LGS cohort. After propensity score matching, a paired sample of 1,746 patients, 873 in each cohort, was examined. The results showed that, when compared to non-LGS patients, patients with LGS were significantly more likely to have an epilepsy-related inpatient admission (10.0% vs. 13.3%, respectively, P <0.001) and more outpatient visits (4.3 vs. 6.3, P <0.001) annually. No differences were found for average length of inpatient stay or likelihood to have an ER visit. Epilepsy-related costs also differed significantly between the two cohorts. Annual medical costs for the LGS cohort averaged $10,786 compared with $7,898 for non-LGS patients, P <0.001.

CONCLUSIONS: The results of this study indicate that epilepsy-related inpatient utilization and healthcare cost were significantly higher for patients with generalized convulsive or non-convulsive epilepsy in combination with a developmental delay (LGS) compared to those without the developmental delay (non-LGS).

SPONSORSHIP: Eisai.

Healthcare Utilization and Annual Direct Costs in Patients with Migraine in a Commercial Claims Database

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BACKGROUND: The economic burden of migraine is not well understood.

OBJECTIVE: Describe healthcare utilization and annual direct costs in commercially insured migraine patients.

METHODS: This retrospective cohort study identified migraine patients (ICD-9 code 346.XX and/or migraine-specific medications) in the Truven Health MarketScan Research Databases between January 2008 and June 2013. Patients were required to have 12 months continuous enrollment before and after the day they received migraine diagnoses and/or medications (index) and no diagnosis of HIV or malignancy during the study period. Based on pre-index use of prescription acute and/or prophylactic medications, patients were stratified into 4 mutually exclusive cohorts. Outcomes assessed over the 12-month post-index period included all-cause and migraine-specific HCU (inpatient [IP] stays, outpatient visits, emergency room [ER] visits, and acute and prophylactic migraine medication use) and direct costs.

RESULTS: Of 857,073 patients meeting inclusion criteria, 22.9% had both acute and prophylactic use, 36.6% acute-only, 3.8% prophylactically, and 16.7% neither. Mean age was 43.2 years (SD = 12.5) and 83.2% were female. Average annual all-cause costs for migraine patients were $13,045 (SD = $25,328) with the top tenth percentile at $29,051.
All-cause annual costs were $10,317, $12, 494, $16, 440, and $10,892 among patients using prophylactic-only, acute-only, both, and neither, respectively. Opioid use was seen in nearly one-half (46.1%) of patients, with mean opioid days’ supply of 96.7 days (SD = 176.4); 13.8% of opioid users had at least 9 months’ supply during the 1 year follow-up period. NSAID and triptans were used by 30.4% and 63.4% of patients with mean days’ supply of 75.8 and 107.5, respectively. Total annual costs were significantly higher for patients who used an opioid ($19,762 vs. $7,291) or NSAID ($16,766 vs. $11,424) during the post-index period (P<0.001) but lower for triptan-users ($11,491 vs. $15,442, P<0.001). Migraine-related ER visits were common (15.4%) with higher rates among patients without acute or prophylactic use (29.9 %) than acute-only (13.2%), prophylactic-only (9.1%) or both (11.1%).

CONCLUSIONS: Migraine is associated with considerable economic burden. Costs showed substantial variation with higher costs among patients treated with migraine-specific or non-specific acute medications. While this study included patients across the spectrum of migraine severities, future research should focus on patients with frequent migraines and on indirect costs which account for a substantial proportion of costs for these patients.

SPONSORSHIP: Research was funded by Amgen.

CONCLUSIONS: Rapid/early relief of migraine is a top priority for patients yet early relief outcomes are under reported in migraine clinical trial publications. We found that of the 99 clinical trial publications collectively cited in at least one of the 3 major meta-analyses, only 49% reported headache relief at 60 minutes and 34% at 30 minutes. This represents a gap between clinical evidence reporting and the needs of the patient.

SPONSORSHIP: Avanir Pharmaceuticals.

MINI-SESSION: Comparative Effectiveness Research: Patient-Centered Outcomes in Migraine

G24 Comparative Emergency Room Utilization and Cost Following Drug Initiation for Neuropathic Pain

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BACKGROUND: Neuropathic pain alone has been associated with an approximately 3-fold increase in use of healthcare resources verses those without neuropathic pain.

OBJECTIVE: To examine the emergency room (ER) cost and utilization differences in patients with neuropathic pain treated with anti-epileptic medications.

METHODS: Utilizing Gemini Healthcare’s proprietary Pain Benchmarks Disease Modeling process and IMS LifeLink Health Plan Claims and Longitudinal Prescriptions databases, integrated medical and pharmacy claims data were analyzed to select patients with chronic pain syndromes treated with either gabapentin, gastroretentive gabapentin, or pregabalin and were continuously enrolled with at least 2 claims for relevant ICD-9 codes 30+ days apart. Additionally, no exposure to the drug of interest could be present in the preceding 90 days before the first fill (index date). Eligible patients were then followed for the 180 days following the index date to evaluate relevant outcomes. 869,701 patients with a new prescription (81% gabapentin, 1% gastroretentive gabapentin, 18% pregabalin) were evaluated for emergency room utilization and costs in the six-month follow-up period.

RESULTS: From the database, 35.2% of patients on gabapentin were seen in the ER in the first 180 days compared to 28.9% of patients on gastroretentive gabapentin and 32.3% of patients on pregabalin. The ER visit rate/100 patients at a population level was 0.52 for gabapentin, 0.39 for gastroretentive gabapentin, and 0.47 for pregabalin.

The average ER visit cost for these patients was ~$1463. Patients on gabapentin were seen more frequently but their average ER cost was slightly lower ($1,451). Conversely, patients on gastroretentive gabapentin were seen less frequently but their average ER costs were slightly higher ($1694). Patients on pregabalin were seen more frequently than gastroretentive gabapentin but less frequently than gabapentin and their average costs were also higher ($1,520).

CONCLUSIONS: The lower rate of ER visits for gastroretentive gabapentin compared to gabapentin was borderline statistically significant (P = 0.032). The difference in average cost between the two was statistically significant (P = 0.02). The reason for the lower rate of ER visits for gastroretentive gabapentin patients compared to gabapentin or pregabalin was not examined in this study and is something for future study.

SPONSORSHIP: Depomed, Newark, CA.
Treatment Initiation Timing and Healthcare Costs in Newly Diagnosed Patients with Fibromyalgia

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BACKGROUND: Fibromyalgia (FM), a chronic condition characterized by widespread musculoskeletal pain, costs the U.S. $12-$14 billion annually.

OBJECTIVE: To estimate the rate of CV events among Medicare patients with atherosclerotic cardiovascular disease (ASCVD) and/or diabetes.

METHODS: Medical, pharmacy, and lab claims data from Humana were utilized to identify Medicare Advantage-Prescription Drug (MAPD) members at high risk for CV events. The first LDL-C measurement between January 1, 2006 and June 30, 2009 was used as the index date. Other criteria included 24 months of continuous enrollment.

BACKGROUND: Poor adherence to chronic medications, particularly to diabetes (OAD), hypertension (RASA) and hyperlipidemia (STATIN), increases health care costs by about $100 billion a year.

RESULTS: Out of 31,464 patients enrolled into the program, a total of 5,780 patients were contacted within the measurement period. Patients in treatment group demonstrated significantly higher post-30 days successful fill rates than the control group (n = 1,853, 69%; P < 0.0001).

OBJECTIVE: To quantify the impact of improving adherence to chronic medications among Medicare patients using predictive analytics and a coordinated care model by clinical pharmacists and technicians.

METHODS: A multivariable logistic regression model was built using enrollment, medical, pharmacy and utilization data from 47,501 patients aged ≥ 18 to identify patients at risk of becoming non-adherent to OAD, RASA, or STATIN regimens. Qualifying criteria were defined as having 40%-80% chance of adherence and needing to refill a targeted medication within the next 7 days of assigned interventions. Qualified patients were ranked using priority scores from 0-100 based on priority successful contact rates, calculated adherence probability, current and past adherence histories, and number of comorbidities.

RESULTS: The most frequently reported comorbidities were rheumatic conditions, hyperlipidemia, back and neck pain, and depression. Proportion of patients receiving pain-related medications were similar in both cohorts, with >20% receiving opioid, anti-inflammatories, anti-anxiety, and selective serotonin reuptake inhibitor (SSRIs) medications, respectively. Using P < 0.1, only baseline depression and SSRIs use during follow-up were unbalanced after matching. Total health care costs for baseline and 12-month post-index diagnosis (follow-up) were estimated. We assessed the cohort balance post matching using Fisher’s exact tests. We compared follow-up costs for the early versus late initiation cohorts, adjusted for baseline costs, unbalanced baseline comorbidities and follow-up non-ACR recommended pain-medication use, using a generalized linear model with gamma distribution and log link function.

CONCLUSIONS: Total healthcare costs were significantly lower among early initiation patients, suggesting early use of ACR recommended pain medications as a potential cost-saving strategy. Additionally, the study patients with FM had a substantial comorbidity burden and most did not receive ACR recommended medications.
enrollment prior to index and presence of ≥1 high CV risk condition (identified by ICD-9 and procedure codes in the 2-year pre-index period). Those in long-term care facilities or hospice or with evidence of non-atherogenic causes of CV disease were excluded. Patients were assigned to 1 of 7 hierarchical CV risk categories: acute coronary syndrome (ACS) <12 months; ischemic stroke, ACS 12-24 months; coronary heart disease (CHD) with history of myocardial infarction (MI), other CHD, peripheral arterial disease (PAD), or, diabetes mellitus (DM). Baseline characteristcs and time to 1st event [composite of MI or unstable angina (UA) requiring hospitalization, ischemic stroke, coronary revascularization, or CV death] was estimated via Kaplan-Meier curves.

RESULTS: Of the 367,783 patients meeting inclusion criteria, 254,387 (69%) had ASCVD and 113,396 (31%) had DM only. The average (±SD) age was 72.1 (±8.5) years, 49.1% were male, and the mean follow-up time was 1,065 (±571) days. Overall, 56.7% of the patients had a lipid-lowering agent (53.2% statin, 3.5% non-statin agents) at index, and among those on statins, only 11% were treated with a high intensity statin (atorvastatin 40/80 mg, rosuvastatin 20/40 mg, simvastatin 80 mg). Mean LDL-C was 96.0 (±34.9) mg/dL, and 39% had an LDL-C >100 mg/dL at index. The composite CV event rate in the available post-index period was 16.9%; mean time to the first CV event was 643 (±479) days. Among the hierarchical risk categories, ACS <12 months had the highest composite event rate (32.2%), mean time to event 473 (±450) days while DM had the lowest [10.7%, mean time to event 698 (±483) days].

CONCLUSIONS: Suboptimal utilization of statins, especially high intensity, may contribute to higher CV event rates among Medicare patients at elevated risk. Additional multivariate research is planned to fully understand these effects.

SPONSORSHIP: This research was sponsored by Regeneron Pharmaceuticals.

105 Decreased Rates of Health Plan Disenrollment for Patients with Cardiovascular Disease

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BACKGROUND: Chronic medical conditions, such as cardiovascular disease (CVD), may affect patient enrollment behavior in their health plan.

OBJECTIVE: To quantify the time to and rates of health plan disenrollment for patients with CVD compared with a matched group of patients without CVD.

METHODS: CVD patients ≥18 years old were identified from the HealthCore Integrated Research Environment according to the presence of myocardial infarction, angina, coronary atherosclerosis and/or revascularization, ischemic stroke, peripheral artery disease, carotid endarterectomy (≥1 inpatient or emergency department claim or ≥2 outpatient claims for any of the preceding conditions) and/or use of P2Y12 inhibitors. The index date for CVD cases was the earliest date at which they met the criteria for CVD during January 1, 2007-November 30, 2013. Non-CVD controls include those who did not meet the criteria for CVD. Cases and controls were matched using exact 1-to-1 matching according to age, gender, health plan type, region, policy holder status, and length of pre-index enrollment. Non-CVD patients were assigned an index date equal to that of their matched CVD case. All patients were required to have ≥12 months of pre-index enrollment.

RESULTS: Approximately 1.7 million patients (881,801 per cohort) were identified and matched. Median follow-up time was 2.3 years for CVD and 1.5 for non-CVD patients. During follow-up, 55% of CVD cases disenrolled compared with 63% of controls (rate ratio = 0.67, 95% CI=[0.67, 0.68]), within those who disenrolled, time to disenrollment was almost twice as long among cases (median = 560 vs. 282 days). Survival analysis demonstrated similar results (hazard ratio (HR) = 0.70) and were statistically significant (P<0.05) and consistent across all sensitivity analyses: (a) including death as a disenrollment event (HR = 0.73), (b) excluding patients who died at any time (HR = 0.70), and (c) excluding patients who died during the first 30 days of follow-up (HR = 0.74). Results were largely driven by higher rates of disenrollment during the first 12 months in the non-CVD group, with the difference between the cohorts diminishing over time.

CONCLUSIONS: Presence of CVD was found to be associated with a longer duration of health plan enrollment and decreased risk of disenrollment. This may be due to risk aversions associated with job-lock whereby patients with chronic medical conditions are reluctant to leave their employer due to the fear of losing health insurance. Future research should examine the impact of the Affordable Care Act and its provisions relating to pre-existing conditions on health plan disenrollment.

SPONSORSHIP: HealthCore received no external funding for this research.

109 Pulmonary Arterial Hypertension (PAH) Episodes of Care: Costs Associated with PAH-Related Inpatient and Outpatient Episodes and Functional Class

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BACKGROUND: Retrospective database studies of pulmonary arterial hypertension (PAH) using claims data have limitations due to lack of PAH specific ICD-9 codes and inability to identify patient severity. A previous study validated an algorithm using non-specific PH codes and claims for a PAH specific drug. This study used provider-reported severity-function-class (FC) to examine how costs associated with PAH episodes of care differ as a function of FC.

OBJECTIVE: To determine whether functional decline is associated with increased PAH-related healthcare costs for inpatient and outpatient episodes of care.

METHODS: Medicare and commercial patients who received an endothelin-receptor antagonist (ERA), phosphodiesterase-type-5 inhibitor (PDE5) or prostacyclin (PGI2) and reported a medical claim with ICD-9-CM 416.0, 416.8 or 416.9 or medical claim indicating right heart catheterization were identified from 2009-2013 data. The date of initial therapy served as the index date. Provider-reported data from prior authorization forms required for advanced PAH therapies were examined for reported FC. An inpatient episode was triggered by acute inpatient or outpatient services that led to an inpatient admission. An outpatient episode was triggered by PAH treatment intensification. Wilcoxon rank sum tests were performed comparing FCIV to FCII and FCIII. All median costs represent monthly averages.

RESULTS: WHO-FC was found for 437 patients (FCII = 99, FCIII = 282; FCIV = 56). Percentage of patients with a PAH inpatient episodes was highest for FCIV (42% FCII; 46% FCIII; 71% FCIV; P<0.05). Median analyses indicated that FCIV incurred highest PAH-related drug costs ($0 FCII; $0 FCIII; $1,060 FCIV; P>0.10), the highest medical costs ($7,152 FCII; $7,212 FCIII; $8,958 FCIV; P>0.10) and the highest PAH-related total costs ($8,215 FCII; $10,400 FCIII; $12,294 FCIV; P>0.10). FCIV patients had more outpatient episodes than the other two cohorts (17% FCII; 22% FCIII; 34% FCIV; P<0.05), the lowest median PAH-related drug costs ($7,898 FCII; $7,608 FCIII; $6,849 FCIV; P>0.05) but the...
highest median medical costs ($623, $439; $3,425; $P>0.10) and highest median total costs ($9,216, $9,197, $11,072; $P>0.10).

CONCLUSIONS: FCIV PAH patients experienced more PAH inpatient and outpatient episodes and incurred higher median total costs than less severe FCs. Disease severity, WHO FC, was associated with greater likelihood of inpatient episodes and higher PAH-related costs for FCIV patients suggesting that patients progressing to FCIV generate more services and preventing this progression through early treatment is desirable.

SPONSORSHIP: Evidera; Actelion Pharmaceuticals US.

Incident Events Associated with Use of Prostaceyclins for Pulmonary Arterial Hypertension

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BACKGROUND: While the efficacy of prostaceyclins (PGI2) in the treatment of pulmonary arterial hypertension (PAH) is well understood, the burden of side effects and complications of such therapy in real-world settings is not.

OBJECTIVE: To characterize the burden of incident events associated with use of PGI2 for PAH among patients newly started on such therapy.

METHODS: Using the Truven Commercial and Medicare Databases (2010-2014), two cohorts were constituted. The first consisted of initiators of parenteral PGI2 (P-PIG2); the second, non-parenteral PGI2 (NP-PIG2). Within each cohort, the earliest date of receipt of PGI2 was deemed the “index date,” and all patients were required to have evidence of PAH as determined by at least one of three specified algorithms. Events associated with P-PIG2 and/or NP-PIG2 therapy were identified using ICD-9-CM diagnoses from medical claims (e.g., localized infections, syncope, hypotension, bronchospasm, Cor pulmonale) or information from prescription claims (e.g., narcotics for infusion-site pain). Each event was assessed separately from index date until the first of PGI2 discontinuation, disenrollment, or end of study.

RESULTS: A total of 755 P-PIG2 and 1003 NP-PIG2 patients were identified who met all selection criteria; mean (standard deviation [SD]) follow-up was 270 (302) days and 262 (300) days, respectively. In the P-PIG2 cohort, 387 (51.3%) experienced at least one event of interest; with the most common being narcotic use (27.3% of all such patients initiated narcotics), ondansetron use (15.4%), gabapentin use (12.3%), hypotension (12.3%), blood dyscrasias (10.9%), localized infections (7.7%), epistaxis/hemoptysis (6.4%) and bronchospasm (6.2%). In the NP-PIG2 cohort, 326 (32.5%) experienced at least one event of interest; the most common were narcotic use (16.6%), bronchospasm (6.8%), hypotension (5.7%), syncope (5.6%), epistaxis/hemoptysis (4.3%), blood dyscrasias (4.1%), Cor pulmonale (3.1%), and gabapentin use (3.1%).

CONCLUSIONS: About 40% of patients who initiated PIG2 experienced at least one event of interest, typically within a year of initiating such therapy. The frequency of many of these events was nominally greater among patients who initiated therapy with parenteral PIG2 versus non-parenteral PIG2.

SPONSORSHIP: Actelion Pharmaceuticals US (South San Francisco, CA) was the source of funding for this abstract.

Treatment Trends Among High Cardiovascular Disease Risk Commercially Insured and Medicare Advantage Patients Treated with Lipid-Lowering Therapies: A U.S. Real-World Study

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BACKGROUND: There is strong evidence demonstrating low density lipoprotein-cholesterol (LDL-C) as a causal factor in atherosclerotic cardiovascular disease (CVD) development. Statins are the cornerstone for LDL-C lowering; it is important to understand lipid-lowering therapy (LLT) trends in light of current treatment guidelines.

OBJECTIVE: To evaluate LLT trends in a U.S. real-world setting among commercially insured and Medicare Advantage patients.

METHODS: Patients (aged ≥18 years) who initiated LLT (statins and/or ezetimibe) January 1, 2007-June 30, 2011 were retrospectively identified from IMS commercial claims database. Patients were classified into two cohorts: (a) Prior CVD: myocardial infarction, unstable angina, ischemic stroke, coronary artery bypass graft, percutaneous coronary intervention or transient ischemic attack and (b) Prior coronary heart disease risk equivalent (CHD RE) conditions: chronic ischemic heart disease, stable angina, peripheral artery disease, abdominal aortic aneurysm and diabetes mellitus and stratified by commercial and Medicare Advantage age groups (<65, ≥65 years). Eligible patients had continuous health plan enrollment for ≥1-year pre- and post-index date (LLT initiation date). Index statin intensity (defined by ACC/AHA 2013 guidelines), first treatment modification (switch, re-initiation after temporary discontinuation of >60 days, permanent discontinuation of all LLT) and time-to-first treatment modification were assessed.

RESULTS: A total of 41,934 patients with prior CVD (mean age 58 years) and 170,344 patients with CHD RE (mean age 57 years) were analyzed. For patients with recorded LDL-C data during the 12-month pre-index period, the average LDL-C levels were 126.8 mg/dL for CVD cohort and 121.2 mg/dL for CHD RE cohort. Among commercially insured patients aged <65, from 2007-2011, 66.6-77.8% and 88.2-25.1% of the cohorts were prescribed moderate-intensity and high-intensity statins, respectively, on the index date. Among the CVD and CHD RE cohorts, 18.8% and 26.2% re-initiated index LLT, 11.6% and 13.2% permanently discontinued all LLT and 19.5% and 13.6% switched to a different statin, respectively, as the first treatment modification. A similar trend was observed among Medicare Advantage patients aged ≥65 years. Average number of days to first treatment modification was 130-399 days.

CONCLUSIONS: With 79% of patients modifying their index LLT, of which 12%-13% permanently discontinuing all LLT, such treatment modifications may potentially indicate index statin intolerability and/ or ineffectiveness. High-intensity statin therapy initiation is low, potentially resulting in residual CVD risk.

SPONSORSHIP: This study was sponsored by Amgen.

Factors Associated with High Healthcare Costs Among Patients with Heart Failure

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BACKGROUND: Heart failure (HF) is a major cause of morbidity and mortality in older adults, and accounts for substantial economic burden to health systems. Data sources with detailed survey/claims-linked data may provide information that helps improve cost modeling/management in patients with HF.

OBJECTIVE: This study assessed patient factors associated with higher healthcare costs among individuals with HF.

METHODS: A retrospective study was conducted using data from the Medicare Current Beneficiaries Survey (MCBS), a Medicare claims-linked survey. Included patients were ≥65 years old with any combination of 2 outpatient/physician visits or claims with ICD-9 CM diagnosis codes for HF, and at least one-year continuous follow-up between 2005 and 2010. Date of earliest claim for HF was defined as index date. Total one-year healthcare costs were assessed during the follow-up period. Regression models were developed to examine associations between patient factors and each of one-year total healthcare costs (Generalized Linear Model or GLM, with log-link & gamma distribution), and being in the top cost tertile (logistic regression). Patient factors examined included year of index date, age, gender, race/ethnicity, education, income, living arrangement, assistance with activities of daily living, number of physician encounters, Charlson Comorbidity Index (CCI), veteran status, self-reported health status, and geographic region.

RESULTS: A total of 645 patients (67% female, median age 83 years) met sample inclusion criteria. Average one-year total healthcare costs for patients in sample were $40,173, with individuals identified in the top cost tertile (defined as costs ≥$41,258) having average costs of $84,857. Non-Hispanic black race (cost ratio = 1.451, P < 0.05), and having more physician encounters (cost ratio = 1.005, P < 0.03) were associated with higher one-year total healthcare costs. Higher CCI scores (cost ratio = 1.185, P < 0.0001) were also associated with higher one-year total healthcare costs, however, no associations were found with self-reported health status. Older age (OR = 0.935, P < 0.002) was associated with increased costs, and higher CCI scores (OR = 1.574, P < 0.0001) associated with increased odds of being in the top cost tertile.

CONCLUSIONS: Average one-year healthcare costs were high among older HF patients and associated with specific patient demographic and clinical characteristics. Findings highlight factors associated with higher healthcare costs among HF patients and suggest a need to further understand ways to reduce resource use and costs in the Medicare population.

SPONSORSHIP: Precision Health Economics received payment from Novartis Pharmaceuticals for conducting the research analysis.

All-Cause and Bleeding-Related Hospitalizations in Non-valvular Atrial Fibrillation Patients Initiating Oral Anticoagulant Therapy

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Ochsner Clinic; Bristol-Myers Squibb; Pfizer; Mu Sigma Business Solutions

BACKGROUND: Rate and risk of hospitalization in the context of real world data (RWD) for patients with non-valvular atrial fibrillation (NVAF) is a factor for therapy selection with an oral anticoagulant (OAC).

OBJECTIVE: Assess hospitalizations (all-cause and bleeding related) in NVAF patients initiated with an OAC: apixaban, dabigatran, rivaroxaban, or warfarin.

METHODS: A retrospective cohort study using Humana Medicare Advantage data from July 1, 2009 to September 30, 2014 was conducted. NVAF patients ≥18 years receiving one OAC on the index date with 6 months continuous enrollment prior and 3 months post-index prescription were eligible. Hospitalizations were identified by codes for inpatient admission. Bleeding-related hospitalizations required an additional code for major or clinically relevant non-major (CRNM) bleeding. Hospitalization rate per 100 person years was calculated, and a cox proportional hazards model estimated hazard ratios (HR) of hospitalizations adjusted for age, sex, region, prior hospitalization, comorbidities, and medications. Adherence was calculated using a proportion of days covered approach.

RESULTS: 53,168 patients were initiated on an OAC: 2,028 (3.8%) on apixaban, 5,644 (10.6%) on dabigatran, 7,667 (14.4%) on rivaroxaban, and 37,829 (71.1%) on warfarin. The apixaban cohort was older (mean 75.5 years, P < 0.05), and had a higher CHA2DS2-VASc score (mean 3.8, P < 0.05). Apixaban patients had a higher mean HAS-BLED score vs. dabigatran (P < 0.0001), but lower score vs. warfarin (P < 0.0001). Patients on apixaban had the lowest all-cause hospitalization rate per 100 person years at 58.2, while rivaroxaban was highest at 77.2. Bleeding-related rates were lowest for apixaban and dabigatran (11.9 and 11.2) and highest for rivaroxaban and warfarin (19.2 and 18.5). After adjusting for baseline characteristics, patients on apixaban had a significantly lower risk for all-cause hospitalization across cohorts (apixaban as reference, HR = 1.14 for dabigatran, 1.30 for rivaroxaban, and 1.29 for warfarin, P < 0.05 for each), and a significantly lower risk for bleeding-related hospitalization vs. patients receiving rivaroxaban or warfarin (apixaban as reference, HR = 1.59 for rivaroxaban, 1.49 for warfarin, P < 0.001 for each) Mean adherence rates were 88.3% for apixaban, 87.8% for dabigatran, 90.4% for rivaroxaban, and 87.8% for warfarin.

CONCLUSIONS: RWD indicate potential differences in rates and risk for hospitalization among patients receiving OACs for NVAF. These data contribute to the evolving clinical evidence and may be valuable for therapy selection.

SPONSORSHIP: This research was funded by Bristol-Myers Squibb and Pfizer.

A Systematic Review of Heart Failure-Related Medical Costs and Cost-Offsets from Newly Approved Heart Failure Medication Entresto

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BACKGROUND: Heart failure (HF) is a complex clinical disease state that involves structural or functional impairment in the ability of heart to pump blood. HF results from existing disease states such as hypertension, diabetes, metabolic syndrome, and atherosclerotic disease. The estimated prevalence of HF in the United States (U.S.) is about 2%-3% of the population with a mortality occurring in about 1%-1.5% of these patients.

OBJECTIVE: The goals are to (i) identify existing cost studies in HF treatment from published literature (ii) identify different medical costs from the reviewed studies (iii) calculate direct medical cost associated with HF treatment (iv) forecast potential cost-offsets from the newly approved HF drug Entresto.

METHODS: A systematic review was conducted using search databases such as PubMed, Ovid, and Cochrane Reviews identifying cost studies published in the last 10 years. All direct and indirect medical costs reported in those studies were extracted. Further, direct medical costs were calculated from national databases such as HCUP and MEPS. Micromedex Solutions Redbook and CPT codes were utilized for calculating medication and office visit costs respectively. All costs were adjusted to 2015 U.S. dollars based on inflation data reported.
by the Bureau of Labor Statistics. Sensitivity analysis was conducted to determine the variability in the study results. Efficacy rates were taken from PARADIGM-HF clinical trials data of Entresto to forecast the potential cost-offsets.

RESULTS: The systematic review yielded seven studies evaluating HF costs. Direct medical costs included in these studies were hospitalization, outpatient visits, medications, and emergency department visits. Using HCUP data, there were 875,585 discharges due to HF in 2012 with a mean length of stay as 5.2 days at an average cost of $11,412 ($12,300 2015 value). The total direct medical cost for treatment of HF was estimated to be around $16,000-$18,000 per patient annually. Entresto clinical trial reported a 21% and 20% decrease in hospitalization and cardiovascular-related mortality respectively. Assuming an initial 10% market share for this newly approved drug, the cost offsets can be estimated to be around $226 million.

CONCLUSIONS: HF imposes a substantial economic burden on the health care system. The total medical cost for treatment of HF seems to be increasing each year. There is a necessity for new innovative medications that can help decrease the number of hospitalizations related to HF. Introduction of medications such as Entresto into the market could prove beneficial in terms of cost-offsets each year.

SPONSORSHIP: Duquesne University Mylan School of Pharmacy.

Comparison of Medical Costs Among Treatment-Naïve Non-valvular Atrial Fibrillation Medicare Advantage Patients Initiating Apixaban, Dabigatran, Rivaroxaban or Warfarin

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BACKGROUND: Apixaban, a novel oral anticoagulant (NOAC), has been shown to significantly reduce stroke and systemic embolism risk in patients with non-valvular atrial fibrillation (NVAF).

OBJECTIVE: The study aimed to compare real-world stroke-related, major bleeding-related, and all-cause medical costs after initiation of apixaban compared to other oral anticoagulants (OACs) among treatment-naïve non-valvular atrial fibrillation (NVAF) patients.

METHODS: Adult members in the Medicare advantage population who were prescribed apixaban, rivaroxaban, dabigatran, or warfarin were selected from the Optum Research Database from January 1, 2013 through December 31, 2014. The first OAC prescription date was designated as the index date. Members were required to have an AF diagnosis (ICD-9-CM: 427.31) and continuous health plan enrollment for 6 months pre-index date. Members with evidence of mitral valvular heart disease, valve replacement procedures, pregnancy, or OAC claims before the index date were excluded. Members were categorized into four cohorts based on their index prescription: apixaban, dabigatran, rivaroxaban, and warfarin. All-cause, major bleeding-related and stroke-related medical costs were calculated per member per month (PMPM) and compared using propensity-weighted generalized linear models.

RESULTS: The study included 36,260 NVAF members: 3,762 apixaban, 2,677 dabigatran, 8,740 rivaroxaban, and 21,081 warfarin members. Members treated with apixaban were significantly older and had a higher CHADS2 score (2.5) compared to those treated with dabigatran (2.3) and rivaroxaban (2.3) but had a lower score compared to those prescribed warfarin (2.6, P < 0.001). After adjusting for baseline characteristics, members in the apixaban cohort had significantly lower PMPM stroke-related medical costs compared to members in the warfarin cohort ($53 vs. $96, P = 0.0007). Additionally, PMPM major bleeding-related medical costs were lower in apixaban members ($53) compared to rivaroxaban ($111) and warfarin ($138) members (P < 0.001). All-cause PMPM medical costs were also lower in apixaban members ($1,646) compared to dabigatran ($1,974, P = 0.020), rivaroxaban ($1,909, P = 0.002), and warfarin ($2,162, P < 0.001) members.

CONCLUSIONS: In a large national Medicare advantage population, treatment-naïve NVAF members prescribed apixaban incurred significantly lower stroke-related medical costs compared to warfarin members, lower major bleeding-related costs compared to rivaroxaban and warfarin members, and lower all-cause medical costs compared to dabigatran, rivaroxaban and warfarin members.

SPONSORSHIP: This study was sponsored by Pfizer.

A Cost-Consequences Analysis of Inpatient Tolvaptan Compared with Fluid Restriction Among CHF Patients with Hyponatremia

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BACKGROUND: Tolvaptan is a vasopressin-receptor antagonist used as an alternative to fluid restriction (FR) for the treatment of dilutional hyponatremia (HN) in hospitalized patients with congestive heart failure (CHF). The efficacy of tolvaptan, compared to FR, as a treatment for HN was investigated in a prospective, multicenter, randomized, active-controlled, open-label trial (Gheorghiade et al., 2006).

OBJECTIVE: The objective of this cost-consequences study was to estimate the potential economic and health outcomes associated with tolvaptan, in comparison with FR.

METHODS: A decision-analytic model was developed from the perspective of a U.S. hospital system to estimate potential economic and health outcomes associated with tolvaptan compared to FR among hospitalized CHF patients with HN. The model considers patients with severe HN (serum sodium [SNa] levels <125 mEq/L) and patients with mild-moderate FR-resistant HN (SNa levels ≥125 mEq/L). Patients’ response to treatment with tolvaptan, based on response rates among all hyponatremic patients reported in Gheorghiade et al. (2006), was assumed not to change with HN severity. FR-resistant patients with mild-moderate HN were assumed not to respond to treatment with continued FR. The model assumes patients’ response to treatment influences their health consequences: hospital length of stay, probability of an intensive care unit admission, and probability of a 30-day all-cause hospital readmission. Health consequences data were obtained from published studies that compared patients with and without HN (Shorr et al., 2011; Amin et al., 2013).

RESULTS: Among hospitalized CHF patients with severe HN, the model suggested that tolvaptan may yield a total cost-savings of $243 per patient compared to continued FR. Among hospitalized CHF patients with mild-moderate FR-resistant HN, a total cost-savings of $608 per patient compared to continued FR. Tolvaptan drug costs were completely offset in both cases. Among hospitalized CHF patients with severe HN, the model suggested reductions of 7.2% and 4.6% in the numbers of ICU admissions and 30-day readmissions, respectively. The model suggested reductions of 14% and 9% in the numbers of ICU admissions and 30-day readmissions, respectively, among hospitalized CHF patients with mild-moderate FR-resistant HN.

CONCLUSIONS: As an effective treatment for HN among hospitalized CHF patients, tolvaptan, in comparison with FR, is expected to save hospitalization costs.

SPONSORSHIP: The study was funded by Otsuka America Pharmaceuticals.
Budget Impact Analysis of Edoxaban for Stroke Prevention in Non-valvular Atrial Fibrillation

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BACKGROUND: Edoxaban is a once-daily oral Factor-Xa inhibitor recently approved for stroke prevention in non-valvular atrial fibrillation (NVAF) patients. In a Phase 3 clinical trial, edoxaban 60mg (30 mg dose reduced) regimen was shown to lower the risk of stroke/systemic embolism by 32% and significantly reduced the rate of major bleeding by 16% vs. well-controlled warfarin in NVAF patients with creatinine clearance ≤ 95 mL/min.

OBJECTIVE: To assess the potential financial impact to a hypothetical U.S. health plan one year after adding edoxaban to an oral anticoagulant (OAC) formulary for stroke prevention in NVAF patients.

METHODS: A budget impact model using Markov health-state transitions was developed to simulate health care resource use and costs associated with ischemic and hemorrhagic stroke, systemic embolism, major bleeding, clinically relevant non-major bleeding, myocardial infarction, and death in NVAF patients treated with edoxaban, apixaban, dabigatran, rivaroxaban and warfarin. Efficacy and safety data were from published pivotal trials (ARISTOTLE, ENGAGE AF-TIMI 48, RE-LY, and ROCKET-AF). Warfarin and novel oral anticoagulants (NOACs) costs were based on 2013 wholesale acquisition cost without rebates. Copayment per prescription was $4 for warfarin and $40 for NOACs. NVAF prevalence, OAC utilization rate and healthcare cost were from published sources. In the base case analysis, OAC formulary shares prior to adding edoxaban were based on January 2015 Symphony Retail Prescription data (warfarin share = 67.3%; NOAC total share = 32.7%). Edoxaban was assumed to comprise a total of 3% share in the first year after formulary adoption, taking 0.75% share equally from warfarin and each existing NOAC. Sensitivity analyses varying edoxaban and NOAC shares were performed to test the robustness of study results.

RESULTS: In the base case analysis, adding edoxaban increased per-member-per-month (PMPM) pharmacy budget by $0.0031 and reduced PMPM medical cost by $0.0009 (primarily driven by reduction in bleeding cost), resulting in a minimal overall PMPM budget increase of $0.0022. When edoxaban share was doubled to 6%, overall PMPM budget increase remained small ($0.0043). Adding edoxaban to a formulary with 20% higher or lower NOAC total formulary share yielded similar overall budget increase ($0.0022 PMPM in both scenarios).

CONCLUSIONS: Placing edoxaban on formulary would result in negligible budget increase. These results would facilitate evidence-based coverage and access decision making about OACs.

SPONSORSHIP: Funded by Daiichi Sankyo.

The Relationship Between Pharmaceutical Manufacturer Funding and Prescribing Patterns for Anticoagulants in the United States

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BACKGROUND: The Physician Payments Sunshine Act created the Open Payments Program, designed to create greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals.

OBJECTIVE: To examine the relation between pharmaceutical funding and prescribing patterns for anticoagulants at the Metropolitan Statistical Area Level using Open Payment and Medicare Provider Utilization and Payment Data.

METHODS: The 2013 Medicare Provider Utilization and Payment Data: Part D Prescriber Public Use File (PUPF) identified providers using their National Provider Identifier (NPI) and the specific prescriptions that were dispensed on their behalf, listed by brand name (if applicable) and generic name. For each prescriber and drug, the dataset includes the total number of prescriptions that were dispensed (original and refills), days’ supply, and the total drug cost. Analyses focused on anticoagulants (warfarin sodium, apixaban, dabigatran, rivaroxaban). We examined the correlation between pharmaceutical funding per prescribing physician for the three brand name anticoagulants and percent NOAC use over total anticoagulants at the Metropolitan Statistical Area (MSA) level.

RESULTS: There was wide variation in pharmaceutical manufacturer payments to prescribers for New Oral Anticoagulants (NOACs), which ranged from $10 for Oshkosh-Neenah, WI MSA to $1.2m for the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA. Percent NOAC use also varied widely from 0.6% in Mankato-North Mankato, MN to 38% in Huntsville, AL. While the correlation coefficient between total spending on anticoagulants and pharmaceutical manufacturing funding was 0.85, the correlation between percent NOAC use (NOAC prescriptions divided by total anticoagulant prescriptions) for an MSA and pharmaceutical funding was only 0.07.

CONCLUSIONS: The low correlation between percent NOAC use and pharmaceutical payments to physicians for NOAC-related travel and speaker fees suggests that this funding is not significantly impacting prescribing patterns on the MSA level. Further research is needed to better understand factors affecting differences in percent NOAC use across MSAs.

SPONSORSHIP: None.
METHODS: Of 126,008 patients who were continuously enrolled, 40,567 unique patients had at least 1 statin claim. 22.8% of patients received a high potency statin during the measurement period and 10.5% of patients switched to a different statin potency. Of those switches, 42.1% switched to a lower potency. 17% of statin users discontinued therapy. The mean statin PDC was 79.8%; however only 66% of all patients maintained a PDC of ≥ 80%. 0.2% of unique statin users had greater than 90 day gap in therapy with no statin fills during the remainder of the measurement period. Potential statin intolerance was defined as patients who tried at least 2 low potency statins and the last fill being a low potency statin.

RESULTS: Of 126,008 patients who were continuously enrolled, 40,567 unique patients had at least 1 statin claim. 22.8% of patients received a high potency statin during the measurement period and 10.5% of patients switched to a different statin potency. Of those switches, 42.1% switched to a lower potency. 17% of statin users discontinued therapy. The mean statin PDC was 79.8%; however only 66% of all patients maintained a PDC of ≥ 80%. 0.2% of unique patients on statin therapy demonstrated a proper sequence of therapies to infer potential statin intolerance.

CONCLUSIONS: Current guidelines recommend that patients at high risk for CVD be given high potency statins. Such populations are likely to also be a key treatment group for PCSK9-i. Adherence and proper diagnosis of statin intolerance should be considered when designing utilization management criteria for the PCSK9-i. Our study suggests only a small percentage of the overall statin population may be considered statin intolerant based on guideline-recommended diagnostic protocols. A clinical program aimed at improving statin adherence, proper titration of statin therapy, and diagnosis of statin intolerance represent potential opportunities for managed care organizations.

SPONSORSHIP: This research was conducted by Magellan Rx Management, Newport, RI, without external funding.

1.27 Description of Adherence, Switches, and Discontinuations Among Statin Users in a Regional Medicare Health Plan

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BACKGROUND: Statin therapy is the current standard of care for patients with hypercholesterolemia or at high risk for cardiovascular disease (CVD). The PCSK9 inhibitors (PCSK9-i), a new class of injectable biologics aimed to reduce LDL-C, are projected to be available by summer 2015. Payers will be developing utilization management strategies to target the use of PCSK9-i for patients who are inadequately controlled with or intolerant to statin therapy. There is concern that certain patients may be misclassified as statin resistant or intolerant due to poor adherence or lack of proper statin trials.

OBJECTIVE: To describe utilization patterns and adherence to statins within a regional health plan.

METHODS: Using one regional health plan’s pharmacy claims, Medicare patients continuously enrolled between January 1, 2013 and December 31, 2014 with at least 1 claim for a statin were identified. Adherence (PDC), switches in statin potency, and discontinuations were analyzed for the population. Potency was determined based on the ATP-IV guidelines. Discontinuation was defined as patients who had greater than 90 day gap in therapy with no statin fills during the remainder of the measurement period. Potential statin intolerance was defined as patients who tried at least 2 low potency statins with the last fill being a low potency statin.

RESULTS: Of 126,008 patients who were continuously enrolled, 40,567 unique patients had at least 1 statin claim. 22.8% of patients received a high potency statin during the measurement period and 10.5% of patients switched to a different statin potency. Of those switches, 42.1% switched to a lower potency. 17% of statin users discontinued therapy. The mean statin PDC was 79.8%; however only 66% of all patients maintained a PDC of ≥ 80%. 0.2% of unique patients on statin therapy demonstrated a proper sequence of therapies to infer potential statin intolerance.

CONCLUSIONS: Current guidelines recommend that patients at high risk for CVD be given high potency statins. Such populations are likely to also be a key treatment group for PCSK9-i. Adherence and proper diagnosis of statin intolerance should be considered when designing utilization management criteria for the PCSK9-i. Our study suggests only a small percentage of the overall statin population may be considered statin intolerant based on guideline-recommended diagnostic protocols. A clinical program aimed at improving statin adherence, proper titration of statin therapy, and diagnosis of statin intolerance represent potential opportunities for managed care organizations.

SPONSORSHIP: Prime Therapeutics.

1.26 Statin Therapy, Intensity, Adherence and Number of Distinct Statins Tried Among Commercially Insured Adults with Atherosclerotic Cardiovascular Disease Continuously Enrolled Before and After 2013 ACC/AHA Cholesterol Guidelines

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BACKGROUND: In 2013 the American College of Cardiology (ACC) and American Heart Association (AHA) updated cholesterol guidelines (2013 CG). The new guidelines recommend treating based on risk using fixed-dose statins, rather than the previous strategy, in Adult Treatment Panel (ATP) III, of treating to LDL-C goals, and advise treating those <75 years old with atherosclerotic cardiovascular disease (ASCVD) using a high intensity statin.

OBJECTIVE: To determine what proportion of commercially insured members meeting claims criteria for ASCVD received statin therapy, intensity and adherence to this therapy before and after the new guidelines, and number of distinct statins tried.

METHODS: All commercially insured members in 9 health plans age 18 to 74 continuously enrolled between January 1, 2011 and December 31, 2014 were identified and those meeting criteria based on their last claim, 24.7%, 26.4%, 28.1%, and 30.6% received statin therapy, respectively. Of those, 29.5%, 29.0%, 28.2%, and 26.6% had no statin claim, 24.7%, 26.4%, 28.1%, and 30.6% received high intensity statin, 45.8%, 44.7%, 43.7%, 42.8% had moderate or low intensity as defined in 2013 CG, based on the statin, dose, days’ supply and quantity dispensed. Adherence was calculated as the proportion of days covered (PDC) in each year 2012 to 2014 and in all 3 years together. Number of statins tried was defined as distinct statin chemistries from 2011 to 2014.

RESULTS: 55,962 of 3,062,478 (1.8%) of continuously enrolled members were categorized as having ASCVD. In 2011, 2012, 2013, and 2014, respectively: 29.5%, 29.0%, 28.2%, and 26.6% had no statin claims; based on last claim, 24.7%, 26.4%, 28.1%, and 30.6% received high intensity and 45.8%, 44.7%, 43.7%, 42.8% had moderate or low intensity. For 2012, 2013, 2014, and all 3 years together, respectively, 42.0%, 43.4%, 44.7%, and 39.8% had PDC≥80%. In 2014, 10,856 of 55,962 (19.4%) had high intensity therapy with PDC≥80%. Of members with PDC≥80% for all 3 years, 25.8% tried 2 or more distinct statins, compared with 20.5% of members with PDC ≥ 80%.

CONCLUSIONS: Following ATP III guidelines, some members with ASCVD may not have received a statin because they already met an LDL-C goal. However, the 2013 CG recommend most should receive a high intensity statin. This study found large gaps in care and poor medication adherence. For members with statin intolerance, 2013 CG recommend trial of a different statin; however, most ASCVD members with poor adherence only tried one statin. Care improvement programs should focus on ASCVD members without high intensity statin use.

SPONSORSHIP: Prime Therapeutics.
128 Functional Impairments in Patients with Varicose Veins and Improvement with Treatment: Polidocanol Endovenous Microfoam 1% Versus Placebo

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BACKGROUND: Chronic venous insufficiency (CVI) affects ~20% of the U.S. adult population. Though often mischaracterized as a cosmetic condition, patients seek treatment for symptoms and functional effects of varicose veins (VVs), the most common form of CVI. U.S. health plans mandate the presence of both as medically necessary criteria for intervention.

OBJECTIVE: In this analysis, data from prospective randomized clinical studies with polidocanol endovenous microfoam (PEM 1%, approved in the U.S. as Varithena [polidocanol injectable foam]) vs. placebo was used to characterize functional impairment and improvement after treatment in patients with VVs.

METHODS: Data from PEM 1% (n = 109) and placebo (n = 112) groups were pooled from two randomized studies. Functional limitations data were tabulated from eight items of the Modified Venous Insufficiency Epidemiologic and Economic Study—Quality of Life (VEINES-QOL) scale. Four were scored in terms of three-level ordered response categories and four were dichotomous, (total functional score range = 7-20) higher scores reflecting better function. Baseline impairment on function items and corresponding improvements were evaluated; as well as mean total score change and effect size of change (mean change/ baseline standard deviation [SD]) with treatment.

RESULTS: Baseline total functional scores were 15.0 (SD = 3.6, PEM 1%) and 14.8 (SD = 3.5, placebo, P = 0.76). Greatest impairment was on social/leisure activities requiring standing for long periods, with 73.4% (PEM 1%) and 78.6% (placebo) of patients being limited (P = 0.73) followed by social/leisure activities requiring sitting for long periods, with 60.5% (PEM 1%) and 63.4% (placebo) of patients being limited (P = 0.94). At end of treatment (week 8), the proportion limited on these activities declined to 59.0% and 54.5% (placebo) compared with 35.8% and 29.4% (PEM 1%), (P = 0.004 and P = 0.003, respectively). Mean improvement in total functional score was 1.1 (effect size = 0.31) and 2.7 (effect size = 0.75) in placebo and PEM 1% groups, respectively (P = 0.0002). 57.8% of PEM 1% vs. 36.6% of placebo patients had clinically meaningful improvement (effect size > 0.5, P = 0.0016).

CONCLUSIONS: Patients with symptomatic VVs are statistically functionally impaired, especially in activities requiring prolonged standing or sitting. Treatment with PEM 1% showed clinically meaningful improvement on functionality compared with placebo. Emphasis on functional limitations as part of medical necessity by U.S. health plans is appropriate but treatment outcomes should also be considered by improvements in functionality.

SPONSORSHIP: BTG International.

130 Expected Costs and Projected Annual Budget Impact of Treatment of Varicose Veins with Polidocanol Endovenous Microfoam 1%

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BACKGROUND: Varicose veins (VVs) and resulting sequelae contribute to morbidity associated with chronic vein disorders, impacting quality of life and resulting in ~$1 billion in medical costs per year.

OBJECTIVE: We evaluated the expected one-year patient-level total costs and health plan budgetary impact of polidocanol endovenous microfoam (PEM 1%, approved in the U.S. as Varithena [polidocanol injectable foam]) from a U.S. third-party payer perspective compared with traditional interventions.

METHODS: Treatment options included single modalities—PEM 1%, endovenous laser ablation (EVLA), radiofrequency ablation (RFA), surgery—and multi-modality treatment, defined as receipt of >1 treatment on the same day. Cost inputs included published (wholesale) costs of drug acquisition, professional (Center for Medicare Services physician fee schedule) and institutional (Hospital Outpatient Prospective Payment System) service fees related to initial intervention, weighted for each modality, plus additional intervention costs, adjusted by corresponding rate of additional interventions. One-year additional intervention rate was 35.8% for PEM 1% (based on phase 3 studies, 1-year extension), and for other modalities—based on a U.S. retrospective claims analysis of patients with VVs—was 66.8% (EVLA), 53.3% (RFA), 26.1% (surgery), and 46.8% (multi-modality treatment). Budget impact was modeled for a hypothetical 1-million-member health plan with evidence-based assumptions: 76% adults, 2% diagnosed incidence, and 31% rate of interventional treatment among patients with diagnosed VVs, and derived as total and per-member-per-month impact for 5% and 10% initial utilization of PEM 1%, with proportionate reduction in utilization of other modalities.

RESULTS: All single-modality interventional treatments had similar 1-year total costs: PEM 1% ($2,469), EVLA ($2,018), RFA ($2,331), and surgery ($2,523), but less than multi-modality treatment ($3,093). High additional intervention rates for EVLA and RFA were partly offset by lower initial costs and lower cost mix of additional treatments; the opposite was true for surgery. Projected annual budget impact for a health plan with 1 million members, assuming 5% utilization of PEM 1%, is a total budget impact of $165,107 and a per-member-per-month impact of $0.01; and assuming 10% utilization of PEM 1%, $330,213 and $0.03, respectively.

CONCLUSIONS: PEM 1% was associated with similar costs to other single-modality interventions (EVLA, RFA, surgery) for VVs treatment and projected to have minimal annual budget impact to a U.S. health plan.

SPONSORSHIP: BTG International.

131 Medication Therapy Management Comprehensive Medication Review Impact Assessment

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BACKGROUND: CMS requires Part D sponsors to have a medication therapy management (MTM) program aimed at improving medication use and reducing adverse events. Adherence is associated with improved clinical outcomes. However, there is a paucity of quality data examining the impact of MTM services on adherence.

OBJECTIVE: Assess the impact of MTM services on adherence in 3 drug classes: statins, diabetes, renin angiotensin system (RAS) inhibitors.

METHODS: Pharmacy claims data for 1.2 million Medicare members were queried in 2013 to determine eligibility for MTM services based on CMS criteria of three or more specific conditions, six or more drugs for the conditions and high spend on drugs. Exclusions in hierarchical order were (a) hospice, (b) deceased, (c) disenrolled from plan, and (d) opted out of MTM services. Intervention group was defined as received a comprehensive medication review (CMR) in 2013 and control group was no CMR completed (no response after outreach attempts). Members were required to be continuously enrolled for one year from the first claim following their CMR or January 1, 2013 for...
the control group. We calculated a proportion of days covered (PDC) using CMS star rating criteria for the 3 drug classes during one year post the first claim. Adherence was defined as PDC≥80%. Logistic regression models were run for each class to evaluate the proportion of members adherent in the intervention versus control group adjusting for age, gender, ZIP code derived education, race and income, Pharmacy Risk Group score, contract type, number of drug classes, and low income subsidy status.

RESULTS: 117,785 Medicare members were eligible for MTM services in 2013 and after exclusion criteria we had 106,915 analyzable members, 7,306 intervention and 99,609 control group. The unadjusted proportion of intervention group adherent members was 2.5% points higher in statins, 3.7% points higher in diabetes and 2.2% points higher in RAS inhibitors. After multivariate adjustment for the above confounders, results were unchanged. Logistic regression results demonstrated higher proportion of adherent members in the intervention group, statin relative risk [RR] 1.2, 95% confidence interval [CI] 1.1-1.3; diabetes RR 1.4, 95% CI 1.2-1.6; RAS inhibitor RR 1.2, 95% CI 1.1-1.3.

CONCLUSIONS: A completed CMR as part of MTM services for Medicare members was associated with statistically significantly higher proportion of adherent members across 3 drug classes. These findings should be validated through a prospective randomized trial to eliminate the potential bias in this study of using patient CMR opportunity non-response as the control group.

SPONSORSHIP: Duquesne University Mylan School of Pharmacy.

A Budget Impact Analysis of Alirocumab in Heterozygous Familial Hypercholesterolemia Treatment

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BACKGROUND: Heterozygous familial hypercholesterolemia (HeFH) is a genetic disease affecting an estimated 1,500 people. The disease results in LDL levels far above the recommended range which results in an increased risk of adverse cardiac events. Current standard of care treatment options such as high intensity statins and ezetimibe, only achieve recommended LDL levels, instituted by ATP III guidelines, in 20% of treated patients. PKC9 inhibits are a new class of effective but highly priced drug therapy recently approved to treat HeFH that have been shown to be more effective in lowering LDL.

OBJECTIVE: The aim of this study was to prepare a budget impact analysis based on pharmacy drug costs only, as outcomes data was not yet available, to assist a commercial health plan in evaluating the overall projected cost of various treatment options such as high intensity statins and ezetimibe, only for those members who did not meet ATP III guidelines, in 20% of treated patients. PKC9 inhibitors are a new class of effective but highly priced drug therapy recently approved to treat HeFH that have been shown to be more effective in lowering LDL.

METHODS: A budget impact analysis was developed for a hypothetical commercial U.S. health plan consisting of 1 million members ages 18-64 years old. Data were input into an Excel model. Inputs included disease prevalence reported from the CDC, target population, drug costs obtained from wholesale acquisition costs from Red Book (accessed June 2015), and estimated drug market shares based on treatment guidelines and clinical studies. Costs were reported in 2015 U.S. dollars as total overall costs, PMPM, and PTMPM. A one-way sensitivity analysis was performed on the study assumptions.

RESULTS: An estimated 1,600 of the hypothetical 1,000,000 enrollees were projected to be treated for heterozygous familial hypercholesterolemia. It was estimated based on current treatment data that 70% of enrollees would be placed on alirocumab due to lack of meeting ATP III LDL goals by current basic standard of care treatments. Statistical analysis was done on drug costs only. It was found that the addition of alirocumab as a treatment option resulted in a total drug spend of $11,712,160 over a 1-year time horizon. The estimated PMPM for all covered lives was $0.976 while the estimated PTMPM for all covered lives was $610.

CONCLUSIONS: Alirocumab has been proven by multiple double blind, placebo, controlled clinical trials to be safe and effective. It is an effective treatment option for patients who are not achieving their LDL goals on a high intensity statin with or without ezetimibe. However, the high projected cost of $10,000 for 1 year of treatment with alirocumab will need to be weighed when making formulary decisions. A better analysis will be able to be formed when data from the ODYSSEY OUTCOMES trial is released in 2017.

SPONSORSHIP: None.
**J01** Healthcare Resource Use and Costs Associated with Side Effects of High Oral Corticosteroid Use in Asthma: A Claims-Based Analysis

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**BACKGROUND:** Oral corticosteroids (OCS) are used in the management of asthma exacerbations and severe asthma. Patients using OCS bear the risk of side effects (SEs) associated with OCS exposure; the economic burden of such SEs is unknown. This analysis estimated the prevalence of OCS-related SEs and associated healthcare resource use (HRCU) and costs.

**OBJECTIVE:** To estimate all-cause healthcare resource use (HCRU) and healthcare costs that could be attributed to SEs of high-OCS use in patients with asthma.

**METHODS:** This cross-sectional, matched-cohort, retrospective study included adult patients in a 2008 and 2009 commercial administrative claims database using diagnosis codes for asthma and evidence of asthma medication use. We formed two groups: (a) high-OCS (≥ 30 OCS days annually) and (b) non-OCS users (matched [1:1] exactly on age, sex, geographic region and chronic obstructive pulmonary disease [COPD] status). We further divided high-OCS users into two groups: (a) those with diagnoses indicating possible OCS side effects (PSEs) or (b) those without such diagnoses. PSE diagnoses included: bone-related conditions, pneumonia, opportunistic infections, diabetes mellitus, hypertension, lipid disorders, glaucoma, obesity, cataracts, and ulcer disease. In high-OCS patients, we compared HCRU and healthcare cost using t-test in ordinary linear regression models, or Wald Chi-square test in negative binomial regression models, adjusting for age, sex, geographic region, Charlson Comorbidity Index, and COPD status.

**RESULTS:** The matched groups included 3,604 high-OCS and 3,604 non-OCS asthma patients (mean age: 54.4 years; 68.1% female; 44.9% with COPD). High-OCS users had significantly higher rates of any PSE (83.5% vs. 78.1%; P < 0.001) and mean healthcare costs ($24,627 vs. $12,479 P < 0.001) than non-OCS group. After adjustment, high-OCS users with PSEs were more likely to have office visits (23.0 vs. 19.6, P < 0.001) and hospitalizations (0.44 vs. 0.22, P < 0.001) than those without PSE. ED visit rates were not statistically significant between the groups. Among high-OCS users with PSEs vs. without PSEs, adjusted total annual mean healthcare cost totaled $25,168 vs. $21,882 (P = 0.009).

**CONCLUSIONS:** High OCS use was associated with significantly higher costs than non-OCS use. Furthermore, among the high-OCS group, patients with PSEs were more likely to use healthcare services, than those without PSEs. Although OCS may help with asthma control and the management of exacerbations, they are associated with a high rate of SEs and additional HCRU and costs, highlighting the need for OCS-sparing asthma therapies in asthma patients.

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

**J02** Predictors of Pharmacotherapy Management of COPD Exacerbations Post-hospitalization/ED Visit as Defined by HEDIS

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**BACKGROUND:** Suboptimal treatment of exacerbations is a major concern in COPD management. The Pharmacotherapy Management of COPD Exacerbation (PCE) HEDIS quality measure focuses on appropriate use of corticosteroids and inhaled bronchodilators after an acute COPD exacerbation.

**OBJECTIVE:** This study evaluated baseline patient and treatment factors associated with receipt of pharmacotherapy after a COPD hospitalization or emergency department (ED) visit as defined by HEDIS.

**METHODS:** A retrospective observational group of COPD-related hospital (IP) and ED visits from 2007-2013 were identified from an integrated delivery network in Central Texas. Index date was defined as the date of admission. Subjects aged > 40, with ≥1 primary medical claim for COPD (ICD-9 491.xx, 492.xx, 493.2x, or 496.xx) or a pharmacy claim for a COPD maintenance drug were eligible. Visits were excluded if they resulted in transfer to another facility. Study groups were identified based on the receipt of PCE: a systemic corticosteroid ± 14 days of discharge (PCE-C) or an inhaled bronchodilator ± 30 days of discharge (PCE-D). Bivariate analyses were performed using t-tests for continuous data and chi-square tests for categorical data. Generalized estimating equations including significant predictors from the bivariate analyses were used to determine independent factors associated with the odds of receiving PCE-C or PCE-D post-discharge.

**RESULTS:** Of 375 index visits identified, 254 (68%) received PCE-C, 299 (80%) received PCE-D, and 229 (61%) received both. Mean age was 59 (SD = 7) and 64% were female. Patients on a rescue medication during the pre-index period were more likely to receive both PCE-C (RR = 3.42; 95% CI = 1.19 to 6.11; P < 0.01) and PCE-D (RR = 2.56; 95% CI = 1.24 to 5.27; P = 0.01). IP visits were more likely to result in receipt of PCE-C compared to ED visits (RR = 1.94, 95% CI = 1.04 to 3.61; P = 0.04). Those with a history of exacerbations during the pre-index period were more likely to receive PCE-C (RR = 2.43; 95% CI = 1.17 to 5.03; P = 0.02). In addition, every $10 increase in pre-index COPD-related pharmacy costs was associated with a 2% greater likelihood of receiving PCE-D (RR = 1.02, 95% CI = 1.00 to 1.03; P < 0.01).

**CONCLUSIONS:** The use of pharmacotherapy after a COPD-related ED or IP visit are more likely to occur in patients with previous history of either bronchodilator or rescue medication use, inpatient visits or previous exacerbations. The likelihood of treatment may be related the severity of the COPD or the severity of the index COPD exacerbation.

**SPONSORSHIP:** GlaxoSmithKline (study HO-14-15081).
that poor inhaler technique is widespread in COPD, resulting in poor efficacy and adherence. Understanding relationships between patient characteristics and poor inhaler technique may help physicians identify patients at risk for poor inhaler technique.

**OBJECTIVE:** To investigate patient characteristics associated with poor inhaler technique.

**METHODS:** Data were drawn from the 2013 Adelphi COPD Disease Specific Programme, a cross-sectional survey in which participating U.S. physicians completed records for their next 5 consecutive COPD patients, who were also invited to complete a questionnaire. Patient characteristics such as demographics, device type, training provision, disease severity and comorbidities were collected. Patients and physicians reported on patient’s confidence of correct inhaler device usage via a 5-point Likert scale, ranging from not at all to completely confident. Stepwise logistic regressions were used to show relationships between confidence in correct inhaler technique (categorized high vs. low) and patient characteristics.

**RESULTS:** 373 patients (median age 67 years, 45% female) and 134 physicians participated. Most patients used ≥ 1 inhaled device type (75% dry powder inhaler [DPI], 79% metered dose inhaler [MDI]). Low confidence in device technique was reported by 37% of patients on DPI and 33% on MDI, while physicians reported 42% and 43% of patients had low confidence in use of these respective devices. Fewer comorbidities (OR = 0.88, P = 0.015), college education (OR = 1.72, P = 0.023), and trained on inhaler use by self or a family member (OR = 5.09, P = 0.004) were significantly associated with high physician perceived confidence. No depression (OR = 0.45, P = 0.016), college education (OR = 2.09, P = 0.008), and self or family member taught on inhaler use (OR = 4.94, P = 0.008) were significantly associated with high patient perceived confidence. Age, COPD severity, and device type were not significant predictors of inhaler confidence.

**CONCLUSIONS:** In this study, confidence with inhaler use was poor among 1 in 3 COPD patients regardless of device type used. Patient characteristics such as number of comorbidities, depression, education level, and self or external help available for learning need to be taken into account when assessing inhaler training needs and may help inform the decision to consider an alternative form of drug delivery such as a nebulizer.

**SPONSORSHIP:** Adelphi Real World received funding for this study from Sunovion Pharmaceuticals.

**J07 Cost of Hospitalization and Length of Stay for Inpatients with COPD Treated with Arformoterol or Tiotropium**
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**BACKGROUND:** Resource utilization and costs can be affected by several factors, including symptom severity, in hospitalized patients with COPD. COPD medications are typically administered through an inhalation device such as metered-dose or dry powder inhaler. The impact on choice of inhalation medication on outcomes and costs in hospitalized patients with COPD has not been fully elucidated.

**OBJECTIVE:** To compare length of stay (LOS) and hospitalization cost of hospitalized COPD patients treated with nebulized arformoterol tartrate (ARF) or inhaled tiotropium bromide (TIO) dry powder inhaler (DPI).

**METHODS:** Retrospective analysis using data from Premier, Inc. (Charlotte, NC), included patients ≥ 40 years old, hospitalized between 2011-2012, diagnosed with COPD, not diagnosed with asthma, and treated with either nebulized ARF or DPI TIO. Index day was the first day a pt received ARF or TIO during the hospital stay. TIO patients were propensity-score matched (1:1) to ARF patients on demographics, hospital characteristics, comorbid diagnoses (eg, ischemic heart disease, congestive heart failure, cardiac arrhythmias, hypertension, diabetes, renal failure, depression, other neurological and respiratory disorders), and pre-index use of respiratory treatments or tests. Hospital LOS and cost were measured starting with the index day and conditional mean models were fit using generalized estimating equations, controlling for concomitant medication use. Treatment effects were tested against the 3% alpha level and average model predicted outcomes were estimated.

**RESULTS:** The study included 2,405 patients, 147 (6%) of whom developed severe asthma. EOS and CCI score were significant in ≥ 500 bootstrapped samples and were used in the final risk score model. The hazard ratios obtained from the derivation cohort were 1.9 (95% CI = 1.17-3.08) for elevated EOS and 2.0 (95% CI = 1.28-3.13) for positive CCI score. Both were assigned a weight of 2. Total risk score was categorized as 0, 1, 2, and 4. Models using the validation cohort and the entire cohort produced similar hazard ratios. All models showed good C-statistics (0.79-0.8), indicating favorable model discrimination. There were significantly greater numbers of patients with severe asthma in the risk score segments of 2 and 4 compared with 0 (P < 0.0001).

**CONCLUSIONS:** A risk stratification tool was developed that predicts severe asthma development. Patients with elevated EOS and/or CCI score greater than 0 are at increased risk of developing severe asthma.

**SPONSORSHIP:** This study was sponsored by Teva Pharmaceuticals, Global Health Economics, and Outcomes Research.

**J05 Development and Validation of an Asthma Severity Risk Tool**
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**BACKGROUND:** This study sought to empirically derive a risk equation to identify asthma patients at risk of developing severe asthma who would benefit from advanced treatment options.

**OBJECTIVE:** Develop a risk-scoring algorithm to identify patients at greater risk of developing severe asthma defined by European Respiratory Society-American Thoracic Society (ERS-ATS) guidelines.

**METHODS:** Asthma patients were extracted from EMRClaims+ database from January 2004-July 2011. Patients with continuous enrollment 12 months before and after the date of the first asthma diagnosis (index) with at least 1 blood eosinophil (EOS) test result in the 12-month post-index period prior to development of severe asthma or study end date were included. “Severe asthma date” was defined as the date on which all criteria of ERS-ATS definition of severe asthma were satisfied. Age (≥ 50 vs. < 50 years), race, and gender were measured at index; Charlson Comorbidity Index (CCI) score (> 0 vs. 0) was measured in the pre-index period. Elevated EOS was defined as a test result with ≥ 400 cells/µL. The study cohort was randomly split 50-50 into derivation and validation samples. Cox proportional hazards regression was used to develop the risk score for severe asthma using the derivation cohort with independent variables of age, gender, race, EOS, and CCI. A bootstrapping procedure was used to generate 1,000 samples from the derivation cohort. Variables significant in ≥ 50% of the samples were retained in the final model. Risk score was then calculated based on the coefficient estimates of the final model. C-statistic was used to test the model’s discrimination power.

**RESULTS:** The study included 2,405 patients, 147 (6%) of whom developed severe asthma. EOS and CCI score were significant in ≥ 500 bootstrapped samples and were used in the final risk score model. The hazard ratios obtained from the derivation cohort were 1.9 (95% CI = 1.17-3.08) for elevated EOS and 2.0 (95% CI = 1.28-3.13) for positive CCI score. Both were assigned a weight of 2. Total risk score was categorized as 0, 1, 2, and 4. Models using the validation cohort and the entire cohort produced similar hazard ratios. All models showed good C-statistics (0.79-0.8), indicating favorable model discrimination. There were significantly greater numbers of patients with severe asthma in the risk score segments of 2 and 4 compared with 0 (P < 0.0001).

**CONCLUSIONS:** A risk stratification tool was developed that predicts severe asthma development. Patients with elevated EOS and/or CCI score greater than 0 are at increased risk of developing severe asthma.

**SPONSORSHIP:** This study was sponsored by Teva Pharmaceuticals, Global Health Economics, and Outcomes Research.
RESULTS: The analysis included 3,942 matched patients (1,971 patients in each treatment cohort). COPD was the primary diagnosis for 50% of patients in each group, and 67% and 55% of patients in both groups received oxygen therapy and had a blood gas assessment, respectively, prior to the index day. After adjusting for concomitant medication use, there was no difference between the ARF and TIO cohorts in LOS (4.26 vs. 4.17, \( P = 0.45 \)) or costs ($7,420 vs. $7,015, \( P = 0.087 \)).

CONCLUSIONS: Similar hospital LOS and hospitalization costs were observed between COPD patients receiving nebulized ARF and DPI TIO. Patients may have differed on unmeasured indicators of clinical severity. Nebulized ARF is a potential viable treatment option for patients hospitalized with COPD.

SPONSORSHIP: None.

K02 A Predictive Model to Estimate the Cost Savings of a Novel IBS Diagnostic Blood Panel Versus an Exclusionary Diagnostic Strategy for the Diagnosis of Diarrhea Predominant IBS in the United States

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BACKGROUND: Irritable bowel syndrome (IBS) is a disease with a relatively high prevalence in the United States ranging between 10%-15%, and is associated with a significant direct medical cost burden as well as an indirect cost burden (absenteeism, presenteeism). The diagnosis of diarrhea predominant irritable bowel syndrome (IBS-D) is based on clinical presentation, laboratory tests and diagnostics procedures to exclude other organic conditions.

OBJECTIVE: To estimate the potential cost savings of novel IBS diagnostic blood panel which tests for two biomarkers (anti-CdtB and anti-vinculin) associated with IBS-D.

METHODS: A cost-minimization (CM) decision tree model was constructed to compare the costs associated with two possible diagnostic pathways: (a) diagnostic pathway with novel IBS diagnostic blood panel and (b) exclusionary diagnostic pathway (i.e. standard of care). The model structure was based on current literature and guidance from IBS expert clinicians. The probability that patients will proceed to treatment was modeled as a function of the sensitivity, specificity and likelihood ratios of the individual biomarker tests. One-way sensitivity analyses were performed for key input variables. A break-even analysis was performed with respect to the pre-test probability of disease (IBS-D). The budget impact analysis (BIA) extrapolates results of the CM model to a health plan with 1 million covered lives.

RESULTS: Colonoscopy, CT, and ultrasound were the most common diagnostic (instrumental) procedures reported with estimated utilization rates of 63%, 31%, and 30%, respectively. For the base case, the CM model predicts a cost-savings of $363 for the novel IBS diagnostic blood panel vs. the exclusionary diagnostic pathway, due to the avoidance of downstream testing (e.g., colonoscopy, CT scans). A one-way sensitivity analysis for the likelihood ratios indicated that an increase in both positive likelihood ratios was associated with a modest increase in cost savings. The break-even analysis estimated that the pre-test probability of disease would be 0.541 to attain cost neutrality. The BIA predicts a cost savings of $1,400,444 or $0.12 per member per month when the novel test is introduced to a plan.

CONCLUSIONS: Current medical literature suggests that extensive diagnostic testing to diagnose IBS is often not necessary. This evaluation predicts that the inclusion of a novel IBS diagnostic blood panel in the diagnostic process has the potential for significant cost savings by allowing patients to proceed to treatment earlier in the diagnostic process, and hence avoid unnecessary testing.

SPONSORSHIP: Commonwealth Laboratories, Salem, MA.
**K03 Health-Related Quality of Life, Work Productivity, and Indirect Costs Among Patients with Irritable Bowel Syndrome with Diarrhea**

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**BACKGROUND:** Irritable bowel syndrome (IBS) affects 10%-15% of U.S. adults, with approximately one-third having the diarrhea subtype (IBS-D). IBS-D is associated with reduced health-related quality of life (HRQoL) and work productivity, however, information specific to IBS-D is lacking.

**OBJECTIVE:** To assess the impact of IBS-D on HRQoL, work productivity, daily activities, and indirect costs among a sample of the U.S. population.

**METHODS:** Adult IBS-D patients were identified from the 2012 U.S. National Health and Wellness Survey (NHWS), a representative, cross-sectional general health survey, via self-reported IBS-D diagnoses or IBS-D-related symptoms based on Rome II criteria. Controls included patients without IBS-D. HRQoL was assessed via the SF-36v2 mental and physical component summary (MCS, PCS; range: 0-100) and SF-6D (health utility; range 0-1). Work Productivity and Activity Impairment Questionnaire—General Health (WPAI-GH) assessed absenteeism, presenteeism, and daily activities (higher percentages indicate greater impairment). Work days missed annually was calculated using reported work hours missed on WPAI-GH. Mean annual indirect costs were estimated based on overall work productivity loss (absenteeism + presenteeism) using the U.S. Bureau of Labor Statistics and subject-level NHWS data. Multivariable generalized linear models compared IBS-D patients vs. controls, controlling for demographic and health characteristics (e.g., gender, comorbidities) to assess burden attributable to IBS-D.

**RESULTS:** A total of 66,491 respondents were identified (11,02 IBS-D; 65,389 controls). Compared with controls, IBS-D patients had significantly lower HRQoL based on MCS (mean 45.16 vs. 49.48), PCS (47.29 vs. 50.67), and SF-6D (0.67 vs. 0.74) scores (all P < 0.001). IBS-D patients also reported significantly greater absenteeism (5.10% vs. 2.87%), presenteeism (17.85% vs. 11.34%), overall work productivity loss (20.69% vs. 13.19%) [all P < 0.01], and activity impairment compared with controls (29.58% vs. 18.92%; P < 0.001). Assuming a 40-hour work week, overall work losses translate to more missed work days/year for IBS-D patients vs. controls (10.09 vs. 6.24; P < 0.03). Indirect costs were $2,486 higher per patient/year for IBS-D patients vs. controls ($7,008 vs. $4,522; P < 0.001).

**CONCLUSIONS:** Compared with controls, IBS-D patients have significantly lower HRQoL, greater impairments in work and daily activities, and higher indirect costs, imposing a substantial burden on patients and employers. A substantial unmet need exists for treatments to effectively alleviate and manage IBS-D symptoms.

**SPONSORSHIP:** Design and analyses were conducted by Kantar Health, paid consultants of Actavis.

**K04 Economic Burden of Treatment Failure Among U.S. Commercially Insured Patients with Irritable Bowel Syndrome with Diarrhea**

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**BACKGROUND:** Irritable bowel syndrome with diarrhea (IBS-D) is a chronic functional gastrointestinal disorder with cardinal symptoms of abdominal pain and diarrhea. Treatment often includes lifestyle/diet modifications and pharmacologic therapy with over-the-counter and prescription medications, many associated with low efficacy and poor tolerability, leading to treatment switching or discontinuation, or addition of concomitant therapies.

**OBJECTIVE:** To estimate incremental costs associated with failure on current prescription therapies used to treat IBS-D among U.S. commercially insured IBS-D patients.

**METHODS:** Patients aged ≥18 years with ≥1 medical claim for IBS (ICD-9 564.1x) and either ≥2 claims for diarrhea (ICD-9 787.91, 564.5x) or ≥1 claim for diarrhea plus ≥1 claim for abdominal pain (ICD-9 789.0x) or ≥1 claim for diarrhea plus ≥1 pharmacy claim for a symptom-related (IBS, diarrhea, or abdominal pain) prescription after and within 1 year of an IBS diagnosis, and no constipation claims (ICD-9 564.0x) or constipation-related pharmacy claims during the 6 months prior to treatment index date, were identified from the Truven Health MarketScan database. Treatment failure, health-care resource use, and costs were assessed during the 1-year period following index date (i.e., first symptom-related pharmacy claim within 1 year of IBS diagnosis). Patients were classified as having treatment failure if any of the following occurred while receiving a symptom-related prescription: (a) switch or addition of new symptom-related therapy; (b) IBS-D-related inpatient or emergency room admission; (c) IBS-D-related medical procedure; (d) diagnosis of condition indicating treatment failure; or (e) use of a more aggressive prescription. Generalized linear models assessed incremental costs of treatment failure, controlling for demographics, Elixhauser comorbidity index (ECI) score, and 14 general and 11 gastrointestinal-related comorbidities not included in the ECI score.

**RESULTS:** Of 20,624 IBS-D patients identified, 66.4% experienced treatment failure within 1 year of initiating treatment (mean age 49 and 48 years; 79.5% and 74.6% female among patients with and without treatment failure, respectively). After adjusting for demographics and comorbidities, incremental total annual health-care costs associated with treatment failure were $3,065 (2013 USD), primarily driven by medical ($10,873 vs. $8,482) rather than prescription ($3,283 vs. $2,609) costs (all P < 0.01).

**CONCLUSIONS:** Treatment failure on IBS-D therapies presents a significant economic burden for payers and IBS-D patients.

**SPONSORSHIP:** Analyses were conducted by Axtria, paid consultants of Actavis.

**K05 Understanding the Costs of Biologic Dose Escalation: A Crohn’s Disease Cost Model Comparing Dose Escalation in Patient Cohorts Who Start on Adalimumab Versus Infliximab in the Maintenance Year**

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**Janssen Scientific Affairs**

**BACKGROUND:** Data on cost of dose escalating after initiating adalimumab (ADA) vs. infliximab (IFX) in patients with Crohn’s disease (CD) is limited.

**OBJECTIVE:** This CD cost model evaluates the cost-of-care of patients maintained on adalimumab vs. infliximab over a one-year period.

**METHODS:** Maintenance trials had an initial 4-week (ADA) and 2-week (IFX) run-in period to assess response. Only run-in period responders were included in the maintenance phase. The model has two time periods of interest after the run-in: weeks 5-12 and 13-56 for ADA and weeks 3-14 and 15-52 for IFX, labelled as the re-assessment and sustained response periods respectively. For comparability of drug cost attribution, these periods were standardized to weeks...
0-14 (run-in and re-assessment periods, 14 weeks) and weeks 15-54 (sustained response periods, 40 weeks). Phase 3 trial data provided the placebo-subtracted sustained response efficacy data. At the 14-week re-assessment, patients could be redistributed by response. Responders continued on original therapy, those with loss of response had three options: dose-escalate, switch to the alternative TNFi or switch to vedolizumab. Data on the redistribution at 14 weeks was not available in all maintenance trials, so equal redistribution was assumed across all 4 options (25% probability each). Patients who subsequently lose response in the sustained response period could dose escalate, receive a standard mix therapy (SMT) (if already dose escalated), or surgery. The SMT was an average between price and dose of the two alternative products. Drug costs were attributed to the induction period as per label, and the maintenance period based on an assumption that no-response occurred at the half way point (e.g. after 20 weeks of 40-week of sustained response period). Payer drug costs for IFX and ADA were allocated based on a mixture of Wholesale Acquisition Cost (WAC)/Average Sales Price (ASP + 6%), 10%/90% for IFX and 95%/5% for ADA. Weight based dosing assumed 80 kg patient Costs included rebates (8%-18%), surgery ($45,000) and infusion costs ($257). No discounting was applied.

RESULTS: The estimated annual per patient total cost was $50,802 for ADA cohort and $47,848 for IFX cohort. Double dosing IFX contributed less to the total average cost-of-care than did double dose ADA. This CD cost model was sensitive to cost of drug and infusion costs, but insensitive to cost of surgery and efficacy rates.

CONCLUSIONS: Double dose IFX is not a significant cost driver and ASP+6%/WAC cost distribution is important to the overall cost results.

SPONSORSHIP: Janssen Scientific Affairs supported this study.

K07 Evaluation and Surveillance of Patient Adherence to Sofosbuvir Regimens for the Treatment of Hepatitis C Within a PPO Health Plan

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BACKGROUND: Sofosbuvir (SOF) was launched in December 2013 leading to a great debate over cost and value in health care. A top concern is patient adherence to such an expensive drug regimen. Effective treatment and possible cure of hepatitis C is highly dependent on patient adherence. Factors such as treatment complexity and side effects make adherence difficult and decrease patients’ chance of successful treatment. Evaluation of patient adherence rates and identification of risk factors which may lead to non-adherence is warranted due to high costs and possible risk to the patient.

OBJECTIVE: To determine adherence rates of SOF based hepatitis C treatment and identify factors that may increase risk of non-adherence.

METHODS: Retrospective review of commercially insured members with Blue Cross Blue Shield of Michigan (BCBSM) pharmacy benefit from December 1, 2013 to August 1, 2014 with an approved prior authorization (PA) request for SOF. Of the 232 requests reviewed, eight were excluded due to incomplete data. Patients were categorized into one of two groups: (a) adherent or (b) non-adherent. Category was adherent if the entire regimen had claims for the full treatment duration. If a PA was initiated and claims were lacking for the whole regimen, category was non-adherent. Sex, age, physician specialty, copay of first SOF claim, genotype, length of SOF based treatment, treatment naive status and pharmacy type were analyzed between groups. Data were presented as means with standard deviations or frequencies with percentages. Pearson chi-square tests were used to compare differences between groups with \( P<0.05 \) considered statistically significant.

RESULTS: Among 224 approved PA requests, 186 (83%) patients were adherent and 35 (15.6%) non-adherent. Mean age was 55.6 years. Factors that influence patients’ adherence to SOF-based regimens include genotype, copay amount and pharmacy type (\( P<0.05 \)). Compared to adherent patients, non-adherent patients were identified as having genotype 3, SOF copay >$10,000 and filled at a non-specialty pharmacy (\( P<0.05 \)). SOF copay of $0-$50 was associated with adherence to SOF-based regimens (\( P<0.05 \)). A total of three patients (1.34%) received extra fills beyond their prescribed regimen.

CONCLUSIONS: A 15.6% non-adherence rate for SOF-based treatments was identified in this patient population. Evaluation of the data have led to updates in BCBSM’s hepatitis C policy: stricter approval lengths and attestation of patient adherence to treatment. Mandatory use of a specialty pharmacy for hepatitis C medications may be considered as a means to increase adherence.

SPONSORSHIP: Blue Cross Blue Shield of Michigan.

WITHDRAWN
of probable PBC in a large clinical laboratory database representing approximately 30% of tests conducted in the U.S.

METHODS: > 576,000 patients received AMA testing between January 2010 and December 2013. Patients were considered AMA+ if their antibody titre > 1:20 or M2 antibody > 25.0 U. According to U.S. guidelines, patients were identified as probably PBC patients if they were AMA+ and had an alkaline phosphatase (ALP) > 120 U/l. We examined patient demographics, insurance status and site of testing.

RESULTS: Of the 576,000 patients tested, 16,492 were AMA+ and had at least 1 ALP test over the 4 year period (2.9%). 6107 had an ALP > 120 U/l and could be classified as probable PBC (1%). Of these, 2,726 (30%) were commercially insured. Given current estimates that 54% of Americans are commercially insured, the annual incidence of probable PBC in commercial plans is estimated at 0.001%. More than half (53%) of AMA+ tests were conducted in a hospital. A significant minority of incident probably PBC patients were male (19%). The age at first AMA+ tests were < 20 (0.4%), 20-49 (21%); 50-64 (39%); > 65 (40%).

CONCLUSIONS: The signal detection of both positive AMA and probable PBC were very low. Since AMA testing is almost exclusively conducted for the purposes of diagnosing PBC, these data suggest the need for better testing protocols to avoid the costs of unnecessary tests. The incidence of probable PBC diagnoses in commercial plans is low. In part, this is due to the fact that PBC is most common in peri- and postmenopausal women, so a significant percentage of patients are older and fall under Medicare. This may also be explained by the fact that most patients’ first AMA+ test was conducted in a hospital setting. This suggests that patients are being diagnosed either by “crashing” into care or as the result of standard screening through other emergent conditions, with low detection in primary care settings. These data indicate that primary care physicians need to be better educated around testing and diagnosis for this rare disease. Little is known about the costs of treating PBC in the U.S., thus further research is needed to understand the implications of these findings for commercial health plans.

SPONSORSHIP: Intercept Pharmaceuticals.

K09 Incident Primary Biliary Cirrhosis Patients in a Large U.S. Laboratory Sample: Implications for Commercial Health Plans

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Intercept Pharmaceuticals

BACKGROUND: Primary biliary cirrhosis (PBC) is a rare autoimmune disease liver disease. Left untreated, PBC progresses to liver fibrosis and cirrhosis, culminating in liver transplant or death.

OBJECTIVE: Understand the characteristics of incident patients with probable PBC in a large clinical laboratory database representing approximately 30% of tests conducted in the U.S.

METHODS: > 576,000 patients received AMA testing between January 2010 and December 2013. Patients were considered AMA+ if their antibody titre > 1:20 or M2 antibody > 25.0 U. According to U.S. guidelines, patients were identified as probably PBC patients if they were AMA+ and had an alkaline phosphatase (ALP) > 120 U/l. We examined patient demographics, insurance status and site of testing.

RESULTS: Of the 576,000 patients tested, 16,492 were AMA+ and had at least 1 ALP test over the 4 year period (2.9%). 6107 had an ALP > 120 U/l and could be classified as probable PBC (1%). Of these, 2,726 (30%) were commercially insured. Given current estimates that 54% of Americans are commercially insured, the annual incidence of probable PBC in commercial plans is estimated at 0.001%. More than half (53%) of AMA+ tests were conducted in a hospital. A significant minority of incident probably PBC patients were male (19%). The age at first AMA+ tests were < 20 (0.4%), 20-49 (21%); 50-64 (39%); > 65 (40%).

CONCLUSIONS: The signal detection of both positive AMA and probable PBC were very low. Since AMA testing is almost exclusively conducted for the purposes of diagnosing PBC, these data suggest the need for better testing protocols to avoid the costs of unnecessary tests. The incidence of probable PBC diagnoses in commercial plans is low. In part, this is due to the fact that PBC is most common in peri- and postmenopausal women, so a significant percentage of patients are older and fall under Medicare. This may also be explained by the fact that most patients’ first AMA+ test was conducted in a hospital setting. This suggests that patients are being diagnosed either by “crashing” into care or as the result of standard screening through other emergent conditions, with low detection in primary care settings. These data indicate that primary care physicians need to be better educated around testing and diagnosis for this rare disease. Little is known about the costs of treating PBC in the U.S., thus further research is needed to understand the implications of these findings for commercial health plans.

SPONSORSHIP: Intercept Pharmaceuticals.

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

L02 Burden of Disease Among Employees with Atopic Dermatitis: Comorbidities, Healthcare Resource Utilization/Costs, and Absenteeism

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1Sanofi; 2Regeneron; 3Human Capital Management Services

BACKGROUND: Atopic dermatitis (AD), an immune-mediated inflammatory disease, is associated with a disease burden that has been mainly characterized in the pediatric population.

OBJECTIVE: This retrospective analysis evaluated comorbidity, healthcare resource use, and work absenteeism in employees with AD, and assessed the impact of AD severity on these burdens.
**L13 Finding the Sweet Spot for Treating Pressure Ulcers with Clostridial Collagenase Ointment: Results from the U.S. Wound Registry**

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1Strategic Solutions; 2Smith & Nephew; Intellicure

**BACKGROUND:** Pressure ulcers (PU) are localized injuries to the skin and/or underlying tissue that usually occur over a bony prominence as a result of pressure, or pressure in combination with shear and/or friction. PU are grouped by their severity and classified in Stages I through IV. Stage I is the earliest least severe PU while Stage IV is the worst. In a Stage IV PU the wound becomes so deep that there is damage to the muscle and bone and may involve the tendons and joints. Debridement is an important part of the treatment for serious wounds. Debridement is defined as the medical removal of necrotic tissue which improves the healing potential of the remaining healthy tissue.

**OBJECTIVE:** The objective of this study was to assess the clinical effectiveness of enzymatic debridement with clostridial collagenase ointment (CCO) as an adjunct therapy to sharp debridement compared to sharp debridement alone for the management of PU in the hospital outpatient department setting.

**METHODS:** Using datasets from the U.S. Wound Registry from 2007-2013 at the patient, wound, and visit encounter levels, 3,594 PU received CCO and 16,745 PU did not. Applying sharp debridement criteria and propensity score matching resulted in 1074 wounds belonging to each group. Propensity score results showed that characteristics of the group were reasonably matched.

**RESULTS:** Mean patient age was 67-69 years and nearly two thirds of patients had home health care. The majority of the PU were stage III (56%-59%) with stage IV wounds being the next most common. When PU were analyzed by PU stage, it was found that the proportion of wounds closed at any time (e.g., at 1 year or 2 years) was double for stage IV PU who received CCO compared to those not treated with CCO. Furthermore, Kaplan-Meier analysis showed that time to wound closure at 1 year was significantly faster (and clinically meaningful) for PU treated with CCO versus PU not treated with CCO. When groups

**CONCLUSIONS:** During the first year of psoriasis treatment, patients initiating ETN had 20% lower actual-versus-expected dosing ratio while persistent and 25% lower total annual psoriasis-related costs than UST patients.

**SPONSORSHIP:** Research was funded by Immunex, a wholly owned subsidiary of Amgen.

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**L05 Dosing Patterns with and Cost Impact of Etanercept and Ustekinumab for Psoriasis in a Real-World Setting**

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1Truven Health Analytics; 2Amgen

**BACKGROUND:** There is a lack of evidence on the actual versus expected dosing patterns and costs of biologics used for psoriasis.

**OBJECTIVE:** To estimate actual dosing of etanercept (ETN) and ustekinumab (UST) (index event) from 2011-2013 were identified in the MarketScan Commercial Database. Patients were required to have 12 months of continuous enrollment pre- and post-index without any psoriasis-related biologic use during the pre-index period. Patients with other biologic-indicated comorbid conditions were excluded. Actual-to-expected dose ratios were computed for ETN/ UST users while persistent on therapy. Ratios > 1 indicated that actual drug dose was greater than the expected dose. Expected dose was calculated according to USP for both therapies. However, as UST was approved as a weight-based dosing regimen, expected UST dose was based on clinical trial data reporting 69% of psoriasis patients weighing ≥100 kg (‘low weight’). Specifically, patient weight was randomly assigned to match this distribution with low index dose patients being assigned as ‘low weight.” Annual psoriasis-related costs consisting of biologics, non-biologic psoriasis therapies, and psoriasis-related healthcare utilization were calculated. Chi-square and t-tests were used to compare categorical and continuous variables between ETN and UST, respectively.

**RESULTS:** A total of 2,997 patients met the study selection criteria with approximately two-thirds initiating ETN (n = 2,128). The ETN and UST cohorts were similar in terms of age (45.2, both) and baseline Depo Charlson Comorbidity Index Score (0.3, both). ETN patients were more likely to be female (49.4% versus 44.1%, P = 0.008). While persistent, the actual dose of ETN patients were closer to the expected dose than UST patients (ratio 0.939 versus 1.169, P < 0.001). Total psoriasis-related costs were lower for etanercept than ustekinumab patients during the 12 months follow-up period ($28,291 versus $37,537, P < 0.001). Both index biologic costs ($24,629 versus $34,962, P < 0.001) and non-biologic, other psoriasis costs ($1,507 versus $1,850, P = 0.034) were lower for etanercept patients.

**CONCLUSIONS:** Early decisions regarding biologic initiation and dosing are important to ensure appropriate therapy and cost effectiveness.

**SPONSORSHIP:** Medical Affairs, Sanofi Genzyme, a subsidiary of Sanofi Aventis.

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**METHODS:** De-identified data from the Human Capital Management Services (HCMS) insurance claims and productivity database were used to identify employed adults (18-64 years) diagnosed with AD (ICD-9 code 691.8; index event) from January 1, 2010 to December 31, 2013 who had ≥12-month continuous post-index enrolment and full-time employment. Each AD patient was propensity-score matched (1:1) to a non-AD control based on demographic characteristics. AD patients were categorized into 3 increasing AD severity groups using AD therapies prescribed during the year post-index as surrogate. Comorbidities, all-cause healthcare use and costs, and absenteeism during the 12-month post-index period were compared between AD and control cohorts, and among AD groups.

**RESULTS:** Data for 8,214 patients (mean age 43 years; 56% female) were analyzed, with 4,107 in the AD cohort. AD patients had a significantly greater comorbidity burden than controls, including Charlson Comorbidity Index (CCI; mean 0.34 vs. 0.22, P < 0.001), and individual comorbidities such as asthma (9.1% vs. 4.2%), allergic rhinitis (19.6% vs. 8.0%), anxiety (9.0% vs. 6.1%), sleep disorders (9.3% vs. 5.3%), and fungal infections (6.7% vs. 1.8%; all P < 0.001). The mean CCI increased with greater AD severity, with similar trends for individual comorbidities. Relative to controls, AD patients had significantly higher mean annual outpatient (1,449 vs. 869 visits per 100 patients; P = 0.001) and emergency room visits (15.9 vs. 10.8 visits per 100 patients; P = 0.002). Resource use increased with greater AD severity. AD was associated with significantly higher annual healthcare costs per patient ($6,601 vs. $5,203; P = 0.002); costs also increased as AD severity increased. For patients with absenteeism data, sick leave days were significantly higher with AD (5.3 vs. 4.5; P = 0.005). Short- and long-term disability increased with greater AD severity.

**CONCLUSIONS:** Employees with AD had significantly more comorbidities and higher healthcare use and costs relative to those without AD; these burdens appeared to be driven by increasing disease severity. Work disability also increased with greater AD severity.

**SPONSORSHIP:** Research was funded by Sanofi and Regeneron Pharmaceuticals.

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were matched by number of CCO applications versus number of debridements (no CCO) when the number was $\geq 5$ (i.e., 5 or more CCO applications, or 5 or more debridements and no CCO) the proportion of PU closed at 1 or 2 years was significantly different with more CCO-treated PU being closed than non-CCO-treated PU.

CONCLUSIONS: CCO as an adjunct therapy to sharp debridement yielded better clinical outcomes, providing faster rates of closure for the treatment of stage IV PU’s relative to sharp debridement alone. Healthcare providers should consider CCO as an effective adjunct therapy to sharp debridement.

SPONSORSHIP: This study was sponsored by Smith & Nephew.

L14 Comparative Effectiveness of Clostridial Collagenase Ointment to Medicinal Honey for Treatment of Venous Leg Ulcers in the Hospital Outpatient Department Setting

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BACKGROUND: Venous leg ulcers (VLU) are the most common type of leg ulcer, accounting for over 90% of all cases. VLU occur secondary to underlying venous disease whereby damage to the superficial, deep or perforating veins leads to venous hypertension. Elements of good VLU care consist of compression dressings to control the underlying venous insufficiency, debridement to remove necrotic tissue and reduce bacterial burden and topical infection management. Debridement may be sharp, enzymatic, biologic, mechanical or autolytic.

OBJECTIVE: The objective of this study was to assess the clinical effectiveness of enzymatic debridement with clostridial collagenase ointment (CCO) relative to autolytic debridement with medicinal honey in the hospital outpatient department (HOPD) setting for the treatment of VLU.

METHODS: Retrospective de-identified electronic medical records from 2007-2013 were extracted from the U.S. Wound Registry (USWR). The USWR is a longitudinal observation database of chronic wounds from more than 100 HOPD wound centers in the U.S. A propensity score matching method was used to adjust for selection bias and to test for treatment effect between wounds treated with CCO versus medicinal honey.

RESULTS: A total of 9,313 patients, 22,312 wounds, and 186,023 visits for VLU were identified. The majority of patients were female (51.9%) with an average age of 61.6 (SD = 17.7). Approximately 21.3% had a history of hypertension, 8.3% had a history of venous insufficiency with diabetes, and 2.5% received immunosuppressive agents. Mean baseline wound surface area was 7.9 cm$^2$ (SD = 14.4). The average wound age at baseline was 8.5 months (SD = 27.8) and average treatment duration was 2.9 months (SD = 4.9). Of the 22,312 VLU, approximately 13.2% received CCO (n = 2,939) and 2.3% received medicinal honey (n = 495). VLU treated with medicinal honey were significantly more likely (P(<0.0001)) to be active and chronic after 60 days relative to wounds treated with CCO (13% versus 9%, respectively). Furthermore, VLU treated with CCO were significantly more likely (P(0.01)) to achieve 100% granulation by the end of therapy compared to wounds treated with medicinal honey (30% versus 19%, respectively). Finally, VLU treated with CCO were significantly more likely (P(<0.0001)) to close by the end of therapy relative to wounds treated with medicinal honey (45% versus 31%, respectively).

CONCLUSIONS: Over the course of therapy VLU treated with CCO demonstrate greater clinical improvement, particularly achieving 100% granulation and closure than VLU treated with medicinal honey.

SPONSORSHIP: This study was funded by Smith & Nephew.

L18 Long-term Efficacy in Apremilast: Results from the ESTEEM Trials

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Celgene

BACKGROUND: The ESTEEM phase III program comprises 2 randomized, placebo-controlled studies evaluating apremilast (APR) in approximately 1,235 patients with moderate-to-severe plaque psoriasis.

OBJECTIVE: This pooled analysis assessed the sustainability of efficacy in patients treated with APR up to Week 52.

METHODS: Patients with moderate-to-severe plaque psoriasis (Psoriasis Area and Severity Index [PASI] score $\geq 12$, body surface area $\geq 10\%$, static Physician Global Assessment score $\geq 3$) were randomized (2:1) to APR 30 mg BID (APR30) or placebo. At week 16, all placebo patients switched to APR30 through week 32. This was followed by a randomized treatment withdrawal phase up to week 52. The primary outcome was the proportion of patients achieving a $\geq 75\%$ reduction from baseline PASI score (PASI-75) at Week 16. The week 16, 32, and 52 findings were based on observed data, with no imputation for missing values.

RESULTS: At week 16, 260 out of 738 patients (35.2%) in the APR-30 arm and 21 out of 358 patients (5.9%) in the placebo/APR30 arm achieved a PASI-75 response. At week 32, 227 out of 616 patients (36.9%) in the APR30 arm and 107 out of 314 patients (34.1%) in the placebo/APR30 arm achieved a PASI-75 response. At week 52, 190 out of 472 patients (40.3%) in the APR30 arm and 97 out of 243 patients (39.9%) in the placebo/APR30 arm achieved a PASI-75 response.

CONCLUSIONS: The efficacy of APR30 in patients with moderate to severe plaque psoriasis who remained on treatment was generally sustained to week 52. The response to treatment at week 52 was similar between the APR30 and placebo/APR30 treatment arms.

SPONSORSHIP: This study was sponsored by Celgene.

M02 Dosing Patterns, Healthcare Costs, and Provider Characteristics in Patients with Rheumatoid Arthritis Being Treated with Biologic Disease-Modifying Drugs


Bristol-Myers Squibb; aComprehensive Health Insights, Humana

BACKGROUND: Biologic therapies have become one of the primary treatment modalities for rheumatoid arthritis (RA). Due to their increasing usage more data are needed to understand dosing patterns, cost and provider characteristics as new biologic options continue to emerge.

OBJECTIVE: To describe the dosing patterns and healthcare costs observed among adult RA patients newly initiated on biologic disease-modifying anti-rheumatic drug (bDMARD) monotherapy and identify potential variations by patient, provider and site of care characteristics.

METHODS: A retrospective, observational cohort study was completed using a payer’s administrative claims data. Adult RA patients with a confirmed diagnosis of RA prescription claim for a bDMARD between January 1, 2008 and December 31, 2013 without a prior claim for another bDMARD within twelve months were identified. Patients were assigned to treatment cohorts based on the specific bDMARD initiated.
and were followed for 12 months following their bDMARD initiation. Dosing patterns and healthcare expenditures were the primary outcomes of interest.

**RESULTS:** The predominantly female (77.9%) sample of RA patients consisted of 1,386 (30.6%) commercial plan members and 3,594 (69.4%) Medicare Advantage and Prescription Drug Plan (MAPDP) members with a mean age of 60.3 (SD = 12.72). Of the 1,322 (25.5%) total members with dosage changes, 696 (52.6%) were dose escalations. More changes occurred in the infliximab (37.9%), etanercept (21.2%) and adalimumab (20.6%) cohorts. Dose escalators ($2,707.14, SD = 1,713.30) had higher medical expenditures ($P = 0.01) per patient month (PPPM), than non-escalators ($2,633.49, SD = 2,098.70). The same trend was also seen in members with dosage decreases ($P = 0.05). The majority of commercial members on intravenous therapy (IV) sought care at their physician’s offices while MAPDP members were treated at either a physician’s office (60.7%) or an outpatient hospital (27.3%). RA patients initially treated with IV therapy had higher medical expenditures ($P < 0.001) PPPM of $2,323.60 (SD = 1,774.23) compared to $1,959.02 (SD = 1,360.34) for those that initiated on a subcutaneous formulation.

**CONCLUSIONS:** Dosing changes occurred in 25.5% of all RA patients, with the majority being dose escalation. Dosing changes and formulation choice resulted in a significant increase in expenditures.

**SPONSORSHIP:** Funded by Takeda Pharmaceuticals USA.

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**M03 The Impact of Urate-Lowering Therapies on Cardiovascular Event Rates and Expenditure in Gout Patients with Pre-existing Cardiovascular and Chronic Kidney Disease**

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**BACKGROUND:** Lower serum uric acid levels are associated with reduction in cardiovascular (CVD) risk but the association between urate-lowering therapies (ULT) and CVD cost is unclear. Major cardiovascular events (MCE) and CVD cost are measured during the study period and compared between the two cohorts using Wilcoxon signed-rank tests for continuous variables and McNemar’s tests for categorical variables. All-cause total healthcare, pharmacy and medical costs were compared using generalized linear models controlling for demographics, insurance type, and individual non-PsA-associated comorbidities.

**RESULTS:** A total of 35,061 matched pairs were included in this study, with a mean age of 49.1 ± 10.2 years and 47.3% were male. PsA patients had higher rates of chronic pulmonary disease (22.7% vs. 14.5%), liver disease (excluding fatty liver) (12.8% vs. 5.5%) and co-prevalent rheumatic disease (6.3% vs. 1.0%) than controls (all $P < 0.0001). Proportion of patients with ≥1 inpatient [IP], emergency room [ER], and outpatient [OP] visit were significantly higher among PsA patients vs. controls (IP: 8.4% vs. 5.2%, ER: 21.6% vs. 16.2%, OP: 99.2% vs. 86.9%, respectively; all $P < 0.0001). In addition, PsA patients had significantly higher mean numbers of IP (0.11 vs. 0.06), ER (0.37 vs. 0.25) and OP (18.59 vs. 9.23) visits and significantly longer length of stay (0.60 days vs. 0.34 days) than controls (all $P < 0.0001). Costs were also higher in PsA patients compared to controls, with mean adjusted annual difference for total cost being $18,482; pharmacy cost, $11,737; and medical cost, $6,440 (all $P < 0.0001).

**CONCLUSIONS:** Compared with matched subjects without PsA and PsO, PsA patients incurred significantly higher resource utilization and healthcare costs.

**SPONSORSHIP:** Funded by Novartis Pharmaceuticals.
Patients with > 3% BSA > 3% were younger, mean age of 52.2 years [vs. 54.4], with 451 (36.4%) had > 3% and 789 (63.6%) had ≤ 3% BSA. Patients with > 3% BSA had a significant difference in patient reported outcomes such as work productivity, pain and fatigue compared to those with BSA ≤ 3%. Similarly, we observed significant differences seen in PsA patients with dactylitis. Adjusted models showed patients with dactylitis had a significantly higher mean difference in pain and fatigue (mean diff. in pain = 7.4, 95% CI = 3.8, 11; mean diff. in fatigue = 7.3, 95% CI = 3.8, 10.8) compared to patients without dactylitis. Adjusted models showed patients with dactylitis had a significantly higher mean difference in pain in patients with enthesitis (mean diff. in pain = 7.4, 95% CI = 3.8, 11; mean diff. in fatigue = 7.3, 95% CI = 3.8, 10.8) compared to patients without enthesitis. Patients with enthesitis were 1.9 times more likely (95% CI = 1.19-2.87) to have some kind of overall work impairment compared to those without enthesitis. Patients with dactylitis had a higher mean difference in patient reported outcomes such as pain and fatigue (mean diff. in pain = 7.3, 95% CI = 1.19-7.7) although not significant compared to patients without dactylitis. Similarly, patients with dactylitis did not have a significant increase in mean percentage of overall work impairment compared to patients without dactylitis (OR = 1.07, CI = 0.6, 1.7).

CONCLUSIONS: Patients with enthesitis had significantly higher pain, fatigue and more likely to have overall work impairment compared to those without enthesitis. Similar significant differences were not seen in PsA patients with dactylitis.

SPONSORSHIP: The design, study conduct, and financial support for this analysis was provided by Novartis Pharmaceuticals.

M08 Patient Feedback and Satisfaction with the RAPID3 Pilot Program

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BACKGROUND: RAPID3 (Routine Assessment of Patient Index Data 3) is a brief patient self-report questionnaire that is a simple arithmetic composite index of 3 American College of Rheumatology (ACR)
Adherence to Quality Standards for Time to Initiation of Disease-Modifying Anti-rheumatic Drugs Among Newly Diagnosed Rheumatoid Arthritis Patients

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1Evidera; 2Amgen

BACKGROUND: Health-related quality standards have been established by health organizations to mitigate gaps in and improve quality of patient care. The National Committee for Quality Assurance and American College of Rheumatology have established quality standards recommending the use of disease-modifying anti-rheumatic drugs (DMARDs) for patients newly diagnosed with RA.

OBJECTIVE: To determine the proportion of patients and time to initiating a DMARD therapy in newly diagnosed RA.

METHODS: Using the Medco pharmacy benefits management database between January 1, 2009 and June 30, 2012, all patients with ≥2 medical claims with a diagnosis of RA within 120 days were identified; the earlier claim for RA was set as the index date. Eligible patients aged ≥18 years at index date with continuous enrollment for the 12-month periods before and after this date (pre- and post-index, respectively). Patients with a RA diagnosis or use of any DMARDs during pre-index periods were excluded. Proportion of DMARD initiating patients were identified and classified according to type of RA therapy first received during the post-index period (cDMARD [conventional DMARD] or “biologic,” respectively). Time to any DMARD therapy initiation (from index date) was ascertained using Kaplan-Meier method.

RESULTS: A total of 4,099 patients met all selection criteria, of whom 39.8% initiated any DMARD therapy during the post-index period (37.6% cDMARD, 2.2% biologic initiators). More than half (53.8%)
of cDMARD initiators began therapy with methotrexate, followed by 30.7% starting with hydroxychloroquine. Forty-two percent of biologic initiators began therapy with infliximab, followed by 15.7% initiating etanercept. Overall, most RA therapy initiators (81.6%) began therapy within 90 days of index date; 10.0%, within 91-180 days; 5.0%, within 181-270 days; and 3.4%, within 271-365 days. A higher proportion of cDMARD initiators began therapy within 90 days of the index date compared to biologic initiators (82.8% vs. 60.7%); corresponding mean (SD) times to cDMARD initiation and biologic initiation were 50.0 (74.1) days and 81.6 (81.6) days, respectively.

CONCLUSIONS: Two in five patients initiated therapy with any DMARDs within the year following the initial diagnosis of RA, an indicator of potential non-compliance with quality guidelines and under-treatment of RA. Future research on the impact of time to initiation were 50.0 (74.1) days and 81.6 (81.6) days, respectively.

SPONSORSHIP: None.

Adherence to Infliximab Intravenous Infusion Versus Self-Injectable Biologic Therapies Certolizumab and Etanercept Using Pharmacy Paid Claims Data

M12

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BACKGROUND: Certolizumab, etanercept, and infliximab are some of the most commonly prescribed medications in the treatment of rheumatoid arthritis (RA). RA affects an estimated 1.5 million adults in the United States alone, with 41 out of every 100,000 people being diagnosed every year. Adherence to these costly biologic therapies is key in improving clinical outcomes. Evaluating utilization and adherence helps determine the feasibility and potential place in therapy of the biosimilar for infliximab on the horizon in the U.S. Although RA is the most common indication for these medications, they are used for other inflammatory conditions.

OBJECTIVE: To compare adherence rates of infliximab to patients using the self-injectable biologic therapies certolizumab and etanercept.

METHODS: Using pharmacy paid claims data, a retrospective analysis was conducted assessing adherence to infliximab, certolizumab, and etanercept using proportion of days covered (PDC) at 80% or greater over the course of one plan year. Proportion of adherent and non-adherent members to infliximab was compared to patients on certolizumab and etanercept, and statistical significance was determined using Fisher's exact test. Members at least 18 years old enrolled in a prescription plan managed by the pharmacy benefit manager with paid pharmacy claims for infliximab, certolizumab, or etanercept were included in the study.

RESULTS: Out of 83 members, 83% were female with an average age of 43. 81% used etanercept, 16% used certolizumab, and 3% used infliximab. Average PDC was 0.85, 0.74, and 0.76 for etanercept, certolizumab, and infliximab, respectively. 71% of members were adherent to etanercept and certolizumab combined and 33% were adherent to infliximab. Using Fisher's exact test there is no statistical difference in adherence rate whether a patient is on self-injectable or infusion-administered biologic (P>0.05).

CONCLUSIONS: Adherence to these costly medications is a driving factor in improving clinical outcomes for patients with RA and other inflammatory diseases. Self-injectable medications were more common in the group of patients studied but their respective adherence rates were similar. In Europe, Inflectra, a biosimilar for infliximab, has been estimated to result in additional savings of between €15.3 and €20.8 million euros (approximately $17 to $23 million USD) over a three-year period. With comparable adherence rates with either self-injectable or infusion-administered biologics, this study demonstrates a potential shift in utilization on the horizon as the FDA reviews the Celltrion’s infliximab biosimilar that has been submitted.

SPONSORSHIP: None.

Evaluation of Healthcare Cost Changes from Increased Compliance to Biologics in Patients with Rheumatoid Arthritis

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BACKGROUND: Biologics used for rheumatoid arthritis (RA) slow RA disease progression and may reduce healthcare resource utilization. Patients with better compliance to these therapies should have improved outcomes that may result in reduced healthcare costs.

OBJECTIVE: To describe total and RA-specific net healthcare costs by level of compliance for first-line biologic use (abatacept, adalimumab, certolizumab, etanercept, golimumab, and infliximab) among commercially insured non-elderly adult RA patients in the U.S.

METHODS: This retrospective analysis used the MarketScan Commercial Database to identify non-elderly adults (ages 18-63) with RA in the U.S. initiating a first-line biologic therapy between 2010-2012. Patients were required to be continuously enrolled for 6 months pre- and 12 months post-biologic initiation (index date). Patients with other biologic-approved indications were excluded. All-cause net healthcare costs (all-cause costs excluding biologic costs), RA-specific net healthcare costs (RA-specific costs excluding biologic costs), and compliance (as measured by proportion of days covered [PDC]) were measured in the 12 months post-index. Generalized linear models including gamma distribution error and log link were used to control for baseline demographic and clinical characteristics and index biologic.

RESULTS: A total of 14,696 patients met the selection criteria (mean age 49.3, 78.3% female). Relative to patients with poor compliance (PDC < 20%), patients with PDC of 20%-<40%, 40%-<60%, 60%-<80%, and ≥80% had 9% (P = 0.003), 22% (P < 0.0001), 27% (P < 0.0001), and 42% (P < 0.0001) reduced all-cause net healthcare costs. In the same order, RA-specific net costs increased by 8%, but reduced by 8%, 10%, and 25% in these patients relative to patients with PDC < 20%. Intravenous abatacept, subcutaneous abatacept, certolizumab, and infliximab had 48%, 16%, 17% and 42% significantly higher all-cause net healthcare costs than etanercept, respectively (all P < 0.05). Intravenous abatacept, subcutaneous abatacept, certolizumab, golimumab, and infliximab had 223%, 23%, 21%, 9%, and 236% significantly higher RA-specific net healthcare costs than etanercept, respectively (all P < 0.05). No other differences were seen between etanercept and other therapies.

CONCLUSIONS: While increased level of compliance to RA biologics leads to higher biologic costs, it was found to be associated with lower all-cause and RA-specific net healthcare costs. The clinical benefits of increased compliance and cost offset arising from increased productivity should be further investigated.

SPONSORSHIP: Research was funded by Immunex, a wholly owned subsidiary of Amgen.
Healthcare Resource Utilization and Work Loss in Dermatomyositis and Polymyositis Patients in a Privately Insured Population in the United States

1Analysis Group; 2Mallinckrodt

BACKGROUND: Dermatomyositis and polymyositis (DM/PM) are inflammatory myopathies characterized by muscle inflammation/weakness. Patients with DM/PM have a reduced quality of life and are at an increased risk for a number of comorbidities. Studies have assessed the incidence and prevalence of DM/PM, however, no study has estimated the burden of the disease in terms of healthcare resource utilization (HCRU) or work loss incurred by patients.

OBJECTIVE: The objective of the current study was to provide a comprehensive, current estimate of the annual HCRU and work loss in DM/PM patients in the United States.

METHODS: All patients (age range 18-64 years) with a first diagnosis of DM/PM between January 1, 1998 and March 31, 2014 (“index date”) were selected from a de-identified privately insured administrative claims database (OptumHealth Reporting and Insights). DM/PM patients were required to have continuous health plan enrollment 12 months prior to and following their “index date.” Propensity-score (1:1) matching of DM/PM patients with non-DM/PM controls was carried out based on logistic regression of demographic characteristics, comorbidities, costs and HCRU to control for confounding. Burden of HCRU and work loss (disability days and medically-related absenteeism) were compared between the matched DM/PM and the non-DM/PM cohorts over the 12-month period after the index date (“outcome period”).

RESULTS: Of the 2,617 DM/PM patients, 2,587 (98.9%) met the sample selection criteria and were matched with a non-DM/PM control. The 2,587 DM/PM patients were on average, 49.4 years old, and 35.6% were male. During the outcome period DM/PM patients had on average, 44% more inpatient admissions as compared to matched control patients (3.6 vs. 2.5 inpatient admissions; P < 0.001) and significantly more rheumatologist (1.8 vs. 0.6; P < 0.001), neurologist (0.8 vs. 0.4; P < 0.001) and physical therapy (3.7 vs. 2.6; P < 0.001) visits. On average, DM/PM patients filled 4.7 more prescriptions during the outcome period (32.2 vs. 27.5; P < 0.001), had 17.9% greater corticosteroid use (41.4% vs. 23.6%; P < 0.001), and significantly greater non-biologic DMARD use (28.1% vs. 11.5%; P < 0.001) than matched control patients. The number of work loss days found was 2.0 days greater among DM/PM patients compared with matched controls (17.5 vs. 15.5; P < 0.001), which was predominantly driven by a significant increase in medically-related absenteeism (10.7 vs. 9.5; P < 0.001).

CONCLUSIONS: DM/PM imposes a significant increase in healthcare resource use burden and is associated with statistically significantly greater work loss in the first year of diagnosis.

SPONSORSHIP: This study was sponsored by Mallinckrodt Pharmaceuticals.

Clinical Characteristics, Pain Assessment, and Treatment Patterns Among Fibromyalgia Patients: An Analysis of Linked Electronic Medical Records and Administrative Claims Data

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BACKGROUND: Fibromyalgia (FM), a chronic musculoskeletal pain disorder, is characterized by widespread pain, fatigue, sleep and cognitive impairment. Three medications are approved by the U.S. FDA for management of FM: duloxetine [DLX], pregabalin [PGN], and milnacipran [MLN]. Although existing studies have used retrospective databases to evaluate treatment patterns in FM, no studies have described usual care treatment patterns with these medications using EMR-linked claims data, which enables evaluation of prescription and OTC medications for FM within the context of qualitative information on patients’ self-assessment of pain.

OBJECTIVE: To assess baseline demographics, clinical characteristics, pain intensity, comorbidities, and use of other pain-related therapies among patients with FM newly prescribed FDA-approved therapy.

METHODS: Linked EMR-administrative claims data were used to identify patients aged 18+ years who were newly prescribed DLX, PGN, or MLN between Oct 2013 and Sept 2014 (index defined as date of first filled prescription); had two or more ICD-9-CM diagnosis codes for FM any time before or within 30 days after index; were naive to therapy and continuously enrolled with no evidence of active cancer for 6-months prior to index. Demographic and clinical characteristics, pain-scores, prevalence of comorbidities, and OTC and other pain-related pharmacotherapy were examined during the 6-month baseline period.

RESULTS: Of the 1,510 FM patients identified, 447 (29.6%) initiated PGN, 948 (62.9%) DLX, and 115 (7.6%) MLN. The majority were female (87%) and mean age was about 50 years across treatment groups. Prevalence of musculoskeletal pain, dyslipidemia and hypertension was over 40% each across groups and more than 35% in each group had fatigue. Depression and anxiety were higher in the DLX group (41.7% and 39.6%, respectively) compared to PGN (30.6%, 32.0%) and MLN (34.5%, 34.5%). Intensity of pain, measured on a 0-10 scale, averaged 4.5 (± 2.5), with over half having moderate pain (55.4%). American College of Rheumatology recommended treatments cyclobenzaprine, gabapentin and tramadol were prescribed to over 25% of patients in each group. Other commonly prescribed medications were analgesics (77%), gastroenterologics (45%), and antidepressants (41%).

CONCLUSIONS: The majority of FM patients newly prescribed FDA approved therapies were female, had moderate pain and suffered significant comorbidity and medication burden. Understanding the impact of FM therapies has the potential to lead to improved patient outcomes.

SPONSORSHIP: This study was sponsored by Daiichi Sankyo.

Prevalence and Direct Costs of Opioid Abuse in Medicare Beneficiaries

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BACKGROUND: Opioid abuse and dependence are important and costly problems in the U.S.

OBJECTIVE: Determine prevalence and direct cost of diagnosed prescription opioid abuse, dependence, and misuse (“diagnosed abuse”) and at risk for opioid abuse (“at risk abuse”).

METHODS: Retrospective case-control study of Medicare claims data, including medical, pharmacy and enrollment information from 2010 to 2011. Subjects were Medicare beneficiaries ≥18 years of age, with an index date between July 1, 2010 and June 30, 2011, and >6 months continuous eligibility before and after index date identified as diagnosed abuse (ICD-9 codes) or at risk abuse (based on previously published risk factors) and matched controls (age, gender, disability, region). Prevalence and cost were based on 2010-2011. Index date was date of first diagnosis of abuse, at risk for abuse, or opioid use as
applicable. Costs were modeled using univariate generalized linear regression with gamma distribution and log link.

RESULTS: Total Medicare population was 53,765,609 and those without HMO coverage (population of interest) was 15,526,034. The prevalence of diagnosed abuse and at risk abuse was 13.1/1,000 and 117.4/1,000, respectively. Of diagnosed abusers, 76.2% had disability related eligibility. In 2010-2011, 51.4% of Medicare patients used an opioid. 77,369 controls were matched to diagnosed abuse cases and 150,214 controls were matched to at risk abuse cases. Total annual mean unadjusted costs [SD] were significantly higher for diagnosed abusers ($46,194.13 [$100,607.70]) than matched controls ($21,964.25 [80,530.97]), a difference of $24,229.88 (P < 0.0001). Mean costs for diagnosed abusers were higher than controls in all cost categories (inpatient, outpatient, ED visits, and drug costs). Annual mean unadjusted costs [SD] were significantly higher for at risk abusers ($36,223.99 [$91,735.31]) than controls ($21,685.17 [$74,003.83]); a difference of $14,538.82 (P < 0.0001). Mean costs for at risk abuse $were higher than controls in all cost categories (P < 0.0001).

CONCLUSIONS: In 2010-2011, the majority of abuse diagnosed in the Medicare population was in patients receiving Medicare based on disability (76.2%). The prevalence of at risk abuse was 9 times higher (117.4/1,000) than diagnosed abuse (13.1/1,000). In 2010-2011 approximately half of Medicare patients used an opioid. Medical costs were significantly higher for diagnosed abusers and at risk abusers than controls. Successful interventions to prevent opioid abuse could help to reduce costs associated with opioid abuse in the Medicare population, particularly those qualified based on disability.

SPONSORSHIP: Pfizer.

M18 Real-World Experience with Tofacitinib Versus Etanercept, Adalimumab and Abatacept in Biologic-Experienced Patients with Rheumatoid Arthritis

Harnett J1, Gerber R2, Mardekian J3, Gruben D3, Koenig A4, Chen C5. 235 E. Experienced Patients with Rheumatoid Arthritis
Pfizer. 

CONCLUSIONS: More patients starting tofacitinib after a biologic received monotherapy with at least comparable persistence and adherence and similar (vs. ETN) if not lower (vs. ABA and ADA) total RA-related costs vs. biologic comparators despite significantly higher pre-index costs.

SPONSORSHIP: Pfizer.

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

N01 Impact of Overactive Bladder Step-Therapy Policies on Medication Utilization and Expenditures Among Treated Members
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BACKGROUND: Impact of formulary management strategies on utilization and expenditures in overactive bladder (OAB) treatment has not been extensively investigated. In 2013, step-therapy (ST) policies for two branded OAB treatments (mirabegron and tamsulosin) were removed from Humana Medicare Advantage Prescription Drug (MAPD) plans and Medicare Prescription Drug Plans (PDP) allowing for an examination of the impact of ST on medication use patterns and cost related to OAB treatments.

OBJECTIVE: To examine trends in OAB prescription (Rx) use and expenditures among MAPD and PDP members receiving treatment for OAB in 2013 pre/post ST policy change.

METHODS: Cross-sectional descriptive analysis of MAPD and PDP beneficiaries aged ≥65 years with at least one Rx claim for an OAB medication in 2013 were included. OAB medication use was calculated as a percentage of total claims for that product divided by total number of claims across all OAB products in each month. Total OAB Rx spend was calculated as the sum of pharmacy costs for OABRx and was reported separately for each month and drug during 2013.

RESULTS: 194,511 patients were eligible for inclusion. The number of members with any OAB Rx claim and the number of total OAB claims remained relatively steady throughout the year with some seasonality. Use of branded OAB Rx was after removal of ST increased from 0.19% to 3.18% for mirabegron and 0.79% to 2.26% for tamsulosin. The use of three OAB products, tolterodine ER, solifenacin IR and darifenacin ER, decreased during the second half of the year. The average monthly OAB and expenditures in overactive bladder (OAB) treatment has not been extensively investigated. In 2013, step-therapy (ST) policies for two branded OAB treatments (mirabegron and tamsulosin) were removed from Humana Medicare Advantage Prescription Drug (MAPD) plans and Medicare Prescription Drug Plans (PDP) allowing for an examination of the impact of ST on medication use patterns and cost related to OAB treatments.

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CONCLUSIONS: Removal of ST policies for two OAB medications increased their utilization. The increase in total OAB medication spend was not driven by ST removal but rather by a substantial increase in cost for the highest volume generic product.

SPONSORSHIP: This research was funded by Astellas Pharma Global Development, Medical Affairs, Americas, and conducted as part of the Astellas-Humana Research Collaboration.

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

001 Economic Modeling of Cost Differences Associated with Use of Different Intrauterine Devices from a U.S. Payer Perspective

Law A1, McCoy M1, Lingohr-Smith M2, Lin J2, Lynen R1. 100 Bayer Blvd., U.S. Payer Perspective

Bayer HealthCare Pharmaceuticals; 2Novosys Health

Development, Medical Affairs, Americas, and conducted as part of the Astellas-Humana Research Collaboration.

SPONSORSHIP: This study was sponsored by Bayer HealthCare Pharmaceuticals.

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

R01 The Budget Impact of Adopting Netupitant/Palonosetron for the Prevention of Chemotherapy-Induced Nausea and Vomiting in a U.S. Health Plan

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Eisai

BACKGROUND: Chemotherapy-induced nausea and vomiting (CINV) is a major adverse effect of cancer treatment and can have a significant impact on patients and caretakers. Current NCCN guidelines recommend a combination of a serotonin-3 receptor antagonist (5-HT3-RA), a substance P/neurokinin 1 (NK1) receptor antagonist, and dexamethasone for patients undergoing highly emetogenic chemotherapy (HEC) for the prevention of CINV. This same combination is recommended in patients using moderately emetogenic chemotherapy (MEC) who are at higher risk of CINV.

OBJECTIVE: The purpose of this study was to estimate the budget impact of adopting netupitant/palonosetron (NEPA), an oral fixed-dose combination of a 5-HT3-RA and an NK1, indicated for the prevention of CINV in HEC and MEC, from a U.S. health plan perspective. The modeled budget impact included the costs associated with medication acquisition and potential cost offsets associated with CINV reduction.

METHODS: A decision analytic model compared antiemetics costs before and after adoption of NEPA in a hypothetical one-million member health plan over a 3-year horizon. Estimates of plan cancer rates and utilization of HEC and MEC therapies were derived from U.S. epidemiological and market data. Treatment costs were computed using standard prescribing dosages, U.S. drug cost listings and simple reimbursement and dispensing assumptions. Uptake of NEPA was calculated at 9% a year for 3 years. The market shares of the competing antiemetics were reduced proportionately based on their initial market segment and for each year of the time horizon. Cost offsets, derived from assumptions regarding reduction in CINV and associated costs, were also included. The resulting cost estimates were calculated as total costs, PMPM costs, and cost per utilizing member for each 5-HT3-RA+NK1 combination.

RESULTS: A total of 5,400 patients were identified in the model scenario. Of these, 988 (18.3%) would receive HEC and 395 (7.3%) MEC requiring combination therapy, for a total of 1,383 patients eligible for NEPA. The modeled cost for preventing CINV prior to the adoption of NEPA was $4.1 million. Following NEPA adoption, cumulative costs, including the cost offsets, showed savings of $362K by the end of year 3. PMPM estimates demonstrated cumulative savings of $0.01, $0.02, and $0.03 in years 1 to 3, respectively.

CONCLUSIONS: Based on acquisition costs alone, adoption of NEPA for CINV could have a relatively neutral impact on a U.S. health plan budget. In contrast, adding offset cost savings from a reduction in the rate of CINV could result in overall cost savings for the modeled health plan.

SPONSORSHIP: This study was funded by Eisai.
U01 Patients Who Utilized Retail Healthcare Clinics Have Fewer Emergency Department Visits and Incur Lower Overall Healthcare Cost

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BACKGROUND: The retail healthcare clinic care delivery model started over a decade ago as a convenient, accessible, and less costly alternative to a traditional doctor’s office visit for acute conditions. Initially, these clinics provided a narrow range of services, but as the model has matured, the services provided have expanded to include screenings, preventative, and chronic condition care. It is projected that the Affordable Care Act and the associated patient demand will double the 1,418 clinics in operation in 2012 to 2,868 in 2013 with a projected savings of $800 million annually for the healthcare system.

OBJECTIVE: The objective of this study was to determine whether patients who utilized retail healthcare clinics as part of their medical care have lower healthcare cost and lower emergency department (ED) visits than similar patients who do not utilize retail healthcare clinics.

METHODS: This retrospective propensity matched cohort study selected a two-to-one matched sample from over 195,000 beneficiaries receiving employer based health insurance from a large healthcare company. Patients were matched on age, number of chronic conditions, level of insurance coverage, number of covered beneficiaries, gender, number of therapeutic classes, tobacco use, baseline medical and pharmacy spending, and 27 chronic conditions. Patients had to be continually enrolled from January 2012 through December 2013. The case cohort consisted of patients who utilized retail healthcare clinics as part of their healthcare, while the comparison cohort consisted of patients who did not use retail healthcare clinics at all. We used mixed modelling statistical procedures to assess healthcare utilization and healthcare cost differences between the cohorts. The study was approved by an Institutional Review Board.

RESULTS: In sum, the results of this study showed that the healthcare clinic cohort had significantly fewer ED visits than the comparison cohort (7 fewer visits per 100 patients), and out of pocket cost was significantly lower for the healthcare clinic cohort ($319 lower). In addition, medical spending was significantly lower for the healthcare clinic cohort ($579 lower), and total healthcare cost (medical, pharmacy and plan premium) was significantly lower for the healthcare clinic cohort ($579 lower).

CONCLUSIONS: The results from this study imply that retail healthcare clinics staffed primarily by nurse practitioners provide a more affordable alternative for many primary care services. In addition, the results suggest that retail healthcare clinics may avert more costly non-emergent emergency department visits.

SPONSORSHIP: This research was funded by Walgreens.
the development of analytics that reflect drug safety in heterogeneous, real world, populations.

OBJECTIVE: To develop a drug safety statistic that estimates downstream medical costs associated with serious adverse events (AEs) and unfavorable patient outcomes associated with the use of U.S. FDA-approved drugs.

METHODS: All primary suspect case reports for each drug were collected from FDA’s Adverse Event Reporting System database (FAERS) from 2010-2014. Serious AEs and outcomes were MedDRA coded and tallied for each case report. Medical costs associated with AEs and poor patient outcomes were derived from Agency for Healthcare Research and Quality (AHRQ) survey data and corresponding ICD-9 codes were mapped to MedDRA. Non-serious AEs and outcomes were not included. For each case report, either the highest AE cost or the highest outcome cost was used. All costed cases were aggregated for each drug and divided by the number of patients exposed to obtain a downstream estimated direct medical cost burden per exposure. Each drug was assigned a corresponding 1-100 point total.

RESULTS: The 706 drugs showed an exponential distribution of downstream costs and therefore the data were transformed using the natural log to approximate a normal distribution. The minimum score was 8.29 and the maximum was 99.25, with a mean of 44.32. Drugs with the highest individual scores tended to be kinase inhibitors, thalidomide analogs, and endothelin receptor antagonists. When scores were analyzed across Established Pharmacological Classes, kinase inhibitor and endothelin receptor antagonists had the highest total. Other EPCs with median scores of 75 and above included: hepatitis C virus ns3/4a protease inhibitor, recombinant human interferon beta, vascular endothelial growth factor-directed antibody, and tumor necrosis factor blocker. When Anatomical Therapeutic Chemical classifications were analyzed, antineoplastic drugs were an outlier with approximately 80% of their individual scores ≥60, while blood and anti-infective drugs had ~20-30% of their scores ≥60. Within-drug class results served to differentiate similar drugs.

CONCLUSIONS: This scoring system is based on estimated direct medical costs associated with post-marketing AEs and poor patient outcomes and thereby helps fill a large information gap regarding drug safety in real world patient populations.

SPONSORSHIP: None.

U09 Medication Adherence and Biometric Outcomes Among Patients with Diabetes and Dyslipidemia: Before and After Testing

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BACKGROUND: Better adherence to pharmacotherapy is crucial in managing chronic conditions and in achieving target levels of biometric outcomes.

OBJECTIVE: For patients with diabetes or dyslipidemia, examine association of prior medication adherence to biometric test results; controlling for demographics and longevity of medication use (new vs. experienced user). Secondary objective was to investigate changes in medication use patterns among adherent patients with biometric values above the target levels.

METHODS: A cross-sectional analysis using de-identified pharmacy claims and laboratory data from a large national pharmacy benefits manager between January 1, 2011 and December 31, 2014. Analyzed sample of commercially insured patients aged 18 or older who had at least one prescription claim for oral medications to treat diabetes or dyslipidemia prior to having a biometric test (hemoglobin A1C or low density lipoprotein [LDL], respectively) with continuous eligibility 270 days before and 120 days after the biometric test. Patients with medication possession ratio (MPR) of 0.8 or greater in the 180-day period prior to biometric test were considered adherent, and the rest as nonadherent. Sensitivity was performed by calculating 90-day MPR (clinically relevant period that reflects in test results) prior to the test. Ninety days prior to the adherence measurement period was used to establish longevity of use. Multivariate logistic regression was used to evaluate the association between being adherent and achieving target levels on biometric test (<8 for A1C and <100 for LDL). Medication use patterns for adherent patients with above target levels were examined for 120 days after the test and compared to 120 days before the test to ascertain any changes.

SPONSORSHIP: None.
RESULTS: The final sample for adherence analysis consisted of 9,347 diabetes and 17,451 dyslipidemia patients. Compared to nonadherent patients, the adjusted odds of achieving target levels among adherent patients was 1.72 (95% CI = 1.55-1.90) for diabetes and 1.97 (1.84-2.11) for dyslipidemia. Sensitivity results were consistent. Among adherent patients with above target levels, no change in medication was observed for 64.4% of diabetes (n = 1,008) and 76.1% of dyslipidemia (n = 2,897) patients.

CONCLUSIONS: Being adherent to medications is associated with a greater likelihood of achieving target levels of A1C and LDL. No change in pharmacotherapy for more than two-thirds of adherent patients with above target levels indicates an opportunity for greater collaboration between payers, benefit managers and prescribers to deliver timely and appropriate patient-centric care.

SPONSORSHIP: This study was internally funded by Express Scripts.

U11 Virtual Telepharmacist-Delivered Chronic Care Management Services: A Pilot Program Evaluation
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PROBLEM DESCRIPTION: Pharmacists play a key role in helping patients: monitor their medications; improve health outcomes and quality of life, and reduce medication costs. These factors echo the Institute for Healthcare Improvement’s (IHI’s) Triple Aim Initiative to improve patients’ care experience and population health; and reduce per capita healthcare costs. Balancing quality care with reduced costs presents ongoing challenges for all involved in today’s healthcare arena. Yet, the Affordable Care Act (ACA) provides opportunities to develop cost-saving alternatives and innovative health care delivery mechanisms, such as state-of-the-art, video-based pharmacy counseling. This retrospective review evaluated the impact of virtual telepharmacy on improving patient care.

GOAL: The goals were to improve patient care by: (a) providing access to clinical pharmacy services; (b) reducing pharmacist-related costs (e.g., travel time); and (c) offering an interdisciplinary team approach.

PROGRAM DESCRIPTION: This 6-month pilot program involved a university-based medication therapy management telepharmacist providing “live” chronic care management to patients via virtual technology in an academic family medicine clinic; this program integrated an innovative delivery model with a diverse mix of healthcare professionals. The objectives were to: (a) improve adherence (e.g., medication, guideline), (b) reduce costs, (c) improve safety (e.g., drug interactions, therapeutic duplication), and (d) improve Centers for Medicare and Medicaid Services Part C and D Star Ratings. The weekly clinic was offered by scheduled or walk-in appointment, the nurse coordinator oriented patients to the virtual process at the clinic site. A descriptive analysis was conducted.

OBSERVATIONS: A total of 69 patient record reviews were completed. The telepharmacist made 200 clinical interventions and recommendations including: safety (49.0%); guidelines (vaccine [24.8%]; national consensus [13.5%]); adherence (10.0%); and other (3.0%). More than one third (37.5%) of the recommendations resulted in changes being implemented. Additional preliminary results will be presented.

FINDINGS/RECOMMENDATIONS: Proactive involvement by the primary referring physician and interprofessional care coordinator, in tandem with the professionalism and approachability of the telepharmacist, were key to successful recruitment, patient participation, and program implementation. The “lessons learned” may serve as a guide for other healthcare groups interested in discovering new ways to provide lower-cost, quality healthcare.

SPONSORSHIP: University of Arizona College of Pharmacy, Center for Health Outcomes and PharmacoEconomic Research (HOPE Center).

U16 Implementation of CMS-Recommended MED Point of Sale Edit in a Medicare Part D Population
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BACKGROUND: Pain management, particularly with opioid medications, is an emerging concern for the health care system and must be appropriately managed in order to improve patient outcomes and quality of life. In the 2013 Call Letter, the Centers for Medicare and Medicaid Services (CMS) strongly encouraged Medicare Part D plan sponsors to develop the ability to implement plan-level point of sale (POS) edits based upon the cumulative morphine equivalent dose (MED) across the opioid class.

OBJECTIVE: Describe the effects of a morphine equivalent dose point of sale edit in a Medicare Part D population in the first 6 months post-implementation.

METHODS: In 2014, Navitus used the CMS MED specifications to build an in-house POS edit in our proprietary adjudication system. Morphine equivalent dose is calculated on a per member basis by multiplying the number of opioid dosage units per day by the number of milligrams opioid per dosage unit by the MED conversion factor. Additionally, unique prescribers and pharmacies are calculated for each member for all active prescription claims at the generic product identifier level. The edit calculates unique prescribers, pharmacies, and the total MED across active opioid prescriptions. Descriptive statistical analysis was performed on all prescriptions that met the MED POS edit criteria within the first 6 months of the edit being turned on (August 11, 2014-February 11, 2015).

RESULTS: A total of 75 prescriptions triggered the edit in the 6-month time frame for the Medicare Part D plan analyzed. These 75 prescriptions incorporated 41 unique members. Twenty-six members had a single prescription that triggered the edit and 49 prescriptions were submitted by 15 members. The greatest number of edits per member during the 6-month time frame was seven. T-test statistics were calculated and determined that members with multiple edits exhibited significantly higher average daily morphine equivalent doses (247.184 vs. 129.038), a higher number of pharmacies (4.449 vs. 3.154), and a higher number of prescribers (2.1275 vs. 1.9861) compared with individuals with a single edit. There was no significant difference in member age between groups (55.90 vs. 56.04). During the 6-month time frame, 1,622 total members within the plan had at least one opioid prescription filled and the MED POS edit identified 2.53% of these members (41/1,622).

CONCLUSIONS: There are a small number of Medicare Part D members receiving excessive doses of opioids, in combination with multiple prescribers and dispensing pharmacies. Implementing this edit has the potential to identify and minimize excessive opioid utilization.

SPONSORSHIP: This research was conducted by Navitus Health Solutions, Madison, WI, without external funding.

U17 Managed Care Peer-Led Teaching: An Innovative Learning Approach Outside the College of Pharmacy Core Curriculum
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BACKGROUND: Managed care pharmacy is a growing field, but there is still limited education opportunities available in many pharmacy
core curriculums. Students often seek self-directed learning opportunities to further explore the field.

**OBJECTIVE:** To evaluate the practicality and effectiveness of a student-designed and led managed care pharmacy elective, and to determine emerging best practices for the design and sustainability of peer-led self-directed elective courses.

**METHODS:** The managed care elective was designed as a student peer-led team learning course during the 2012-2013 school year. As the course evolved, class coordinators evaluated the feasibility, effectiveness and sustainability of a student-led elective. The course required students to select a managed care topic of interest and deliver a discussion based presentation. Teleconferencing was used to maximize participation and flexibility of pharmacist delegates from local managed care organizations, who provided industry insight and expert mentorship. Data sources were gathered via course evaluation surveys, peer evaluations of presentations and a post-graduation survey. Data was used to guide course improvement, gain insight on student motivation to participate and evaluate impact on pharmacy career choices.

**RESULTS:** A total of 28 and 17 students participated during Fall 2014 and Spring 2015, respectively, and completed end of semester surveys. 70% of enrollees took the course due to an interest in managed care pharmacy, 12% took the course due to referrals from past students, and 12% enrolled to explore topics outside of the college’s core curriculum. After completion of the course, 50% of students felt “somewhat comfortable” in discussing managed care topics with peers and 31% of the class felt “very comfortable” in the same situation. None of the 17 students from the Spring 2015 class answered “not comfortable” or “somewhat not comfortable” in discussing managed care topics with peers and 31% of the class felt “very comfortable” in the same situation. None of the 17 students from the Spring 2015 class answered “not comfortable” or “somewhat not comfortable” in discussing managed care topics with peers and 31% of the class felt “very comfortable” in the same situation.

**CONCLUSIONS:** Graduates who previously took the course have pursued managed care opportunities to further explore the field. After completion of the course, 50% of students felt “somewhat comfortable” in discussing managed care topics with peers and 31% of the class felt “very comfortable” in the same situation. None of the 17 students from the Spring 2015 class answered “not comfortable” or “somewhat not comfortable” in discussing managed care topics with peers and 31% of the class felt “very comfortable” in the same situation. None of the 17 students from the Spring 2015 class answered “not comfortable” or “somewhat not comfortable” in discussing managed care topics with peers and 31% of the class felt “very comfortable” in the same situation.

**SPONSORSHIP:** None.

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**U18 The Impact of a Telephonic Outreach Program on Medication Adherence in Medicare Advantage Prescription Drug Plan Members**

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**BACKGROUND:** Non-adherence to medications is widely recognized as being a very common and costly problem with many individuals not reaching their intended therapeutic goals. The Centers for Medicare and Medicaid Services (CMS) has adopted quality measures focusing on medication adherence in oral antidiabetic medications and renin-angiotensin system antagonists for hypertension. The University of Florida (UF) College of Pharmacy’s Medication Therapy Management Communication and Care Center (MTMCCC) provides quality measurement improvement initiatives telephonically including adherence services. The MTMCCC engages health plan members enrolled in a Medicare Advantage Prescription Drug (MA-PD) plan in a live, interactive telephonic assessment to determine potential barriers, and provide interventions, to help improve medication adherence.

**OBJECTIVE:** To determine the effectiveness of a telephonic outreach program designed to improve medication adherence as determined by using the proportion of days covered (PDC) calculation for MA-PD plan members diagnosed with hypertension and diabetes.

**METHODS:** This was a retrospective pre-post comparison group study analyzing medication adherence. MA-PD plan members who received at least two oral anti-diabetics and oral anti-hypertensives were considered eligible for this study. Data from the health plan from January 2013 to December 2014 was evaluated. Adherence, as defined by the proportion of days covered (PDC) calculation, was measured using incurred medication prescription claims 6-months before and after the adherence services were implemented. The pre-post differences in the PDC within and between the eligible members and controls were measured (difference-in-differences (DID) analysis).

**RESULTS:** There were 12,133 members analyzed with 2,382 in the hypertension group and 9,751 in the diabetes group. In the diabetes cohort, the treatment group had a pre-post increase in PDC value by 3.19%, while the control group had a decrease of 2.82%. For the hypertension cohort, the treatment group had a pre-post increase in PDC by 17.33%, while the control group had an increase of 9.64%. The PDC finding was confirmed using regression analyses with propensity score adjustment showing the treatment groups had a significant increase in pre-post PDC for hypertension, as compared with the control group, while controlling for baseline characteristics (P = 0.01).

**CONCLUSIONS:** This study found that the telephonic adherence program as administered by the UF MTMCCC demonstrated a statistically significant increase in medication adherence in Medicare MAPD patients as compared with a control group.

**SPONSORSHIP:** Florida Department of Health: grant funding; University of Florida College of Pharmacy: employment

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**U19 A Randomized Clinical Trial of Medication Therapy Management in a Commercial Population**


Independence Blue Cross; Catamaran

**BACKGROUND:** Medication therapy management (MTM) encompasses a broad range of healthcare services provided by pharmacists whose aim is to optimize drug therapy and improve therapeutic outcomes for patients. Although CMS requires Medicare Part D plan sponsors conduct MTM for Part D members, MTM may also be effective in a commercial population. To the best of our knowledge, no study has used a randomized clinical trial (RCT) design in a large commercially insured population to evaluate the impact of MTM interventions. Independence Blue Cross along with its pharmacy benefit manager Catamaran developed an RCT to evaluate the impact and value of the MTM program.

**OBJECTIVE:** To evaluate the impact of MTM services on medical costs in a commercially insured population.

**METHODS:** Approximately 580,000 health plan members were evaluated for qualification. Members between the ages of 18-64 who qualified for MTM based on (a minimum projected annual drug spend of $3,144, at least 2 chronic conditions, and at least 4 chronic medications) were randomly assigned to either the intervention or control group. The intervention group received specific MTM type services including compressive medication review (CMR), pharmacist-to-member counseling about their medication, and interventions to improve on adherence and behavioral changes. The control group received standard pharmacy practice. Patients who qualified between June 2013 and July 2014 were included in the analysis. Randomization checks were done to ensure that participants in both groups were equivalent at baseline. A generalized linear regression models using
RESULTS: After 12 months of follow-up the intervention group (n = 15,407) had a 3.6% ($30.58) per member per month (PMPM) lower medical spend compared to the control group (n = 15,484; P = 0.021). In addition, those patients in the intervention group with the presence of diabetes, heart failure, asthma, COPD, or coronary artery disease (n = 9,207) had a 4.4% lower medical spend (P = 0.029) compared to the control group (n = 9,106). The highest savings were seen in members with COPD or diabetes. Overall, when including pharmacy costs, total savings was $255.72 per member per year.

CONCLUSIONS: MTM programs provide services that can achieve significant medical savings in a commercially insured population.

SPONSORSHIP: Catamaran and Independence Blue Cross.

U22 Meeting the Challenges of the Revised AMCP Format: Continuing Education on Comparative Effectiveness Research

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PROBLEM DESCRIPTION: Comparative-effectiveness research (CER) gained visibility in 2012 when the Academy of Managed Care Pharmacy (AMCP) included CER as an addendum to the AMCP Format. CER enables decision makers to consider not only whether a medical product can work, but how it will perform among beneficiaries. Without training on CER methodology, managed care pharmacists may not feel prepared to evaluate CER findings, even when studies provide valuable information. The need to equip managed care pharmacists with skills to assess CER evidence was identified by the CER Collaborative, a partnership among AMCP, the International Society of Pharmacoeconomics and Outcomes Research, and the National Pharmaceutical Council.

GOAL: To improve managed care pharmacists’ self-rated ability to assess credibility/relevance of CER evidence and use of CER studies in decision making.

PROGRAM DESCRIPTION: The CER Certificate Program provides 19 continuing education hours of CER methodology training, including observational studies, modeling studies, indirect treatment comparisons, and synthesizing a body of evidence. Three cohorts of learners (n = 71) received training between Fall 2014 and Spring 2015. A post-training evaluation asked for self-reported competencies related to CER. Learners rated their abilities on a scale of 1-5 (1 lowest, 5 highest) prior to and immediately following training.

OBSERVATIONS: Participants consisted primarily of managed care pharmacists (85.9%). Mean self-ratings of ability prior to training were 2.31 to evaluate indirect treatment comparisons (ITCs); 2.64 for assess relevance/credibility of observational CER studies; 2.57 to detect presence of confounding in CER studies; 2.93 for confidence to meaningfully incorporate evidence based decision making in work; 2.85 evaluate observational studies for decision making; and 2.88 for critically examine CER studies for bias. Following training, the cohort reported improved ability to evaluate ITCs +43.75 (95% CI 37.32, 49.78); assess observational studies +33.68 (28.92, 38.44); detect confounding +33.68 (28.92, 38.44); meaningfully incorporate evidence based decision making in work + 30.90 (25.55, 36.25); evaluate observational studies for decision making; and 2.88 for critically examine CER studies for bias. Following training, the cohort reported improved ability to evaluate ITCs +43.75 (95% CI 37.32, 49.78); assess observational studies +33.68 (28.92, 38.44); detect confounding +33.68 (28.92, 38.44); meaningfully incorporate evidence based decision making in work + 30.90 (25.55, 36.25); evaluate observational studies for decision making; and 2.88 for critically examine CER studies for bias. Following training, the cohort reported improved ability to evaluate ITCs +43.75 (95% CI 37.32, 49.78); assess observational studies +33.68 (28.92, 38.44); detect confounding +33.68 (28.92, 38.44); meaningfully incorporate evidence based decision making in work + 30.90 (25.55, 36.25); evaluate observational studies for decision making; and 2.88 for critically examine CER studies for bias.

FINDINGS/RECOMMENDATIONS: Participants who completed training improved their ability to evaluate CER evidence. Relatively low initial scores may indicate that the training is reaching the correct target audience, while improved scores indicate that participants feel better equipped to evaluate CER studies when compared to their abilities prior to the training.

SPONSORSHIP: Funding was provided by the CER Collaborative, a collaboration of the Academy of Managed Care Pharmacy, the National Pharmaceutical Council, and the International Society for Pharmacoeconomics and Outcomes Research.
U23 Utilization of Preventative Osteoporosis Therapy in Members on Androgen Deprivation Therapy Using Pharmacy Claims Data

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BACKGROUND: The prevalence of osteoporosis in men with prostate cancer on androgen deprivation therapy (ADT) has been well documented with up to 53% of patients affected by this bone condition. Although osteoporosis is most often associated with the female demographic, it results in higher fracture mortality in men. It is recommended that patients receive osteoporosis prophylaxis treatment as a result of being on these medications. This study attempts to gauge the gap between a lack of preventative care in members on ADT medications in order to reduce long term associated costs and improve quality of life.

OBJECTIVE: The objective of this study is to identify the percentage of members who filled ADT medications within a one-year period and who are not on a preventative osteoporosis treatment regimen.

METHODS: A list of paid pharmacy claims for ADT submitted was generated and investigated using a retrospective claims data analysis. Proportions of men and women on medications used in ADT with and without paid claims for a concurrent prophylactic osteoporosis therapy were determined. Chi-square was used to determine significance in use in men and women. Members over the age of 18 enrolled in a prescription plan managed by the pharmacy benefit manager with paid pharmacy claims for ADT and osteoporosis prophylaxis therapy as labeled by the FDA were included in the study.

RESULTS: Out of 178 members, 1 out of 107 male and 0 out of 71 female members received concurrent osteoporosis prophylactic therapy. Difference between male and females on ADT prescribed osteoporosis prophylactic therapy was not significant (P > 0.05).

CONCLUSIONS: The study results demonstrate a lack of difference in the amount of men or women currently on ADT medication receiving an osteoporosis prophylactic therapy. Despite the fact that women are commonly associated with osteoporosis related bone fractures; our data showed no women and less than 1% of men were receiving additional preventative therapy with their current ADT therapy. Results from this study show that there is a significant gap in preventative care in male and female members taking ADT and respective GnRH therapy. The information from this study can act as a critical communication tool between pharmacists and health care practitioners in order to ensure patients are on adequate therapy to reduce future bone fracture associated costs.

SPONSORSHIP: None.

U26 Newly Diagnosed Narcolepsy: Analysis of Comorbidities, Medication Use, Medical Resource Utilization and Healthcare Costs

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BACKGROUND: There are few published data pertaining to comorbidities and utilization patterns among newly diagnosed narcolepsy patients.

OBJECTIVE: To investigate changes in comorbidities, drug use, healthcare utilization and associated costs, before and after a new diagnosis of narcolepsy.

METHODS: Truven Health Analytics MarketScan Research Databases (2006-March 2013) were used to identify all patients who were continuously insured and had probable new diagnoses of narcolepsy, defined as a de novo medical claim for a multiple sleep latency test (MSLT) preceded by ≥6 months continuous insurance and followed by a de novo diagnosis of narcolepsy (n = 3,757). Claims for 3 subsequent 1-year periods from the MSLT (index) date were compared to annualized claims for the 6-month pre-index period, evaluating narcolepsy-related comorbidities and medication use, and all-cause utilization and costs (inpatient admissions, visits to emergency departments [ED], hospital outpatient [OP], physicians, other OP), inflated to 2015 U.S. dollars.

RESULTS: From pre-index to year 3 post-index, the overall percentage of patients with any claims with codes for sleep-related conditions decreased from 79% to 69%; for sleep apnea (41.7% vs. 21.9%), hypsomnia (8.3% vs. 4.0%) and fatigue (31.8% vs. 19.3%), all P < 0.0001. Total medical service utilization decreased each year from a pre-index average of 28.2 medical claims per patient per year (PPPY) to 26.9, 23.1, and 22.5 medical claims PPPY in post-index years 1, 2, and 3, respectively (P vs. pre-index 0.0134, <0.0001, <0.0001). In each OP service category, utilization decreased from pre-index to year 3 (hospital OP and physician visits, P < 0.0001, other OP and ED visits, P < 0.05). Admissions remained stable at 0.1 PPPY (P = 0.6731). The percentage of patients using narcolepsy-related medications increased from 54.0% (pre-index) to 77.4%, 70.0%, and 66.9% for post-index years 1, 2, and 3 (all P < 0.0001 vs. pre-index). Total service costs PPPY were $12,139 pre-index, decreasing to $10,708, $8,543, and $9,136 in post-index years 1, 2, and 3 (all P < 0.0001 vs. pre-index). Overall, decreased service costs offset costs associated with greater use of narcolepsy medications. Total (medical+pharmacy) costs were $15,986 PPPY pre-index vs. $15,167 in year 3 (P = 0.0847).

CONCLUSIONS: While the analysis is subject to limitations of administrative data and may miscategorize the timing of first diagnosis for some patients, the data suggest that confirmation of a narcolepsy diagnosis may be associated with lower total healthcare utilization and some associated costs within the first 3 years following diagnosis.

SPONSORSHIP: This study was funded by Jazz Pharmaceuticals.

U29 Medicare Beneficiary Satisfaction with Comprehensive Medication Review and the Standardized Format

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BACKGROUND: CMS requires Part D plans provide targeted beneficiaries with an annual comprehensive medication review (CMR), followed by a written summary, using the Medication Therapy Management (MTM) Program Standardized Format (SF). The SF consists of a cover letter, a Medication Action Plan (MAP), and a Personal Medication List (PML).

OBJECTIVE: Per CMS Contract # HHSM-500-2011-00051, Medicare Part D beneficiaries were interviewed to assess their experience and satisfaction with the CMR and the Standardized Format.

METHODS: Two surveys were developed through a process of consultation and testing with experts in geriatric medicine, MTM providers, Medicare beneficiaries and other stakeholders. The focus of survey 1 was to assess aspects related to the process, structure, and outcomes of a CMR, while survey 2 focused on satisfaction of the three areas of the Standardized Format and sought recommendations for changes. Medicare beneficiaries were identified and recruited from a convenience sample of members in two Part D plans, who had received a CMR in the past year. Solicitation letters were sent to a sample of...
Follow-up to a Newly Established Managed Care Course Designed to Increase Early Exposure to Managed Care in Pharmacy School

Barcelon J, Phun J, Pasetes S, Merino O. 470 Warren Dr., San Francisco, Managed Care in Pharmacy School to first- and second-year pharmacy students at UCSF. Subject mat-

RESULTS: Of the 226 beneficiaries eligible for inclusion, the maximum number of 39 (17%) participated (9 for survey 1; 30 for survey 2). For survey 1, 78% of beneficiaries had an in-person CMR. There were 67% who did not think the CMR should be done more than once a year. “Often” or “very often” were chosen by 100% of respondents for questions that the MTM provider “carefully listened,” and “offered chance to ask questions.” The CMR helped 67% of Medicare beneficiaries “better understand the medications” and 78% “help take medi-
cation claims data, end stage renal disease, and respiratory disease.

CONCLUSIONS: The majority of Medicare beneficiaries felt that the CMR was helpful. Approximately one-third of Medicare beneficiaries who received a CMR did not remember the SF. The remaining two-thirds were satisfied with the SF and offered few suggestions for changes.

SPONSORSHIP: CMS Contract # HHSM-500-2011-00015I.

Examining Alternate Standardized Scripts to Improve Comprehensive Medication Review Participation Rate

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BACKGROUND: Starting in 2016 Medicare prescription drug benefit plans (MAPD and PDP) will be rated on a new Star Ratings measure that examines the percentage of medication therapy management (MTM) eligible members that participate in a comprehensive medication review (CMR). In a previous study we demonstrated that enhancing members’ understanding of CMR, with a standardized script, increases CMR acceptance. This study aimed to further improve CMR acceptance rates with modified scripting.

OBJECTIVE: To develop and evaluate the effects of modifying a CMR recruitment script in response to specific patient concerns and reasons for declining an offer for a CMR.

METHODS: Based on the results of a 2012 study of a CMR recruitment script and documented member feedback, a new script was developed to offer responses to common barriers to CMR acceptance. A focus group was conducted in which participants were asked to listen to the new script and discuss their willingness to participate in a CMR. They were also asked to evaluate each element of the script and to discuss additional benefits or barriers that should be addressed. After revisions, a randomized controlled trial was conducted to evaluate the new recruitment script (C) compared to the control script (A) from the original study. The new script was tested in CMR recruitment for MAPD and PDP MTM eligible members in 2013.

RESULTS: Thirty-five percent of members recruited using script C (N = 5,822) compared to 29% of those recruited using script A (N = 6,622) accepted the offer of a CMR (OR 1.07, 95% CI 0.996-

1.147). In the script C group, after hearing scripted responses to a pre-

presented barrier, 18% of members that had initially declined ultimately accepted the CMR offer. Results of a multivariate logistic regression showed that other variables that were predictors of CMR acceptance included female gender, total chronic medication cost based on pre-

scription claims data, end stage renal disease, and respiratory disease.

CONCLUSIONS: Modification to a script used to recruit MTM eligible MAPD and PDP beneficiaries to participate in a CMR was superior to a previously tested script. The new script which provided responses to common barriers presented by beneficiaries to accepting a CMR was effective in converting members that initially declined a CMR to accept. Findings also suggest that further efforts will be required in order to engage member that do not respond to telephonic outreach for recruitment.

SPONSORSHIP: None.
U33 2014 Trends in the Medicare Part D Coverage Gap

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BACKGROUND: Since inception of the Patient Protection and Affordable Care Act, patient cost sharing for Part D medications has reduced year over year to close the coverage gap. Patients were responsible for 100% of prescription costs in the coverage gap in 2010, 47.5% in 2014, and will reach a low of 25% in 2020.

OBJECTIVE: The objective of this analysis was to investigate population characteristics and medication use in a Medicare Advantage Prescription Drug (MAPD) population in 2014.

METHODS: This retrospective analysis evaluated Humana pharmacy claims for individuals with continuous MAPD coverage from January 1, 2014 to December 31, 2014. Population demographic and clinical characteristics were compared for those who did and did not reach the coverage gap. Medication use was reported as the mean number of unique medications per person identified using generic product identifiers. Only maintenance and specialty medications were included. Medication use was reported for the full year for those who didn’t reach the coverage gap and pre/post coverage gap for those who did.

RESULTS: Of the 1.7 million people analyzed, 324,297 (18.8%) entered the coverage gap. Compared to those who did not reach the gap, people who did reach it were younger (28% vs. 14% aged <65 years), with more comorbidities (2.7 vs. 1.5), higher rates of disability (44% vs. 25%), and were more likely to receive low income subsidies (4% vs. 18%), P<0.001 for all comparisons. For all of 2014, people who never reached the gap averaged 4.8 medications per person. People who reached the gap had a mean of 8.3 medications per person prior to entering the gap and 6.2 after reaching the gap (P<0.001). Thirty-one percent of people did not discontinue any medications during the gap (number of pre-gap medications = 6.7). Those who discontinued during the gap had more medications prior to the gap, 9.0. Among people who reached the coverage gap and had a low income subsidy, 62.5% discontinued at least one medication compared to 73.2% who did not have a low income subsidy, P<0.001.

CONCLUSIONS: Less than 20% of people reached the gap, and those who did appear to be eligible for Medicare based on disability status. Although patient cost sharing in the gap has decreased substantially in the past 5 years, medication discontinuation after reaching the gap persists, especially as the number of medications increases. Further research is needed to investigate reasons for medication discontinuation.

SPONSORSHIP: No external support was provided for this study.

U36 Cost-Consequence Analysis for Pharmacogenetic Testing in an Elderly Population

1University of Utah; 2Genelex

BACKGROUND: Genetic testing for drug metabolizing enzyme (DME) coding genes has the potential to optimize medication prescribing dosing and patient outcomes. Elderly patients may realize a greater benefit from genetic testing as they are at higher risk for polypharmacy, adverse drug events and potentially higher health resource utilization (HRU) and its cost.

OBJECTIVE: To determine the impact of pharmacogenetic (PGx) testing via YouScript Personalized Prescribing System on healthcare costs at 4 months follow-up.

METHODS: This cohort study compared patients receiving PGx testing (CYP2D6, CYP2C9, CYP2C19, CYP3A4, CYP3A5 & VKORCI) via YouScript Personalized Prescribing System to historical control patients who did not have PGx testing. The YouScript System includes genetic testing and clinical decision support via evidence-based YouScript software and clinical pharmacist interpretation. Included patients were age ≥65 years, taking ≥3 prescription medications (July 1, 2012-March 31, 2013) and on ≥1 drugs metabolized by a polymorphic DME. The two groups were matched using propensity scores based on age, sex, Charlson comorbidities and baseline medications.

RESULTS: An analysis of 205 tested patients (mean age 75 ± 7 years, 58% female) matched to 820 controls was done. After matching, no significant differences in baseline characteristics between groups were found. Among tested group, there was 39% decrease in number of hospitalized patients (P=0.0273) and 71% reduction in ER visits (P=0.0002). Outpatient visits were 1.97 times as likely in tested group (P<0.0001), possibly due to shifting resources from tertiary to primary care. PGx testing resulted in HRU-related net cost savings of $21/patient compared to untested group, including cost of the test. If outpatient visit costs were excluded, PGx testing resulted in HRU-related net cost savings of $470/patient.

CONCLUSIONS: PGx testing with YouScript Personalized Prescribing System resulted in net cost savings over a 4-month period. This shows the value (benefit vs. cost) of genetic testing of drug variation in elderly population. Additional cost savings may be expected over a longer period of time.

SPONSORSHIP: Genelex, Seattle, WA.

U38 Dispensing Channel Used for Specialty Drugs and Associated Costs in Medicare Part D Population

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BACKGROUND: Specialty drugs require high patient management and can cost from $10,000-$200,000 annually. Cancer (CA), multiple sclerosis (MS) and rheumatoid arthritis (RA) are top specialty therapy classes with high utilization among Medicare Part D beneficiaries. Retail, specialty, mail-order (MO) and long-term care (LTC) are commonly used dispensing channels for specialty drugs. Previous studies have indicated that the specialty dispensing channel is associated with lower costs and better outcomes for these drugs. To our knowledge, no study has examined through which channels specialty drugs are most frequently dispensed and the association of dispensing channel and drug costs in the Part D population.

OBJECTIVE: This study aims to compare use and costs of dispensing channels for CA, MS and RA specialty drugs among Part D beneficiaries.

METHODS: 2010 Medicare Part D Prescription Drug Event (PDE) data were used. Specialty drugs were defined as top 300 drugs (by total care) with a mean cost ≥$600 per prescription for CA, MS or RA. A total of 13 oral or self-injectable specialty drugs were identified: seven...
CA (lenalidomide, imatinib, erlotinib, thalidomide, sorafenib, sunitinib, dasatinib), four MS (glatiramer, interferon beta-1a, interferon beta-1b, interferon beta-1a/albumin), and two RA (etanercept, adalimumab) drugs. Mean drug costs per day’s supply (DS) were computed. RESULTS: Of 59,028 specialty PDEs identified, 42.3% (n = 24,974) were for RA, 32.9% (n = 19,467) were for MS, and 24.7% (n = 14,587) were for CA drugs. About 70.6% (n = 41,684) were dispensed through retail, 17.9% (n = 10,593) through specialty, 4.9% (n = 2,924) through LTC and 3.8% (n = 2,226) through MO. Overall, mean costs per DS were higher for prescriptions dispensed through LTC ($135.8, ± 4.9) and specialty ($128.4, ± 0.9) channels, compared to retail ($111.4, ± 0.6) or MO ($90.7, ± 1.1). However, the mix of drugs dispensed varied by channel. Mean costs per DS were higher for RA and MS drugs dispensed through LTC ($82.9, ± 3.7 and $150.7, ± 7.3), compared to retail ($69.1, ± 0.5 and $108.9, ± 1.4), specialty ($64.4, ± 0.3 and $99.8, ± 0.5) or MO ($64.3, ± 0.5 and $98.7, ± 0.4) at both the therapy class and drug levels. Mean costs per DS were higher for CA drugs dispensed through specialty ($225.5, ± 1.7), compared to retail ($193.3, ± 1.2), MO ($172.0, ± 4.4), or LTC ($161.1, ± 5.4). The most and least expensive channels varied at the CA drug level. CONCLUSIONS: Retail is the most commonly used dispensing channel for top specialty drugs among the Part D population. The least expensive channels varied across therapy classes and drugs. SPONSORSHIP: None.

U39 A Retrospective Evaluation of the Implementation of the 2013 ACC/AHA Blood Cholesterol Guidelines Using Administrative Pharmacy Claims in Patients with Diabetes Mellitus with or without Hypertension

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BACKGROUND: In November 2013, the American College of Cardiology (ACC) and the American Heart Association (AHA) in collaboration with the National Institutes of Health National Heart, Lung and Blood Institute published new cholesterol guidelines with the goal to decrease cardiovascular (CV) risk through the use of moderate-to-high intensity statin regimens, opposed to targeting specific low-density lipoprotein cholesterol (LDL-C) levels as previously utilized. Patients with atherosclerotic cardiovascular disease (ASCVD), a high 10-year estimated CV risk, diabetes mellitus (DM) and/or high LDL-C are shown to benefit from high-to-moderate intensity statin therapy according to the 2013 guidelines. OBJECTIVE: To analyze the impact of implementation of the 2013 ACC/AHA guideline for the treatment of blood cholesterol in patients with DM with or without hypertension (HTN). METHODS: Administrative pharmacy claims were retrospectively collected from April-September 2013 (pre-guideline implementation) and July-December 2014 (post-guideline implementation) allowing an adjustment period for providers to implement the guidelines. Patients between the ages of 40-75 years with DM only and patients 21-75 years with DM and HTN who filled a low-intensity statin were identified based on ICD-9 diagnosis codes and/or if the patient had a fill of a medication to treat DM or HTN. According to the 2013 ACC/AHA guidelines these patients should be treated with a moderate-to-high intensity statin in order to decrease CV risk. These patients were then evaluated 2 quarters (Q3-Q4 2014) after the release of 2013 ACC/AHA guidelines to analyze observational changes in utilization related to statin intensity. RESULTS: A total of 10,207 patients filled a statin prescription in Q2-Q3 2013. Of those patients, 84 were between the ages of 21 and 75 who filled a low-intensity statin and had a diagnosis of DM with or without HTN. In Q3-Q4 of 2014, 63 of the 84 that filled a statin medication. Of the 63, 55 (87.3%) remained on a low-intensity statin and 8 (12.7%) patients were switched to a moderate-to-high intensity statin. CONCLUSIONS: Although a relatively small target population was analyzed, results of the study may suggest a slow integration of the 2013 ACC/AHA guidelines; potentially exposing some patients to increased CV risk through sub-therapeutic levels of statin medications. Slow incorporation of treatment guidelines into quality control programs that are often associated with financial incentives for providers, may explain observational treatment patterns among the population analyzed.

SPONSORSHIP: No external funding was provided for this research.

U48 Misdiagnosis and Underdiagnosis of Alzheimer’s Disease: A Systematic Review

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BACKGROUND: Alzheimer’s disease (AD) is an increasingly prevalent and costly disease. Early screening and diagnosis can lead to better life planning and care. However, difficulty in diagnosis still exists and contributes to patients being misdiagnosed or underdiagnosed, resulting in a diagnosis late in the disease course. OBJECTIVE: The objective of this study is to conduct a systematic review of the literature to explore the potential causes and barriers that lead an underdiagnosis and/or a misdiagnosis of AD. METHODS: PubMed, PsycINFO, EMBASE, and Cochrane databases were searched to identify studies published from January 2005 to February 2015. Two reviewers screened the title, abstract, and full text against the inclusion criteria of articles with findings on misdiagnosis and/or underdiagnosis of AD. Publications were excluded if they did not meet those criteria.RESULTS: A total of 132 articles were obtained from the literature. After screening, 105 original articles were included in this study. Twenty-four studies did not focus on the misdiagnosis or underdiagnosis of AD and were excluded. Three articles were duplicates and were also excluded. The lack of a clear understanding of the exact cause of AD and specific tools for diagnosis, in combination with other confounders, contribute to the misdiagnosis and underdiagnosis of AD. Even though the 2011 guidelines of the National Institute on Aging and Alzheimer’s Association identified three stages of AD, they do not establish diagnostic criteria that clinicians can use. Clinical guidelines only have 50%-60% specificity when diagnosing AD as compared to other dementias. Clinicians can also be hesitant to diagnose a patient with AD because the symptoms of the disease may be associated with normal aging or the patient and/or family members may not recognize indicators. Furthermore, newer diagnostic tools are still inconclusive. A delay or absence in the diagnosis of AD deprives a person affected by AD of available treatments to slow its progression and help manage symptoms. This can negatively impact the quality of life of the patient and contribute to financial and personal risks, including poorly treated comorbidities. CONCLUSIONS: Early diagnosis or detection of AD may help to decrease the social and economic burden of both patients and their caregivers. It allows caregivers to avoid risks associated with cognitive impairment and to utilize community resources in understanding AD.
U53 A Retrospective Analysis of an Underserved Population of Hepatitis C Patients Using a Health System-Based Specialty Pharmacy Services Case Management System

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BACKGROUND: Hepatitis C virus (HCV) prevalence is approximately 2.7 million in the United States. Ledipasvir/sofosbuvir (L/S), approved in October 2014, is the first fixed-dose combination tablet demonstrating superior cure rates with lower rates of side effects compared to other regimens. Specialty Pharmacy Services (SPS) is a health system-based specialty pharmacy at the University of Illinois Hospital and Health Sciences System. SPS provides services that include prior authorizations (PA), patient education and training, financial assistance programs, and monthly refill management. Advantages of SPS include direct communication with providers in the specialty clinics and access to patient electronic medical records.

OBJECTIVE: To analyze medication utilization and outcome parameters of patients receiving L/S using the SPS Case Management System.

METHODS: A retrospective study of 206 patients enrolled in SPS who received at least one prescription for L/S between October 2014 and June 2015 was performed. Metrics were collected using the SPS case management system, including patient demographics, payer, time to PA approval, medication tolerability, correct medication administration, and patient satisfaction with medication. Monthly refill surveys and health literacy assessments were initiated in April 2015. A total of 216 surveys were completed and 39 patients were evaluated for low health literacy.

RESULTS: The average age of a L/S patient was 61 years. The average time from a prescriber request to PA approval was 12.13 days, and average time from PA submission to approval was 2.96 days. The payer mix was 45.6% Medicaid, 33.5% Medicare Part D, and 20.9% commercial. Sixty-two percent of patients were found to be at risk for low health literacy. Eighty-five percent of patients reported no problems tolerating their medication; 6.6% reported tolerable medication-related side effects, and 4.7% reported side effects unrelated to their medication. One hundred percent of patients reported correct medication administration. Ninety percent of patients reported excellent or good satisfaction with their medication. Six percent of patients reported missing one or more doses of medication during the previous month.

CONCLUSIONS: Health system-based SPS with a case management system represents an innovative patient care model. Initial metrics are promising, indicating the health system-based SPS model may help to overcome barriers to access in an underserved population.

SPONSORSHIP: None

U54 Medication Therapy Management Comprehensive Medication Reviews for Residents in Long-term Care Facilities: 2014 Results

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PROBLEM DESCRIPTION: In April 2012, the Centers for Medicare and Medicaid Services (CMS) announced that, beginning in 2013, Medicare Part D sponsors must offer a comprehensive medication review (CMR) to all beneficiaries enrolled in the MTM program at least annually, including those in long-term care settings (LTC, e.g., skilled nursing facilities, assisted living communities). Since that time, MTM providers have found that accessing and successfully completing a CMR with these individuals is often prohibitively complex, as it frequently requires a live, face-to-face interactive interview where the beneficiary resides.

GOAL: To achieve a high CMR completion rate for residents in LTC using the 2014 CMS Standardized Format.

PROGRAM DESCRIPTION: Omnicare’s proprietary consultant pharmacist software was programmed to produce a cover letter, medication action plan, and personal medication list per CMS specifications. Omnicare consultant pharmacists (CP) were trained to perform CMRs and the interactive interviews using this system. MTM-eligible Medicare Part D beneficiaries identified by several contracted clients as residing in LTC serviced by Omnicare were provided a CMR and written summary in CMS Standardized Format by CP. Residents with cognitive impairment were identified using 3 data elements in the Minimum Data Set, including the Brief Interview for Mental Status Summary Score.

OBSERVATIONS: For calendar year 2014, 5,492 MTM-eligible beneficiaries were identified as receiving medications from an Omnicare pharmacy. After excluding those who were disenrolled by their PDP, discharged from the LTC, or residing in LTC no longer serviced by Omnicare, 3,933 residents were available for CMR completion. Of these, only 83 (2.1%) refused the CMR offer, and 3,829 (97%) were completed successfully. There were 1,492 (39%) residents with cognitive impairment per MDS assessments; CMRs were conducted with someone other than the beneficiary in those instances. Based on the CMR and interactive interviews, 4,252 drug therapy problem (DTP) recommendations were made to prescribers, which led to 3,050 drug therapy problem resolutions (72%), including reductions in polypharmacy, high-risk medications, and antipsychotic utilization and dosage.

CP viewed the CMR process as a rewarding, yet sometimes challenging, experience.

FINDINGS/RECOMMENDATIONS: The CMR process and written summary in CMS Standardized Format works effectively for residents in LTC. Based on the high completion and DTP resolution rates, Part D plans should consider further utilizing CP to conduct CMR in LTC.

SPONSORSHIP: None

U56 Self-Medication Practice Among Customers of Community Pharmacies in Riyadh

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BACKGROUND: Owing to the associated benefits and risks, self-medication has become a topic of great interest to public health leaders, pharmaceutical industry investors and policy makers. Despite the ease of access to over-the-counter and prescription-only medications in Saudi Arabia, little is known about self-medication practice among customers of community/retail pharmacies in this country.

OBJECTIVE: To assess the prevalence of self-medication among community pharmacies’ customers in Saudi Arabia, and to identify its associations with the sociodemographics of the population under study.

METHODS: This is a cross-sectional, observational study. Operating through an interview-based approach, data were collected using structured questionnaires distributed at 8 strategically located pharmacies serving over 70 quarters of Riyadh, the capital of Saudi Arabia.
RESULTS: Two hundred ninety-one (62.0%) customers reported practicing self-medication in the past year (n = 469). Non-prescription-based medication acquisition, treatment discontinuation, and leftover medication use were the most common modes of practice (90.4%, 56.4%, and 45.0%, respectively). “Common colds,” aches and nasal congestion were the most commonly self-treated symptoms. Notably, antibiotics were used by 127 (43.8%) of self-medicators. Self-medicators commonly relied on pharmacists’ recommendations for medication selection (61.3%). Illness mildness, easy accessibility, lack of health insurance, and distant appointments were frequent self-reported justifications for indulging in this practice. Health-related occupation (P = 0.029), being married (P = 0.046), positive smoking history (P = 0.008), and higher medication knowledge (P = 0.018) were found to be significantly associated with self-medication practice. No statistically significant difference was found based on age, gender, nationality, level of education, monthly income, or health insurance status.

CONCLUSIONS: Self-medication is common among customers of community pharmacies in Riyadh, Saudi Arabia. Over-the-counter medications were frequently reported, although prescription-only medications were also consumed. Occupation, knowledge, smoking and marital status are important associates of this practice. Incorporation of such findings is needed when developing legislations intended to maximize potential benefits and minimize associated risks of self-medication practice.

SPONSORSHIP: None.

U58 Improving the Safety Protocols for SinfoniaRx’s Cost-Savings Algorithms
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BACKGROUND: SinfoniaRx is one of the largest providers of medication therapy management (MTM) services to Medicare beneficiaries and other qualifying patients nationwide. SinfoniaRx analyzes pharmacy claims using clinical algorithms to identify potential drug-related problems. One such problem is the opportunity for cost savings. The cost-savings algorithms’ exception criteria is a list of medications known to have potential drug-drug interactions (DDIs) with the recommended generic drug. If the patient’s current drug regimen contains one of the listed medications, no cost savings intervention is made.

OBJECTIVE: This project is specifically focused on updating the DDI exception criteria for cost-savings algorithms under three different medication categories: proton pump inhibitors, non-selective beta blockers, and non-dihydropyridine calcium channel blockers.

METHODS: Analysis was performed on SinfoniaRx’s current DDI exception criteria to identify errors of commission and omission. The accuracy and relevancy of the exception criteria were evaluated using the following drug information databases: Facts & Comparisons, Gold Standard, Lexicomp (UpToDate), and Micromedex.

RESULTS: Total number of drugs analyzed for proton pump inhibitors, non-selective beta blockers, and non-dihydropyridine calcium channel blockers were 110, 98, and 115, respectively. Of the classes, the number of omissions found were 1, 12, and 29, respectively. Errors of commission were only found in proton pump inhibitors. The percent error of omission was highest in the non-dihydropyridine calcium channel blockers. The percent error of omission was lowest in the proton pump inhibitors.

CONCLUSIONS: It is important that the DDI exception algorithms are assessed and updated often to ensure patient safety.

SPONSORSHIP: SinfoniaRx and University of Arizona College of Pharmacy.

Z00-Z99 Factors Influencing Health Status and Contact with Health Services (e.g., Adherence, Oral Contraceptives)

ZO1 Relationship Between Patient Copayments in Medicare Part D and Vaccination Claim Status for Herpes Zoster and Tdap
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BACKGROUND: Prohibitive costs may deter older adults from receiving recommended vaccines.

OBJECTIVE: To assess the relationship between copay amount and vaccination claim status for herpes zoster and tetanus-diptheria-acellular pertussis (Tdap) among United States Medicare Part D patients.

METHODS: We conducted retrospective analyses of 2012-2014 data from TruvenHealthRx, a physician billing system for Medicare Part D vaccines. Patients 65 years or older with at least one claim for herpes zoster or Tdap vaccine were included. Logistic regression was used to assess the impact of copay amount on vaccination claim status separately for zoster and Tdap, controlling for patient and provider characteristics. We performed the analysis in patients who were in the coverage phase of their insurance (i.e., their total financial responsibility was equal to their copay amount), in order to estimate the association between copay amount and vaccine claim status without confounding by other financial responsibility.

RESULTS: 346,404 and 81,026 patients (196,762 [56.8%] and 31,786 [39.2%] with a cancelled claim) were included in the zoster and Tdap analyses, respectively. Mean (standard deviation) copay for cancelled vs. paid claims for zoster and Tdap was $64.9 (36.9) vs. $53.5 (38.8) and $37.2 (18.4) vs. $31.1 (20.1), respectively. 49% and 39% of zoster and Tdap patients with copay ≤ $50, respectively, had cancelled vaccination claims, while 63% and 48% of patients with copay > $50 had cancelled claims. Using copay amount as a categorical variable, adjusted for patient and provider characteristics, the odds ratios (OR) for a cancelled zoster vaccine claim compared to $0 copay were 1.02 ($1-25), 1.39 ($26-50), 1.66 ($51-75), 2.07 ($76-100) and 2.71 (≥ $100), all P values < 0.001 except that for $1-25 (P = 0.172). The adjusted ORs for a cancelled Tdap vaccine claim were 1.19 ($1-25), 1.76 ($26-50), 2.42 ($51-75), and 2.40 ($76-$100), all P values < 0.001.

CONCLUSIONS: Higher copay for zoster and Tdap vaccines significantly increases the odds of having a cancelled vaccination claim in Medicare Part D patients. Effective measures need to be taken to remove financial barriers and improve vaccination rates in older adults.

SPONSORSHIP: GlaxoSmithKline

Z02 A Qualitative Analysis of E-cigarette Use Among College Students in Hawaii
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BACKGROUND: E-cigarette use is rapidly increasing, with 2013 sales topping $1 billion in the United States, but it is still a largely unregulated industry. While e-cigarettes are thought by most to be a healthier alternative to traditional cigarettes, long-term health effects are unknown.
**OBJECTIVE:** To assess behaviors, attitudes, and experiences regarding electronic cigarette use among university students in Hawaii.

**METHODS:** Students attending University of Hawaii at Mānoa or Hilo between ages of 18 and 25 who had ever used e-cigarettes were recruited for the study (n = 23). Upon consent, we conducted semi-structured in-depth, face-to-face interviews focused on patterns of use, reasons for use, perceived risks and benefits, and preference over different flavors available. All interviews were recorded and transcribed. Qualitative analyses were conducted using NVIVO software. Data processing involved codebook development, code applications, and data reduction, using an iterative process. Two coders independently coded all of the text and intercoder agreement checks were conducted. Approved by University of Hawaii Committee on Human Subjects.

**RESULTS:** Of the 27 participants, approximately half were female, three quarters were Caucasian, and three quarters had previously smoked cigarettes. When asked where they use them, the most common response was “everywhere.” Preliminary analyses found three themes related to main reasons for use: (a) quitting or reducing use of regular cigarettes or marijuana; (b) recreational/social; (c) stress reduction. Men were more likely to use modified e-cigarettes “mods.” Perceived benefits fell into four categories: (a) able to quit or reduce smoking cigarettes; (b) lacks bad smell/taste of regular cigarettes; (c) health improvements (no cough, able to compete better in sports, or “walk uphill”); (d) more socially acceptable. Perceived risks include: (a) bad for lungs; (b) nicotine dependency; (c) risk to children; (d) not well tested. Most preferred fruity flavors (blue raspberry, honeydew, watermelon, guava, mango, peach lycce, pineapple, green apple) or ones that taste like candy (Parker Rancher [tastes like Jolly Rancher]); Unicorn Blood [tastes like skittles]; Bubblegum).

**CONCLUSIONS:** Findings contribute to our understanding of the behavior, attitudes and experiences of e-cigarette users. It is of relevance to manged care pharmacists and other pharmacists who may be discussing smoking cessation options with patients. Most users said e-cigarettes helped them to reduce or quit using regular cigarettes, but almost all would like more information about health risks of e-cigarettes.

**SPONSORSHIP:** Hawaii Community Foundation, Leahi Fund grant #64494.

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**Z04 Improving Medication Adherence and Healthcare Outcomes Through a Retail Pharmacy Chain**

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**BACKGROUND:** Non-adherence to medication therapy is associated with poorer health outcomes and increased healthcare costs. Retail pharmacy chains can provide the population access to a variety of interventions that improve medication adherence, lower healthcare utilization, and reduce overall healthcare costs.

**OBJECTIVE:** This study evaluated the impact of an omni-channel set of medication management interventions offered by a retail pharmacy chain on medication adherence, healthcare utilization, and healthcare costs.

**METHODS:** Patients initiating therapy within 16 drug classes from February 7, 2013 to October 6, 2013 were offered varied combinations of face-to-face or telephonic new-to-therapy consultations, email or telephonic refill reminders, telephonic medication pick-up reminders, and face-to-face or telephonic late-to-refill consultations by Walgreens pharmacy. Patients were linked deterministically to the IMS Health PharMetrics Plus database such that 6 months of pharmacy and medical claims data pre and post their index date could be analyzed. Outcomes were compared at the intent-to-treat level between Walgreens patients (Intervention) and patients using all other pharmacies included in the database (Control). The control group was propensity-score matched to the intervention group using baseline demographics, clinical factors, utilization, and costs. Intervention and control groups were evaluated using difference in differences estimation and a GEE regression model to control extraneous confounders.

**RESULTS:** The intervention group (n = 72,410) and control group (n = 72,410) had similar age (47.1 vs. 45.7 years), gender (58.8% vs. 59.8% female), and disease burden (0.02 vs. 0.04 for Charlson Comorbidity Index, CCI). In the 6-month post-index period, the intervention group had 3.0% greater medication adherence, 1.8% lower hospital admission rate, 2.7% lower ER visit rate, and 0.53 lower mean outpatient visits compared with the control group (all P < 0.0001). The intervention group incurred significantly lower GEE-adjusted pharmacy costs (~$92, P < 0.0001), outpatient costs (~$120, P < 0.0001), ER costs (~$38, P < 0.0001), and higher inpatient costs ($86, P < 0.004). Summing the cost components yields a significant total healthcare cost savings of $164 (3.0%) per patient.

**CONCLUSIONS:** A retail pharmacy chain offering a variety of medication management interventions was associated with patients having significantly greater medication adherence and lower healthcare utilization and costs. This study demonstrates how a retail pharmacy chain can help payers improve population health and help manage overall healthcare costs.

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