Meeting Abstracts

Academy of Managed Care Pharmacy
2014 Nexus
Boston, Massachusetts
October 7-10, 2014
Abstract Submission Process

Abstracts provide a forum during which authors can share their insights and outcomes to advance 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 the findings of the primary authors. The main poster presentation is Thursday, October 9, 2014; posters are also displayed on Wednesday, October 8, 2014. Some posters were also selected for podium presentations.

The AMCP 2014 Nexus in Boston, Massachusetts, is expected to attract more than 4,000 managed care pharmacists and other health care professionals who manage and evaluate drug therapies, develop and manage networks, and work with medical managers and information specialists to improve the care of all individuals enrolled in managed care programs.

Abstracts were submitted in the following categories:

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

Economic Model: 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.

Encore Research Reports: A presentation that has been presented and published with another organization.

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 are submitted by nonstudents.

Nonreviewed Encore Research Reports: Authors will display their posters using the format required for the meeting. The title and authorship of the abstracts will be included in the meeting program. These will not be eligible for podium presentation. The abstracts will not be published in JMCP due to the copyright ownership of the original presenting organization.

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

Thirteen reviewers and 4 JMCP editors were involved in the review process for the 2014 Boston meeting. Each abstract (with author name and affiliation blinded) was reviewed by 3 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 to managed care
- Originality
- Quality of the work
- Bias
- Clarity

Each of the 3 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 editor, who made an accept/reject decision. These decisions were further reviewed by the JMCP Editor-in-Chief to ensure consistency of decision making.

The mean rating score was used to award Gold, Silver, and Bronze ratings for the best abstracts submitted. Platinum awards were based on mean rating score and JMCP editor review. The reviewers and editors of the abstracts for the 2014 Boston meeting were as follows:

Reviewers
Chris Bell, MS, GlaxoSmithKline
Doug Burgoyne, PharmD, RPh, VRx Pharmacy Services
Mike Durkin, PhD, Janssen Scientific Affairs, LLC
Abimbola Farinde, PhD, Bayshore Medical Center
Sarah Kachur, PharmD, Johns Hopkins HealthCare
Donald Klepsar, MBA, PhD, University of Nebraska Medical Center College of Pharmacy
Alexandra Lin, PharmD, BlueCross BlueShield of Michigan
Earle (Buddy) Linge, RPh, PhD, High Point University, School of Pharmacy
Bradley Martin, PharmD, PhD, University of Arkansas for Medical Science
Uche Anadu Ndelo, PharmD, BCPS, Texas Southern University, Department of Pharmacy Practice
Gene Reeder, RPh, PhD, Xcenda
Cynthia Sanboris, PharmD, Jefferson School of Pharmacy
Iris Tam, PharmD, Genentec

JMCP Editors
John Mackowiak, PharmD, Academy of Managed Care Pharmacy; Center for Outcomes Research
Laura E. Happe, PharmD, MPH, Humana, Inc.
Eleanor M. Perfetto, MS, PhD, University of Maryland School of Pharmacy
Karen L. Rascati, PhD, The University of Texas College of Pharmacy
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**AMCP 2014 Nexus**

_Boston, Massachusetts_

_October 7-10, 2014_

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**Medal Winning Abstracts**

Each abstract was assessed by 3 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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[JMCP] Journal of Managed Care Pharmacy
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John Grossomanides, PharmD; [U26] Evaluation of Compounded Prescription Medications in a Commercial Health Plan

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Roxanne Meyer, PhD; [M8] Novel Adherence Measures for Infusable Therapeutic Agents in Rheumatoid Arthritis

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Rahul Sasane, PhD; [G5] Adherence and Persistence to Fingolimod Versus Dimethyl Fumarate at Recommended Maintenance Doses in a Real-World Setting

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Ivy Tonnu-Mihara, PharmD, MS; [I9] An Evaluation of the Chronic Use of Clopidogrel in the Veteran Population

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**Mike Durkin, PhD:** [U28] Economic Outcomes of Chronic Pain Patients Treated with Tapentadol ER or Oxycodone CR

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**Folayemi Fashola, PharmD:** [U2] Impact of Medication Therapy Management (MTM) on Quality Outcomes in a Dual-Eligible Population

**Monica Fay, PharmD, MBA:** [G8EM] Cost-Effectiveness Analysis of Peginterferon Beta-1a Compared with Other Disease Modifying Therapies in the Treatment of Relapsing-Remitting Multiple Sclerosis in the United States

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**James M. Gill, MD, MPH:** [E13] The DECIDE Study: Using Electronic Clinical Decision Support in Patient-Centered Medical Homes to Improve Management of Diabetes Mellitus for Primary Care Practices

**Diana Graalum, PharmD:** [P5] Medication Therapy Management Program Return on Investment: A Retrospective Analysis of Medical and Pharmacy Claims

**Keith Heitz, MTS, CSSGB, CPhT:** [U10] A Pharmacy Discharge Program Reduces Readmissions, Improves Patients' Understanding of Their Role in Managing Their Health, and Increases Pharmacy Profits

**Danial Husain, PharmD Candidate:** [G17] Health Services Utilization of Intravenous Immunoglobulin (IVIG): Predictive Variables for Non-Adherence and Adverse Events in IVIG Patients

**Yardlee Kauffman, PharmD, MPH:** [I8] Association of Non-Traditional Risk Factors in Patients with Recurrent Major Adverse Coronary Events (MACE)

**Jasmine Knight, PharmD, MS:** [D2] Managed Care Perspectives on Accountable Care Organization Implementation: Focus on Oncology

**Melinda Kozminsksi, PharmD:** [U40] Controlling High Risk Medication Use in a Dual Eligible Medicare Part D Plan: A Three-Tiered Approach to Impacting the HRM Part D STAR Measure

**Matt Lau, BS:** [E11EM] Understanding Clinical Pharmacists’ Roles in Seeing Patients with Controlled Diabetes: A Retrospective Decision-Tree Model Approach

**Philip Levin, MD:** [E14] Treatment Patterns and Outcomes in Managed Care Patients with Type 2 Diabetes Initiating Injectable Therapies: A Pooled Analysis from the INITIATOR Study

**Gregory Olsen, PharmD Candidate:** [F9] The Impact of Implementing a Prior Authorization Program to Restrict the Use of Buprenorphine Products for Opioid Dependence

**Vaishali Patel, PharmD, MS:** [H1] A Retrospective Cohort Study to Identify Medicare Members at Risk of Low Adherence to Glaucoma Medication

**Anna Purdum, PharmD, MS:** [C8] Trends in U.S. Treatment Patterns and Total Health Care Expenditures of Newly Diagnosed Advanced Melanoma Patients from a Medicare and Commercially Insured Database, 2011-2013

**Patricia Schepman, PhD, MSc, PharmD:** [F8] Prescription of Extended Release and Long Acting (ERLA) Opioid Analgesics for Acute Pain

**Sonali Shah, RPh, MBA, MPH:** [E18] Comparison of Medical and Pharmacy Costs Between Adherence and Non-Adherence to Pain Management Guidelines for Patients with Painful Diabetic Peripheral Neuropathy

**Matthew Sussman, MA:** [I11] All-Cause Healthcare Resource Utilization and Associated Medical Costs Among Newly Diagnosed Non-Valvular Atrial Fibrillation Patients Treated with Dabigatran or Warfarin Within Integrated Healthcare Delivery Networks

**Donna Sweet, MD, AAHIVS, MACP:** [B11] Real-World Medication Persistence with Single Versus Multiple Tablet Regimens for HIV-1 Treatment

**Anson Tang, BScPharm, BA, MBA:** [C3] Politics and Policy-Making in Canada’s Drug Review Process: The Role of Avastin Funding in Ontario in Shaping the Pan-Canadian Oncology Drug Review

**Thomas Tencer, PhD:** [L7EM] Economic Evaluation of Sequencing Strategies in the Treatment of Moderate-to-Severe Psoriasis in the U.S.

**Carlo Tornatore:** [G9] Consensus Opinion of U.S. Neurologists on Practice Patterns in Radiologically and Clinically Isolated Syndrome and Relapsing-Remitting MS

**Kathleen Villa, MS:** [F14] Prospective, Open-Label, Contextual, Validation Study Investigating Potential Errors by Patients with Schizophrenia Using the Instructions for Use (IFU) for the Versacloz (Clozapine) Oral Suspension Kit (the Kit)

**Kathleen Villa, MS:** [F13] Predictors and Costs of Treatment-Resistant Schizophrenia: An Assessment of State Medicaid Programs

**Bethany Withycombe:** [Z1] Timeliness of Clinical Trial Data Reporting for Newly Approved Medications

**Erin Zagadailov, PharmD, MS:** [U13] The Current State of Patient-Reported Outcomes in Managed Care: Payer Perceptions of PROs and Other Measures of Benefit
These sessions highlight the best of managed care research—the 15 top-rated abstracts submitted for presentation at the Annual Meeting (3 describing Hepatitis C programs). The abstracts winning the Platinum medal are as follows:

Research and Evidence: Specialty Pharmacy [see program for session information]
- Cost Per Effectively Treated Patient of Biologics for Rheumatoid Arthritis in the Pharmacy Benefit Management Setting
- Site-of-Care Optimization for Infusion Therapy
- U.S. Managed Care Pharmacy Coverage Trends for New Hepatitis C Treatments
- Incidence Rate of Hepatitis C Screening and New Diagnosis in a Commercially Insured Population
- Overview of a Hepatitis C Medication Monitoring Program in a State Medicaid Program

Research and Evidence: Clinical Management [see program for session information]
- Opioid Over-Utilization Point of Sale Edit in a Commercial Population: A PB M Evaluation
- Examining the Use of ICD-9-CM Diagnosis Codes for Opioid Abuse and Opioid Dependence in Commercial Claims Data
- Two-Year Evaluation of a PBM Asthma Program in a Medicaid Population
- Treatment Patterns and Modifications Among Heart Failure Patients: A Retrospective U.S. Claims Database Analysis
- Compliance with Requirements for Medication Therapy Management (MTM) Program Information on Medicare Part D Plan Websites

Research and Evidence: Adherence and Benefit Management [see program for session information]
- Impact of Out-of-Pocket Costs on Initial and Subsequent Prescription Fills Among New Initiators of Biologic Therapies Indicated for Rheumatoid Arthritis
- Patient-Reported Reasons for Not Initiating Pharmacological Therapy Among Osteoporotic Patients from a Large Managed Care Health Plan
- Electronically Transmitted Prescriptions Involved in Primary Prescription Abandonment
- Economic and Event Outcomes of Members with Carve-In Versus Carve-Out Pharmacy Benefits: A 2-Year Cohort Study
- Association Between Mental Health Status and Medication Access, ER Visits, and Hospitalizations in a Nationally Representative Survey Database

Authors of posters are responsible for the accuracy and completeness of the data presented in the posters and in the abstracts published here. For more information about an abstract, please contact the corresponding author whose addresses are listed.

Cost Per Effectively Treated Patient of Biologics for Rheumatoid Arthritis in the Pharmacy Benefit Management Setting

Wu N1, Bhrurke S1, Shah N2, Harrison D1. Amgen Inc., One Amgen Center Dr., Thousand Oaks, CA 91320; peoples@amgen.com; 805.447.3564
1Evidera, 2Amgen Inc.

BACKGROUND: Several biologics are approved for first-line treatment of moderate to severe rheumatoid arthritis (RA). Their cost is frequently of interest to pharmacy benefit managers (PBMs). A claims-based algorithm was used to estimate the effectiveness of biologics for RA and may allow PBMs to compare effectiveness and costs of these biologics.

OBJECTIVE: To examine the cost per effectively treated patient (CpETP) using health insurance claims in U.S. managed care patients using the Medco PBM database.

METHODS: In the Medco database, adult (18-63 years) patients with a claim from July 2007 to July 2012 for a biologic approved for RA (etanercept [ETN], adalimumab [ADA], abatacept [ABA], infliximab [IFX]; others with patients < 100 excluded from analysis) were identified. The first claim for a biologic defined the index date and biologic cohort. Patients were required to have continuous enrollment for 180 days before and 365 days after their index date, have ≥1 claim for RA (ICD-9 714.0x) in the 180-days pre-index, and have no claims for any biologic in the 180-days pre-index. Patients with claims for other conditions that the core set of biologics are indicated for were excluded. Effectiveness of treatment during the 365-days post-index period was assessed using a validated claims-based algorithm (Arthritis Res Ther 2011; 13: R139). The algorithm categorized patients as effectively treated if they had none of the following: < 80% adherence to their index biologic, increased biologic dose, biologic switch, claim for an additional disease-modifying antirheumatic drug, an additional/increased dose of existing oral glucocorticosteroid, and > 1 joint injection. Costs of biologics were calculated as the total dose of biologic dispensed multiplied by the wholesale acquisition cost for each biologic. CpETP was calculated by dividing the total cost by the number of patients determined effectively treated by the algorithm. Algorithm-based CpETP was calculated by route of administration (subcutaneous [SC], intravenous [IV]) and biologic agent.

RESULTS: There were 1090 eligible patients (mean age 50 ± 9 years; 78% female; SC: ETN 40%, ADA 32%; IV: IFX 18%, ABA 10%). The percentage of patients categorized as effectively treated was 36.4% for ETN, 35.4% for ADA, 24.8% for ABA, and 21.9% for IFX. More SC than IV patients (36% vs. 23%; P < 0.001) were categorized as effectively treated by the algorithm. CpETP was $62,303 for ABA, $62,841 for ETN, $67,266 for ADA, and $90,696 for IFX.

CONCLUSION: In the Medco PBM database, CpETP according to the claims-based algorithm was higher for IV than in SC biologics and lowest for ABA and ETN.

SPONSORSHIP: This study was sponsored by Amgen Inc.

Site-of-Care Optimization for Infusion Therapy

Clark BL1, Einodshofer M1, DuChane J1, Stone S1, Zhu J1, Fitzner K1, Duncan P1. Walgreen Co., 1415 Lake Cook Rd., Deerfield, IL 60015; bobby.clark@walgreens.com; 847.964.6315
1Health Outcomes & Clinical Research, Walgreen Co., 2OendaRx, 3FH Consultants

BACKGROUND: Demand is rising for specialty drugs administered by infusion because many drugs cannot be administered orally and infusion has been proven to be a highly effective mechanism of administration for a variety of conditions and diseases ranging from Crohn’s Disease to cancer to rheumatology. The administration can be moved from high cost sites of care (such as outpatient hospital) to alternate
sites (such as home). The market for alternate-site infusion therapy is estimated to be $9-11 billion dollars a year. Strategies, such as administration of these drugs in alternative sites of care instead of hospital outpatient departments are being considered in an attempt to rein in the costs while ensuring patient safety and quality of care.

OBJECTIVE: The objective of this study was to determine the potential cost savings as a result of the transfer of the site of administration for infusion therapy between hospital outpatient departments, the physician offices, and home infusion services.

METHODS: This was a retrospective cost analysis of a commercial health plans 2011 pharmacy and medical claims data for infusion drug therapy. We used standardization to assess the potential cost savings of transferring infusion therapy from one site-of-care to another. Cost was defined as the amount paid for a pharmacy or medical claim for an infused drug. Administrative or other professional fees associated with the administration of the drug were not included.

RESULTS: Our analysis of data from a pharmacy benefit manager showed that the projected drug-related savings per utilizing member per year (PUMPY) were highest for the transfer of care from the outpatient hospital setting to the home-infusion Ste. ($1,963) with a savings percentage of 39.5%, followed by the transfer from the outpatient setting to the physician office ($1,765 reduction; 39.5% savings), and the lowest savings occurred when care was transferred from the physician's office to home-infusion Ste ($153 reduction; 2.1% savings). Transferring chemotherapy infusion services from outpatient facilities to physician offices resulted in a 57.2% reduction in medication-related cost and a PUMPY saving of $4,329.64.

CONCLUSION: Administration of infusion medications in alternative sites of care instead of hospital outpatient settings appears to be a viable strategy to rein in costs while ensuring patient safety and quality of care.

SPONSORSHIP: Walgreen Co.

U.S. Managed Care Pharmacy Coverage Trends for New Hepatitis C Treatments

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BACKGROUND: During 2011-2014, highly effective new HCV treatments were approved by the FDA. However, due to large prevalence of HCV, the budget impact of these treatments on U.S. managed care can be significant.

OBJECTIVE: The objectives of this study were to review and analyze the access trends for new HCV treatments in U.S. health plans.

METHODS: The coverage trends in five states (i.e., FL, IL, NY, TX and CA), covering ~116 million lives, were obtained from CMS. For each plan the data was obtained for the drug name, tier status, deductibles, and type of restrictions. The coverage trends were analyzed by drug name, state level and at a national level.

RESULTS: In the selected five states, 426 coverage policies were identified for the four approved HCV treatments. Among them, 69% of the coverage policies are for Telaprevir and Boceprevir, while 31% are for Sofosbuvir and Simeprevir. The Tier coverage for these drugs varied from 1-6. In 78% and 72% of the plans, Telaprevir and Boceprevir were covered at Tier 5. For Sofosbuvir and Simeprevir, 95% of the plans covered them at Tier 5. The Tier 3 coverage shows significant variations: Sofosbuvir 2%, Simeprevir 2%, Telaprevir 1% and Boceprevir 18%. Overall, the coverage trends show relatively lower access for Sofosbuvir and Simeprevir versus Telaprevir and Boceprevir. The median co-insurance for the four drugs ranged from 25%-47%. At the state level, coverage in four states (CA, IL, TX and FL) was similar, except for New York, which had reactivity more plans with Tier 4 coverage than other States (12 versus 8).

CONCLUSION: U.S. managed care access for new HCV treatments shows relatively lower access for new products (Sofosbuvir and Simeprevir). For patients to obtain equitable access to drugs either price discounts or payer specific contracting might be needed in the future.

SPONSORSHIP: None.

Incidence Rate of Hepatitis C Screening and New Diagnosis in a Commercially Insured Population

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BACKGROUND: Chronic Hepatitis C Virus (HCV) infection is a serious public health problem because of the large number of individuals who do not know they are infected. Testing recommendations were expanded by the CDC (in August 2012) and USPSTF (in June 2013) to include all persons born from 1945 to 1965.

OBJECTIVE: To determine the extent HCV screening test recommendations have increased screening and new diagnosis in a commercially insured population.

METHODS: Among members continuously insured January 2011 to April 2014, the earliest claim in this interval was identified for each member for: (a) HCV antibody screening, (b) anti-HCV drug treatment, and/or, (c) a diagnosis code for HCV. The incidence of first screening was quantified for three 10 month intervals: (1) before CDC (October 2011 to July 2012) (2) after the CDC (August 2012 to May 2013), and (3) after the USPSTF (July 2013 to April 2014) recommendations. The rate of new diagnosis was deduced as the percentage whose first claim with a diagnosis code or first claim for anti-HCV drug therapy was incurred between 0 and 180 days after their first screening claim. The monthly incidence rate of new diagnosis was calculated by applying the rate of new HCV diagnosis for the two birth year categories by type of screening (acute hepatitis panel [CPT 80074] versus just an HCV screen [CPT 88080]), to the observed incidence rate of screening by type.

RESULTS: In a sample of 5,065,071 members (36.9% birth year 1945 to 1965; 63.1% 1966 to 2014), 256,619 (5.1%) had an HCV antibody test, the first of which was an acute hepatitis panel for 38.3% and just an HCV screen for 61.7%. In the 10 month intervals before CDC, after CDC, and after USPSTF, the monthly incidence rate per of HCV screening per 100,000 members was, respectively: 117.9, 161.3, and 167.4 for those born 1945 to 1965; 117.8, 144.1, and 112.4 for those born 1966 to 2014; and 117.8, 131.5, and 132.7 for all members. Among members screened before November 2013, the fraction with a first claim with an HCV diagnosis code or first claim for anti-HCV drug therapy was incurred between 0 and 180 days after their first screening claim. For the two birth year categories by type of screening (acute hepatitis panel [CPT 80074] versus just an HCV screen [CPT 88080]), the observed incidence rate of screening by type.

CONCLUSION: Testing of older members and new diagnosis of HCV infection increased following announcement of new guidelines, but remain low.

SPONSORSHIP: Prime Therapeutics (employer)
Overview of a Hepatitis C Medication Monitoring Program in a State Medicaid Program

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BACKGROUND: The rising costs of hepatitis C treatment and monitoring for appropriate utilization of the agents are a concern for payers and prescribers. Working with prescribers, to select a regimen with the best chance of virologic cure while providing oversight and medication-adherence monitoring during treatment, is critical to success.

OBJECTIVE: The purpose of our program was to (a) promote cost-effective regimen use through telephonic prescriber outreach on prior authorization (PA) requests, (b) monitor member adherence to the regimen using pharmacy claims data, and (c) identify members achieving virologic cure by conducting prescriber outreach.

METHODS: Clinical Pharmacy Services (CPS) assembled a team to monitor sofosbuvir and simeprevir hepatitis C medications using a comprehensive tracking log. Starting in December 2013, the log includes member and prescriber demographics and disease specific parameters: hepatitis C baseline viral load and genotype, liver disease staging, requested regimen and PA decision, prior regimens with response, prescriber contact and drug fill dates. Automated reports are run to identify members past-due or nearly-due for refill and are used by the team for prescriber outreach.

RESULTS: As of June 30, 2014, 396 members have been approved and included in the monitoring program, of which 13 have been referred to a case management program for comorbid substance use disorders. Of the 113 members whose prescribers were contacted to discuss alternative regimens, 27 were approved for the recommended regimen leading to estimated cost-avoidance of $569K to $1.2M. A total of 105 prescribers were contacted for 181 members who were past-due or nearly-due for refill. PAs for 34 have been closed early for member non-adherence, deferral of therapy, lost to follow-up, and therapy discontinuation due to side effects leading to drug waste cost-avoidance of at least $29K. Viral load screening conducted for 1 of 8 members at least 12 weeks post therapy completion showed virologic cure.

CONCLUSION: Telephonic interventions may help prescribers manage potentially non-adherent members on a drug regimen. Collaborating with the prescriber to identify a regimen that may yield the greatest results and monitoring that regimen for adherence has proven to be successful in this Medicaid program. Tracking these metrics and working closely with prescribers may lead to better overall member outcomes and can lead to cost-avoidance and significant reduction in waste. This model may potentially yield similar results in other disease states and therapeutic classes.

SPONSORSHIP: None.

Examining the Use of ICD-9-CM Diagnosis Codes for Opioid Abuse and Opioid Dependence in Commercial Claims Data

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BACKGROUND: According to the American Academy of Pain Medicine, pain is one of the most widespread ailments in the U.S. There has been a 176% increase in the number of opioid prescriptions from 1991 to 2010. Currently there is no gold standard methodology to identify those individuals who present a high-risk pattern of opioid use. One area of success, according to Daubresse et al., has been in the pharmacy benefit manager (PBM) area, where retrospective drug utilization review programs have been successful in decreasing the utilization of controlled substances.

OBJECTIVE: The purpose of this study was to determine if a point of sale (POS) edit can effect opioid utilization among a subgroup of high opioid utilizers in a commercial population by analyzing 15 months of opioid claim data.

METHODS: A retrospective drug utilization cohort study was conducted on pharmacy claims data for 260 members who were identified during a 6 month capture time frame as high opioid utilizers. Opioid utilization information for each subject was collapsed monthly over the 15 months of the study including total claims, unique pharmacies, unique prescribers, total day supply and amounts reimbursed by the insurance plan was examined. The POS edit was implemented on February 20, 2013, it used a 60 day retrospective time frame to determine if the member met any of the four parameters: ≥ 4 prescribers of opioids, ≥ 150 days’ supply of opioids, ≥ 8 opioid claims, and ≥ 3 opioid dispensing pharmacies when they attempted to fill an opioid prescription. When a parameter was met, it resulted in a denial for pharmacy reimbursement. To receive reimbursement, the provider had to submit a prior authorization stating awareness that their patient met the criteria for opioid utilization review and that they would like the patient to receive the prescription.

RESULTS: Separate R-ANOVA statistics were calculated to determine if any of the measures of opioid utilization changed over the 15 time periods. Significant decrease in the number of opioid prescribers, day supply of opioids, number of opioid claims, and opioid dispensing pharmacies were observed when comparing monthly averages to the last month (P<0.05). There was also a significant decrease in total plan paid (P<0.05).

CONCLUSION: A point of sale edit can result in a significant decrease in opioid over-utilization and a reduction in total plan paid in the highest subset of opioid users.

SPONSORSHIP: This research was conducted by Navitus Health Solutions, Madison, WI, without external funding.

Opioid Over-Utilization Point of Sale Edit in a Commercial Population: A PBM Evaluation

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BACKGROUND: According to the American Academy of Pain Medicine, pain is one of the most widespread ailments in the U.S. There has been a 176% increase in the number of opioid prescriptions from 1991 to 2010. Currently there is no gold standard methodology to identify those individuals who present a high-risk pattern of opioid use. One area of success, according to Daubresse et al., has been in the pharmacy benefit manager (PBM) area, where retrospective drug utilization review programs have been successful in decreasing the utilization of controlled substances.

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CONCLUSION: A point of sale edit can result in a significant decrease in opioid over-utilization and a reduction in total plan paid in the highest subset of opioid users.

SPONSORSHIP: This research was conducted by Navitus Health Solutions, Madison, WI, without external funding.
were well-balanced between abuse patients and their matched controls and 395,901 control patients. After matching, baseline characteristics demonstrated that an educational intervention can result in a significant increase in prescribing that is consistent across settings.

**METHODS:** Pharmacy benefit managers (PBM) may identify nonadherent patients, present complex health care challenges, requiring a coordinated care approach. Pharmacy benefit managers (PBM) may identify nonadherent patients, intervene and increase prescribing that is consistent across settings.

**OBJECTIVE:** To determine if repeated educational interventions to Medicaid members and associated prescribers during two consecutive one-year time frames would result in improved adherence as evidenced by an asthma medication ratio (AMR).

**RESULTS:** Selection criteria identified 2,292 abuse, 6,727 dependence, and 305,921 control patients. After matching, baseline characteristics were well-balanced between abuse patients and their matched controls (n = 1,852 each) and dependence patients and their matched controls (n = 5,369 each). Abuse patients most commonly received their first diagnosis for abuse in a hospital setting (34% in an emergency department (ED), 29% in an inpatient setting) whereas dependence patients most commonly received their first diagnosis for dependence in an office setting (39%). Similarly, abuse patients had higher excess ED costs than dependence patients ($4,220 vs. $1,569) whereas dependence patients had higher excess rehabilitation facility costs ($1,027 vs. $1,949). Abuse patients had higher total excess healthcare costs than dependence patients ($13,554 vs. $9,419). All P < 0.01. Rates of abuse grew from 0.018% in 2006 to 0.039% in 2011; rates of dependence grew from 0.048% in 2006 to 0.147% in 2011.

**CONCLUSION:** Excess healthcare costs differ between abuse and dependence patients, but the costs are substantial for both. Differences may reflect demographics, baseline comorbidities, and place of first diagnosis. Future research should examine whether these findings imply underlying clinical differences or differences in coding practices across settings.

**SPONSORSHIP:** This study was funded by Purdue Pharma L.P.
inertia in HF treatment initiation and the limited use of combination therapies after initial diagnosis, despite guideline recommendations of RAAS-based therapy. Investigation of the effect of this delay in therapy initiation on patient outcomes would also be warranted.

**SPONSORSHIP:** Novartis Pharma AG.

Compliance with Requirements for Medication Therapy Management (MTM) Program Information on Medicare Part D Plan Websites

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**BACKGROUND:** Part D plan websites are required to provide easily accessible information about their medication therapy management (MTM) program in accordance with the Medicare Marketing Guidelines. The 2013 and 2014 Centers for Medicare and Medicaid (CMS) Call Letters outlined requirements for MTM website information. Due to the recent nature of these requirements, there is little published information on how plans are presenting MTM information on their websites.

**OBJECTIVE:** Per CMS Contract #GS-10F-0269K/HHSN-500-2011-00035G, compliance with requirements for information on the Part D plan’s website about the plan’s MTM Program was examined.

**METHODS:** In January 2014, a sample of Part D plans was selected from the “2014 Plan MTM Program Eligibility Information” list available at the CMS website. Each plan’s MTM web page was assessed to determine whether it complied with the 2013 Call Letter requirements of having information about the MTM program, specific eligibility requirements, who to contact for more information, and a high-level summary of MTM services offered. Additionally, there was a review for the expanded 2014 Call Letter requirements of a blank Personal Medication List (PML), or link to one, an individual web page devoted to MTM, and the recommendation of 2 or fewer clicks to access the web page from the plan’s main Medicare drug plan website.

**RESULTS:** A total of 42 plans (50% Prescription Drug Plans (PDPs), 42.9% Medicare Advantage Prescription Drug Plans (MA-PDs), 7.1% MA-PD Special Needs Plans (MA-PD SNPs) or Medicare-Medicare Plans (MMPs)) were reviewed. National plans comprised 24% of the sample. The 2013 and 2014 requirements were met by 92.9% and 59.5% of plans, respectively. There were 7.1% of plans that did not meet any of the 2013 or 2014 requirements. In the remaining 33.4% of plans, only one 2014 requirement was not met: 43% (6/14) required 3 or more clicks to access the MTM web page, 36% (5/14) did not have a blank copy of the PML or a link to one, and 21% (3/14) did not have a web page dedicated to MTM. Compliance with requirements was similar regardless of plan type (PDP vs. MA-PD) or geographic coverage (national vs. regional).

**CONCLUSION:** Medicare Part D plans are showcasing their MTM programs on the plan’s website according to the 2013 requirements set forth by CMS. While improvement in meeting the 2014 requirements is needed, this analysis was done shortly after the expanded requirements went into effect. Future research should evaluate the usability and effectiveness of the MTM website information for Medicare beneficiaries.

**SPONSORSHIP:** CMS Contract #GS-10F-0269K/HHSN-500-2011-00035G.

**Impact of Out-of-Pocket Costs on Initial and Subsequent Prescription Fills Among New Initiators of Biologic Therapies Indicated for Rheumatoid Arthritis**

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**BACKGROUND:** Biologic therapies are a mainstay of treatment for rheumatoid arthritis (RA), yet high member out-of-pocket (OOP) costs for such therapies may limit patient access to these therapies.

**OBJECTIVE:** To understand unmet need among RA patients initiating biologic therapy by examining the relationship between OOP costs and the initial fill as well as subsequent refills of biologics for RA.

**METHODS:** Medicare Advantage and Prescription Drug (MAPD) members from a national health plan with an adjudicated (paid or reversed) claim for a biologic indicated for RA were identified July 1, 2007-December 31, 2012 and followed retrospectively. The first adjudicated claim date was the index date. Members were required 180 days of continuous enrollment pre- and post-index, and ≥1 diagnosis for RA (ICD9-CM: 714.0 or 714.2) during pre-index or < 30 days post-index. Low income subsidy and Medicaid-Medicare Dual Eligible members were excluded. The analysis used multivariate regression models to examine associations between initial prescription (Rx) abandonment rates and OOP costs, and factors influencing the refill of a biologic therapy based on pharmacy claims.

**RESULTS:** The final sample size included 864 MAPD members with an adjudicated claim for a biologic. Majority were female (77.4%) and mean age was 63.5 years (standard deviation = 10.9). Most (78%) had DMARD utilization during pre-index. The overall initial abandonment rate was 18.2%, rising from 1.3% for the lowest OOP cost group ($0-$250) to 32.7% for the highest OOP cost group (> $550), (P<0.0001) for Cochran-Armitage trend test. Odds ratios for abandonment rose from 18.4 to 32.7 to 41.2 for OOP costs of $250.01-400.00, $400.01-550.00, and > $550.00 respectively, relative to OOP costs of ≤ $250.00 (all P<0.0001). Meeting the catastrophic coverage limit and utilization of a specialty pharmacy for the index claim were both associated with a decreased likelihood of abandoning therapy (odds ratios = 0.29 and 0.14, respectively; both P<0.05). Among the subset of 533 members with a paid claim, 82.4% had at least one refill post-index. The negative association between OOP cost and likelihood of refilling a prescription was highly significant (P<0.0001).

**CONCLUSION:** This study suggests the higher the member OOP cost, the less likely a MAPD member is to initiate or refill a biologic therapy for RA. Further research is needed to understand reasons for initial Rx abandonment and lack of refills, including benefit design and adverse events.

**SPONSORSHIP:** Humana Pfizer Research Collaboration.

**Patient-Reported Reasons for Not Initiating Pharmacological Therapy Among Osteoporotic Patients from a Large Managed Care Health Plan**

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**BACKGROUND:** Many women diagnosed with osteoporosis (OP) do not initiate OP treatment. Reasons for non-treatment despite having an osteoporosis diagnosis are not clear.
OBJECTIVE: To conduct a survey to understand patient reported reasons for non-initiation of OP treatment among women diagnosed with OP.

METHODS: Survey recipients included women ≥ 55 years with a qualifying event during January 1, 2010-March 31, 2012. (1) OP diagnosis coupled with bone mineral density (BMD) test within 183 days of diagnosis and/or (2) OP-related fracture were identified from an administrative claims database. Eligibility required no claims for OP medication at least 12 months and up to 5 years prior to and at least 6 months after the qualifying event and 18 months continuous enrollment (6 months pre- and 12 months post-qualifying event). The 2,000 female patients with the most recent qualifying event were mailed a survey. Respondents reporting that they did not initiate physician-recommended OP medication, after either their physician told them they had OP or they experienced a fracture since age 45, completed the survey.

RESULTS: There were 340 patients who returned a complete survey, mean age was 61 and 75% had a BMD test plus OP diagnosis as their qualifying event. A total of 197 (57.9%) patients reported their physician diagnosed OP and 117 (39.3%) were recommended OP medication; 44 patients who did not initiate recommended OP medication completed the survey. The primary reason for not initiating OP medication was concern over side effects (77.3%) followed by medication costs (34.1%) and pre-existing gastrointestinal conditions (25.0%). Most non-initiators (96%) indicated knowledge of OP before diagnosis, but only 34% had a discussion about OP with their physician prior to diagnosis.

CONCLUSION: Among survey respondents, 41% of patients whose physician diagnosed OP were not recommended OP treatment, and 38% of patients recommended OP treatment did not initiate treatment. Concern with OP treatment side effects was the predominant reason for not initiating treatment, followed by medication costs (34.1%) and pre-existing gastrointestinal conditions (25.0%).

SPONSORSHIP: This study was funded by Merck & Co., Inc.

**Electronically Transmitted Prescriptions Involved in Primary Prescription Abandonment**

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BACKGROUND: Primary prescription abandonment is reportedly as high as 22% and may lead to suboptimal clinical outcomes. The dramatic increase in electronic transmission of prescriptions has likely altered the dynamics of medication abandonment.

OBJECTIVE: To describe abandoned electronically-transmitted prescriptions (eTRxs) in terms of drug class, formulary tier and patient copay.

METHODS: This study utilized Medicare and commercial claims data from January 1, 2010 to December 31, 2012 for 18-89 year-olds with continuous eligibility for 6 months pre- and post-index. Index date was defined as a new eTRx without a paid claim for the same drug in the prior 6 months. Prescriptions were considered abandoned if the eTRx had no correlating paid claim within 120 days of index. Switch in drug was defined as a switch within the therapeutic or pharmacologic class within 120 days of index.

RESULTS: Of 17,440,564 prescriptions, 4,592,564 (26.3%) were eTRxs, representing nearly 1.4M members. 12.1% of eTRxs were abandoned and 1.2% were switched. Tier 4 exhibited the highest abandonment (23.1%), compared to 22.3% of Tier 3, 14.7% of Tier 2, and 9.1% of Tier 1. A similar positive relationship was observed between abandonment and member cost share: 31.1% of eTRxs costing $51+ were abandoned versus 22.4% of $41-50, 20.4% of $31-40, 15.3% of $21-30, 11.1% of $11-20, and 9.5% of $0-10 prescriptions. Mean member cost share was $28 for abandoned versus $13 for non-abandoned eTRxs. Greater abandonment occurred with branded drugs (23.0%) compared to generic (9.5%) and dispense as written (DAW) eTRxs (21.4%) compared to non-DAW (12.0%). Drug switch occurred more often for higher tier, branded, and higher cost share eTRxs. Of top 20 most commonly prescribed eTRx classes, azithromycin was least abandoned (3.4%) whereas statins were most abandoned (16.0%); switch in drug was most common in sympathomimetics (5.9%), statins (3.3%), and proton pump inhibitors (3.1%). Of top 100 prescribed classes, the most abandoned were impotence agents (37.7%), smoking deterrents (30.3%), and viral vaccines (29.0%).

CONCLUSION: Primary prescription abandonment is positively related to a patient’s out of pocket cost and differs greatly by drug class. In an era of burgeoning e-prescribing system use, primary abandonment remains a concern given that 12.1% (n=557,463) of eTRxs were abandoned in this study. Opportunities remain for improving patient and provider awareness of plan coverage, which may allow for clinically sound decisions that minimize member cost share and result in less prescription abandonment.

SPONSORSHIP: Bristol-Myers Squibb.

**Economic and Event Outcomes of Members with Carve-In Versus Carve-Out Pharmacy Benefits: A 2-Year Cohort Study**

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BACKGROUND: When purchasing health insurance, decision makers are faced with the question of whether to include the pharmacy benefit as part of the total health package—a Carve-in model—or to treat it as a separate benefit administered by an external pharmacy benefit manager—Carve-out model.

OBJECTIVE: To compare at a national level, using medical claims from 25 insurers across the U.S., the per member per year (PMPY) allowed medical costs between commercially insured members receiving Carve-in to those with Carve-out pharmacy benefits.

METHODS: Continuously enrolled members from 2010 through 2011 and no major benefit changes were randomly identified from the Blue Health Intelligence national database of over 110 million members. Members were matched using 15 year age bands, gender, and region. The primary objective was statistically assessed using a general linear model with gamma distribution to measure the PMPY total medical cost differences adjusting for: age, gender, Verisk diagnostic clinical category score (severity of illness proxy), presence of each of six chronic diseases, insurance product type, rural/urban, region, and group size. A sensitivity analysis was performed excluding members with ≥ $100,000 annual medical cost in 2010 or 2011. The secondary medical event objectives were statistically assessed using multivariate logistic regression models comparing the odds of hospitalization or emergency department (ED) visit adjusting for the same covariates.

RESULTS: The final analyzable dataset included 818,054 Carve-in and 1,042,029 Carve-out members. Carve-in members were found to have a highly statistically significant 11% (P<0.001) lower medical costs after adjusting for baseline population differences and severity of illness. This translates into an average $330 lower PMPY medical cost ($3,506 Carve-out versus $3,176 Carve-in). This difference remained highly significant after excluding high-cost (≥ $100,000 per year)
weighting, clustering, and stratifying were used to make the data representative of the U.S. non-institutionalized population. Participants were categorized with: (1) fair/poor or (2) better than fair/poor mental health (MH). T-tests and chi-squared tests were performed. Multiple logistic regression was used to determine the odds of exposure by MH category for those with any ER visits (≥ 1), hospitalizations (≥ 1), high prescription expenses (≥ $1,000), high number of prescriptions (≥ 11), and inability to access medications. Adjustments for sex, age, race, insurance, income, and marital status were made.

**RESULTS:** Fair/poor MH status was reported by 11.6% of respondents. Higher proportions of fair/poor MH occurred in women, the elderly, the publicly insured, the separated and widowed, and the low income (P < 0.05). Compared to those with better MH status, fair/poor respondents had higher medication cost (OR = 3.22; CI: 2.88-3.60) and more prescriptions (OR = 3.69; CI: 3.28-4.14). Fair/poor respondents had higher likelihood of hospitalizations (OR = 2.55; CI: 2.22-2.95) and ER visits (OR = 2.17; CI: 1.94-2.43). They also had higher likelihood of a delay in receiving medication (OR = 2.68; CI: 2.11-3.41). Those with better than fair/poor MH had lower likelihood of being unable to access medication (OR = 0.31; CI: 0.25-0.38). Those able to access medications had a lower likelihood of ER visits (OR = 0.51; CI: 0.37-0.71) compared to those without access.

**CONCLUSION:** Poor mental health was associated with increased likelihood of ER visit and hospitalization and reduced likelihood of medication access. Our findings suggest that health services use could be reduced with improved care of those with compromised mental health.

**SPONSORSHIP:** None.
Impact of Sofosbuvir on Utilization and Expenditure of Hepatitis C Medications in a Medicaid Population

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Magellan Rx Management

BACKGROUND: Hepatitis C affects approximately 3.2 million people in the U.S. It is estimated that the prevalence of Hepatitis C is doubled in the Medicaid population versus the commercial population. The approval of sofosbuvir (Sovaldi) in December 2013 for the treatment of chronic Hepatitis C offers improved efficacy and tolerability over other Hepatitis C regimens at a significantly greater cost.

OBJECTIVE: To evaluate the impact of sofosbuvir on utilization and expenditure, along with prescribing pattern of Hepatitis C treatment regimens, in a Medicaid population.

METHODS: Using a large state government database of pharmacy claims (approximately 1 million pharmacy lives), patients were identified based on claims for Hepatitis C therapies (i.e., peg interferon, ribavirin, telaprevir, boceprevir, sofosbuvir, and simeprevir) between January 1, 2013 and June 30, 2014. Utilization, expenditure, and Hepatitis C prescribing patterns were evaluated for this population before and after approval of sofosbuvir in December 2013. Additionally, to assess duration of sofosbuvir-based regimens, Hepatitis C patients continuously enrolled between December 1, 2013 and May 31, 2014 were evaluated. Descriptive statistics were used to assess results.

RESULTS: Following the introduction of sofosbuvir, the proportion of Hepatitis C costs as a percentage of overall pharmacy expenditure increased by 138% (2.3% vs. 5.5%). The rate of patients starting on a Hepatitis C regimen increased by 39% between December 2013 and May 2014 (n=384) compared to June 2013 and November 2013 (n=276). Ninety percent of patients newly starting a Hepatitis C regimen after December 2013 were on a sofosbuvir-based regimen (40%, sofosbuvir + ribavirin; 59%, sofosbuvir + ribavirin + peg interferon; 1%, sofosbuvir + simeprevir). Of the patients on sofosbuvir-based regimen, 68% and 7% were on 12 and 24 weeks, respectively; all completed the full regimen and no one was put on a subsequent Hepatitis C therapy.

CONCLUSION: Sofosbuvir has shifted the paradigm for the treatment of chronic Hepatitis C, with 90% of new patients starting on a sofosbuvir-based regimen, and significantly more patients initiating therapy (39% increase). This change in prescribing behavior, along with a greater number of Hepatitis C patients now receiving therapy, has significantly impacted overall pharmacy expenditure; it is unsure what the continued impact will be as other drugs in the Hepatitis C pipeline are approved. Also, further research is needed to assess the real-world impact on sustained viral response rates and clinical outcomes, to determine the overall cost-effectiveness of sofosbuvir.

SPONSORSHIP: This research was conducted by Magellan Rx Management, without any external funding.
options and emerging therapies make a multidisciplinary team approach essential to ensuring patients are able to tolerate, and successfully complete, a full course of treatment resulting in cure. A number of prescribers, including those with little expertise and experience in the management of HCV, were initiating treatment in the management of HCV in the Geisinger Health Plan (GHP) Medical Assistance (Medicaid) population. This can result in negative outcomes due to inappropriate patient selection for treatment, early discontinuation of treatment, inadequate monitoring, and a lack of adequate patient counseling about treatment expectations. These unfavorable outcomes would include a lack of clinical response, as well as a waste of valuable medical resources.

**OBJECTIVE:** To define, develop, and implement a center of excellence (COE) model for the management of HCV to improve outcomes and quality of care of patients with HCV.

**METHODS:** A team of multidisciplinary representatives, which included pharmacists, nurses, and physicians, defined criteria for a COE for HCV management. The COE benchmarking criteria included favorable outcomes in sustained virologic response, discontinuation rates, medication adherence, as well as high volumes of treated patients with HCV. To initiate a COE evaluation, a COE referral form, including a patient information checklist is required. After the COE evaluation and treatment is initiated, the patient may be co-managed with their local specialist if appropriate.

**RESULTS:** With the implementation, appropriate patients are receiving needed treatment and care from a multidisciplinary team improving utilization of HCV medications. The highlights of the program include strong clinical experts who have a history of superior outcomes and alignment of benchmark measurement criteria with policy criteria to standardize the requirements of a COE.

**CONCLUSION:** The implementation of a COE in HCV management has improved the appropriate evaluation and treatment of eligible patients. The multidisciplinary approach provides a collective team effort in the goal of improving outcomes and quality of care for patients. It was recommended to continue the COE approach in the management of Medicaid members with HCV. It will be critical to continually evaluate the designated COE to verify high quality and excellent care is being provided.

**SPONSORSHIP:** Geisinger Health Plan and Geisinger Health System.

**B9 Adherence and Discontinuation Rates for Peginterferon + Ribavirin Compared with Telaprevir + Peginterferon + Ribavirin in Patients Treated for Chronic Hepatitis C**

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**BACKGROUND:** Prior to approval of telaprevir (TPV), the standard of care for chronic hepatitis C virus (HCV) included peginterferon (P) weekly injections and ribavirin (R) taken orally twice daily. In 2011, TPV was approved for coadministration with P + R during the first 12 weeks of therapy. Though TPV improved viral clearance, it also increased the side effects and treatment complexity by 6 pills per day given in 3 doses. The impact of increased regimen complexity on adherence and discontinuation has not been assessed.

**OBJECTIVE:** The objective of this study was to compare treatment adherence and discontinuation rates over 24 weeks in HCV patients treated with TPV + PR compared to those on PR.

**METHODS:** A large U.S. commercial health insurance claims database was used to identify HCV patients initiating treatment with PR in the pre-TPV era (2007-2009) or TPV + PR in the post-TPV era (2011-2013). The index date was the date of HCV treatment initiation and follow-up was 24 weeks. Adherence was measured by medication possession ratio for all patients thru 24 weeks. Discontinuation was defined as a premature refill gap of >60 days for any of the drugs. Outcomes were analyzed at 4 week intervals. A 7-day window was allotted at 12 weeks for TPV and 24 weeks for PR in order to avoid misclassifying patients as discontinuers. Regression analyses adjusted for age, sex, comorbidities, liver disease severity, and pill count prior to HCV treatment.

**RESULTS:** The study included 2,317 and 5,284 patients in the TPV + PR and PR cohorts, respectively. Discontinuation was similar between cohorts at week 4 but was higher for the TPV + PR cohort at all other time points (6.7% [TPV + PR] and 37.2% [PR] at 24 weeks, P<0.0001). Unadjusted and adjusted adherence was high for both cohorts during the study period (82.4% [PR] and 83.0% [TPV + PR] at 24 weeks, P > 0.3859). Adherence rates between the cohorts were not significantly different at any time point except weeks 4 and 12 (99.8% and 88.9% [PR] and 99.7% and 87.7% [TPV + PR] for weeks 4 and 12, respectively). These differences were not clinically meaningful. Age (>60 years), decompensated cirrhosis, and pre-HCV treatment pill count were associated with lower adherence at 24 weeks. However, the impact of pre-HCV treatment pill count was minimal (adherence decreased by 0.3% for each additional pill). Overall, side effects were higher in the TPV + PR cohort.

**CONCLUSION:** Among commercially insured HCV patients, adherence rates were high. Despite higher discontinuation in the TPV + PR cohort, adherence rates were similar between the cohorts.

**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 presentation.

**B11 Real-World Medication Persistence with Single Versus Multiple Tablet Regimens for HIV-1 Treatment**

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**BACKGROUND:** Adherence to antiretroviral (ARV) treatment for HIV-1 is crucial to achieving optimal clinical outcomes. Simplification of regimens with once-daily single-tablet regimens (STRs) can improve adherence compared to multi-tablet regimens (MTRs).

**OBJECTIVE:** To compare real-world persistence (a proxy for treatment effectiveness and adherence) between HIV-1 infected patients receiving (STRs) versus MTRs.

**METHODS:** Adult HIV-1 infected patients starting their first observed ARV regimen (with at least 6 prior months of no ARV treatment) were identified in the MarketScan claims database (October 2008-March 2014). Persistence was measured as the time from the index regimen start date to the end of the first 90-day gap between fills for any ARV in the index regimen, or to the start date of an ARV not in the index regimen. Persistence was described using Kaplan-Meier curves and compared using log-rank tests, and Cox proportional hazards models adjusted for age, gender, insurance type, region, insurance type, employment status, Charlson Comorbidity Index, other comorbidities, hospitalizations, emergency room visits, and office visits. STIs were further stratified by regimen.

**RESULTS:** 3,257 patients (37%) initiated MTRs, and 5,484 (63%) initiated STRs, including 4,409 on efavirenz (EFV)/tenofovir (TDF)/emtricitabine (FTC), 484 on rilpivirine (RPV)/TDF/FTC, and 591 on elvitegravir (EVG)/cobicistat (CObI)/TDF/FTC. Median persistence was 45.0 months for STRs versus 15.2 months for MTRs (P<0.001). Median persistence was not reached for RPV/TDF/FTC, or EVG/CObI/
CONCLUSION: Among HIV-1 infected patients, the use of STRs was associated with longer regimen persistence compared with MTRs. Among STRs, EVG/COBI/TDF/FTC and RPV/TDF/FTC were associated with significantly longer persistence than EFV/TDF/FTC.

SPONSORSHIP: Gilead Sciences, Inc.

C1 Identification of a Cancer Cohort and Antineoplastic Utilization in Maine: Results from the Maine All-Payer Claims Database

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BACKGROUND: Recent concerns over the rising cost and transparency of healthcare have accentuated the need for more data. The establishment of state all-payer claims databases (APCDs) provides one source of data to monitor healthcare utilization and trends within one particular locality. In 2003, the first state-wide APCD was established in Maine. Cancer is a significant cause of disease burden and healthcare-related costs, and the Maine All-Payer Claims Database (MEAPCD) provides an opportunity to conduct analyses of cancer drug utilization and trends at the state-level.

OBJECTIVE: The objective of this study is to identify and describe the demographics of a cohort of patients with a cancer diagnosis and to describe the utilization and expenditures of antineoplastic agents in Maine.

METHODS: We conducted a cross-sectional analysis of the MEAPCD for tumor diagnosis, demographics, antineoplastic utilization, and cost of therapy. The cancer cohort was identified by the presence of at least 1 claim with an ICD-9 diagnoses code for a neoplasm (140-239). HCPCS Level II procedure codes were used to identify intravenously administered antineoplastics within medical claims and NDC codes were used to identify orally administered antineoplastics within the prescription benefit. Descriptive statistics (counts, frequencies, proportions) are used in the analysis and reporting of the data.

RESULTS: There were 43,335 patients with at least one ICD-9 diagnosis code classified as a neoplasm. The cohort was well distributed in terms of age and gender: 56% were female, 44% were male. Almost half (49%) was 65 years or older and 40% was between the ages of 45-64. The most common tumor cases were: breast (11%), lung (7.8%), prostate (7.6%), colorectal (6.2%), and non-Hodgkin lymphoma (4.9%). About 10% of patients had at least one claim for an antineoplastic agent; the most common agents were: carboplatin, paclitaxel, cyclophosphamide, and doxorubicin. The most frequently used biologics were bevacizumab, rituximab, and trastuzumab. From 2006-2009, the highest expenditure drugs were gemcitabine ($618 million), paclitaxel ($407 million), and oxaliplatin ($352 million).

SPONSORSHIP: None.
C5  Real-World Treatment Patterns and Health Resource Utilization Among Patients Diagnosed with Early Stage Resected Non-Small Cell Lung Cancer (NSCLC) at Community Oncology Practices in the U.S.

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BACKGROUND: Several randomized trials have shown a significant survival benefit of adjuvant chemotherapy in early stage resected NSCLC. Few retrospective studies have investigated the treatment patterns and associated health resource utilization (HRU) of early stage resected NSCLC patients from U.S. community oncology practices.

OBJECTIVE: To characterize real-world treatment patterns and HRU during adjuvant therapy, by disease stage, among surgically resected Stage IB-IIIA NSCLC patients.

METHODS: Retrospective analysis of electronic medical record and billing data collected as part of routine care from community oncology sites included in the Vector Oncology Data Warehouse from January 2007 to January 2014. Eligible patients, accrued in random order, were ≥ 18 years, had a primary diagnosis of NSCLC, Stage IB to IIIA, and underwent a qualifying surgical resection. Patients diagnosed with Stage IA or de novo Stage IIIB-IV disease were excluded. Treatment patterns and HRU associated with systemic therapy prescribed between resection and disease recurrence, or through the end of the record (whichever occurred first), were examined by disease stage.

RESULTS: A total of 609 patients met all study criteria (mean age at diagnosis: 64.8 years; 35.3% Stage IB, 39.4% Stage IIA/B, 25.3% Stage IIIA). Of these, 345 received systemic adjuvant therapy following resection; patients with Stage IB disease were less likely to receive adjuvant therapy (39.1%) than patients with Stage IIA-IIIA disease (66.8%; P < 0.0001). The most common initial adjuvant regimens were carboplatin + paclitaxel (29.9%) and cisplatin (13.9%).

CONCLUSION: In this real-world cohort of early stage resected NSCLC patients treated at U.S. community oncology clinics, 39% of Stage IB patients received adjuvant therapy versus two-thirds of Stage IIA-IIIA patients. However, there were few differences in adjuvant treatment patterns or HRU by disease stage. Further studies are warranted to extend these findings as they relate to disease recurrence and long-term outcomes.

SPONSORSHIP: GlaxoSmithKline Biologics SA.

C9EM  A Comparative Budget Impact Analysis for Treatment of Metastatic Non-Small Cell Lung Cancer (NSCLC) Patients with EGFR Exon 19 Deletions or Exon 21 (L858R) Substitution Mutations

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BACKGROUND: Patients with metastatic NSCLC whose tumors harbor exons 19 deletions or exon 21 (L858R) substitution mutations in the epidermal growth factor receptor (EGFR) gene (‘EGFR positive’) are eligible for treatment with erlotinib or afatinib, two tyrosine kinase inhibitors (TKIs) approved for use in the U.S. by the FDA. However, because of uncertainties in relative treatment duration, dosage form pricing, and adverse event profiles, the differential impact of selecting each agent on a health care plan’s budget is unclear.

OBJECTIVE: Evaluate the budget impact of treating all first-line metastatic NSCLC patients who are EGFR positive with erlotinib versus afatinib.

METHODS: The cost analysis was performed from the perspective of a private health insurer with 1M enrollees in the U.S. over a one-year time period. Population-based incidence data from SEER 2000-2010 were combined with U.S. Census data to estimate the expected...
EXHIBITION: Genentech, Inc.

C10 Hospital and Emergency Department Utilization and Expenditures Among Metastatic Breast Cancer Patients Treated with Eribulin or Capecitabine

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BACKGROUND: There is a paucity of data comparing use of eribulin (ERIB) and capecitabine (CAPE) in breast cancer.

OBJECTIVE: To compare rates and costs of hospitalizations and emergency department (ED) visits among metastatic breast cancer (mBC) patients treated with eribulin (ERIB) or capecitabine (CAPE).

METHODS: Women with mBC previously treated with anthracyclines or taxanes and newly treated with ERIB or CAPE on or after November 1, 2010 (index date) were selected from MarketScan Commercial and Medicare Supplemental Databases. Patients were followed until ERIB or CAPE discontinuation, enrollment end, or study end (June 30, 2012). Patients with other primary cancers or < 12 months pre-index data, or treatment with both ERIB and CAPE at any time were excluded. Pre-index demographics and clinical characteristics and post-index utilization and expenditures were measured. Multivariate regression modeling was used to account for possible effects of confounders.

RESULTS: Of 1,219 eligible women, 26% received ERIB. ERIB patients were older (58 years vs. 55 years, P < 0.001), with higher NCI-Deyo-Charlson Comorbidity scores (0.57 ± 0.91 vs. 0.46 ± 0.85, P = 0.042), higher prevalence of liver and bone metastases, coronary artery disease, anemia and renal failure, and significantly more chemotherapy agents pre-index (2.35 ± 1.56 vs. 1.60 ± 1.44, P < 0.001) compared to CAPE patients. Mean length of follow-up was 131 days for ERIB and 155 days for CAPE. Post-index hospitalization rates were 33% of ERIB and 28% of CAPE patients (P = 0.090), while ED visit rates were 30% of ERIB and 26% of CAPE patients (P = 0.132). Logistic regression of inpatient admissions (IP) and ED visits did not show statistically significant differences between treatment groups (IP odds ratio [OR] 1.24, P = 0.106; ED visits OR 1.21, P = 0.274; ref. CAPE). Regression of the number of post-index IP and ED visits also showed no statistically significant differences (IP incidence rate ratio [IRR] 0.982, P = 0.941; ED visits IRR: 0.894, P = 0.619; ref. CAPE). Adjusted mean expenditures for IP ($33,373 ERIB, $33,994 CAPE, P = 0.887) and ED visits ($1,346 ERIB, $1,426 CAPE, P = 0.724) similarly showed no significant differences between treatment groups.

CONCLUSION: mBC patients newly initiated on ERIB were older, had a higher comorbidity burden, and were treated with significantly more chemotherapy agents during 12 months pre-index compared to CAPE patients. ERIB and CAPE patients’ hospitalization and emergency department expenditures post-index showed no statistically significant differences.

SPONSORSHIP: This study was sponsored by Eisai, Inc.
Impact of BRCA Status on Platinum-Sensitive Recurrent Ovarian Cancer in an Academic Cancer Center

BACKGROUND: Ovarian cancer (OC) is the fifth most common cause of cancer death in American women representing a significant economic impact for managed care. The incidence of OC increases in carriers of BRCA mutations (BRCAm), which are responsible for 10-15% of epithelial OC. BRCAm occur more frequently in platinum sensitive recurrent (PSR) OC, which may be more sensitive to platinum agents and novel PARP inhibitors.

OBJECTIVE: To compare the BRCAm status, patient characteristics and treatment patterns in PSR OC to understand the potential impact of PARP inhibitors in this population.

METHODS: Patients with site and histology confirmed OC treated at the University of Utah Huntsman Cancer Institute from 1995 to 2012 were evaluated. The electronic health record was systematically queried to identify evidence of PSR OC (recurrence ≥ 6 months after last dose of platinum therapy), and BRCAm testing. Descriptive statistics were used to evaluate patient characteristics, treatment patterns, and survival rates for PSR OC patients stratified by BRCAm status.

RESULTS: A total of 168 PSR OC patients were included and categorized as BRCA+ (n = 15, 9%), BRCA- (n = 25, 15%), and BRCAm status/unknown (BRCAunk, n = 128, 76%). Mean age was lower for BRCA+ patients (56.6 ± 11.0 years) vs. BRCAunk (62.8 ± 12.7 years, P = 0.03), however no difference was observed vs. BRCA- (56.1 ± 9.7 years, P = 0.90). Mean modified Charlson Comorbidity Index score was 2.73 ± 1.28 for BRCA+ vs. 2.80 ± 1.32 for BRCAunk (P = 0.88) and 3.19 ± 2.29 for BRCAunk (P = 0.31). BRCA+ patients received a greater median number of systemic treatment courses (4 courses, IQR 2-4) vs. BRCAunk (2 courses, IQR 1-3, P = 0.0013), but no difference was observed vs. BRCA- (3 courses, IQR 1-3, P = 0.83). At recurrence 80% of BRCA+ patients (n = 12) received a platinum-containing regimen vs. 64% of BRCA- (n = 16, P = 0.31) and 60% of BRCAunk patients (n = 77, P = 0.24). Median survival in the BRCA+ group was 4.2 years vs. 5.6 years for BRCA- (P = 0.86) and 2.1 years for BRCAunk (P = 0.03).

CONCLUSION: BRCA+ patients with PSR OC were younger, received more courses of systemic treatment, and had superior survival compared with those not tested for BRCAm. The similarities in outcomes between BRCA+ and BRCA- patients may be explained by survivorship and selection biases since tested patients may have been available for testing based on long survival and were younger. Increased germline BRCAm testing in OC is warranted to help improve decision-making and therapy selection, which may impact treatment outcomes and cost to the health care system.

SPONSORSHIP: AstraZeneca.
ing patients with localized stage IA/IB MF-CTCL with two popular skin-directed medications: Valchlor, a mechlorethamine-based topical treatment, and Targretin gel, a topical retinoid also known as bexarotene gel.

METHODS: In our analyses, we compiled publicly available information from the drugs’ clinical trials and prescribing information. We examined the cost, from a payer’s perspective, to purchase the drug, treat adverse effects, and monitor patients for efficacy and adverse effects.

RESULTS: Our model found that, on average, patients on Valchlor treatment used less drug with less frequent dosing which resulted in lower overall drug costs. Additionally, Targretin gel therapy was associated with higher costs to manage treatment emergent adverse effects. Overall, we found that Valchlor had a lower average cost per patient when compared to Targretin gel.

CONCLUSION: Our study reviews the disease burden of patients with early stage MF-CTCL and estimates the average cost per patient using topical therapy from a payer’s perspective. The findings from our model can be used in future economic analyses to compare the budget impact and cost effectiveness of these two medications in this disease state.

SPONSORSHIP: None.

C17 Temporal Relationship of Healthcare Resource Use Costs in Patients with Chronic Lymphocytic Leukemia

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BACKGROUND: Chronic lymphocytic leukemia (CLL) is typically a slow-progressing hematologic malignancy diagnosed predominantly in older individuals. Treatment initiation occurs when symptoms develop or with advanced disease. Healthcare resource use (HRU) and cost of untreated and treated CLL has not been widely reported.

OBJECTIVE: To evaluate cumulative HRU costs before and after initiation of CLL therapy.

METHODS: Adult CLL patients with no evidence of a prior episode of CLL therapy for ≥ 24 months were identified during 2010 in a U.S. healthcare claims database. Patients had ≥24 months continuous enrollment before and after the index date (defined as the date of the first CLL therapy occurring within 90 days of a CLL diagnosis on any claim). CLL therapy combination regimens were defined as all CLL therapies observed 90 days on or after index date. HRU costs were evaluated 24 months prior to and 6 and 24 months following index date.

RESULTS: This analysis identified 311 CLL patients. Mean (SD) age was 67 (12) years; 65% were male. Five regimens were observed in 80% of patients: (1) cyclophosphamide-fludarabine-rituximab (21%); (2) rituximab monotherapy (17%); (3) bendamustine-combinations (20%); (4) chlorambucil monotherapy (13%); and (5) fludarabine-rituximab (9%). The remaining 20% of patients received other mono- or combination CLL therapies. A claim for CLL therapy was observed in 5.4 months of the 24 month post index period. Compared to cumulative 24-month pre-index HRU mean total costs ($32,644), post-index HRU mean total costs increased nearly 200% to $62,856 by 6 months and to $116,497 (nearly 350%) by 24 months. Mean outpatient cost, primarily from chemotherapy administration, was the greatest component of cost increase post-index. Mean pre-index outpatient cost $19,206 increased to $95,648 or nearly 500% in the 24 months post-index with greatest accrual intensity occurring in the 6-month post-index period ($53,983 or 289% increase). Mean inpatient costs 24 months pre-index were $8,328 and increased to $13,646 or 66% by 24 months post-index. Mean pharmaceutical costs were $4,588 pre-index, $2,182 at 6 months and $6,585 or 1.4 fold greater at 24 months post-index. Mean emergency room costs were $412 in the 24 months pre-index and $618 24 months post-index.

CONCLUSION: This analysis illustrates the significant HRU cost burden, driven by outpatient therapies most notably in the 6 months after therapy initiation, among CLL patients that received antineoplastic therapy.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C19 Cost of Treatment Failure in Patients with Chronic Lymphocytic Leukemia: Results of a Large U.S. Observational Study

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BACKGROUND: There is a large variation in survival among patients with chronic lymphocytic leukemia (CLL), driven by the fact that treatment for patients with CLL is often not curative and that most patients with CLL eventually experience disease progression, with limited treatment options.

OBJECTIVE: The objective of this retrospective observational study is to assess the cost of treatment failure (TF) in patients with CLL. This is achieved by comparing healthcare costs between patients with CLL who experienced TF and those who did not experience TF.

METHODS: Adult patients with ≥ 1 diagnosis of CLL and ≥ 1 claim for a medication used to treat CLL were identified in the IMS PharMetrics Plus database (January 2008-September 2013). Patients were excluded if they had evidence of a non-hematologic malignancy, used a non-CLL antineoplastic agent, or received a stem cell transplant during the 12-month baseline period. Initial therapy was defined as the single agent or the combination of medications used to treat CLL that was given to patients in the first 30 days following the 1st claim for a medication (index date) used to treat CLL. TF was identified based on earliest occurrence of one of the following events: initiation of a new treatment for CLL that was not part of the initial therapy, resumption of any CLL treatment following a minimum of 3-month break in treatment, radiotherapy, stem cell transplant, hospital mortality, or hospice care. Costs were reported in 2013 $US per patient per month (PPPM).

RESULTS: A total of 6,015 patients with CLL were identified (mean patient age: 63 years old; proportion female: 36%), of which 2,734 (45%) experienced TF. Average total cost PPPM was $7,850 for patients with TF and $4,555 for patients without TF. For patients with TF, average total cost PPPM was $6,721 during the initial therapy period and $8,404 during the period following TF. Once adjusted for baseline characteristics, average total cost difference between patients with and without TF was $3,757 PPPM (95% CI = 3,316, 4,175, P < 0.0001). For the subset of patients with index date 2010 onward, average total cost difference between patients with and without TF was $4,175 PPPM (95% CI = 3,407, 4,995, P < 0.0001).

CONCLUSION: Patients with CLL experiencing TF are associated with higher healthcare costs compared to those without TF. This difference is mainly driven by the high costs PPPM that are observed during the period following TF. These data help in our understanding of the cost burden of TF of patients with CLL.

SPONSORSHIP: Janssen Scientific Affairs, LLC.
**C20 Evaluation of Direct Medical Care Costs in First-Line and Relapsed Chronic Lymphocytic Leukemia (CLL)**

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**BACKGROUND:** Understanding the total cost of care for treatment of CLL, in both the first-line and relapsed setting, is essential for evaluating treatment options as new agents enter the market.

**OBJECTIVE:** This study focused on direct medical care costs of newly diagnosed and relapsed CLL patients.

**METHODS:** Using proprietary MORE Registry Research Edition Claims, patients with CLL therapy were retrospectively identified using ICD-9 codes (204.1, 204.10, 204.11, and 204.12) between August 2009 and August 2013. Patients with secondary malignancies, pregnancy codes, age <18, and patients with cost outliers at the highest and lowest 2.5% of the cost range were excluded. Wholesale Acquisition Cost (WAC) and Average Sales Price (ASP) were used for drug costs; Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Payment System (OPPS) were used for procedure costs. Descriptive statistics were used to analyze overall, outpatient, inpatient, and emergency room costs in the first-line and relapsed settings.

**RESULTS:** 2,013 CLL patients met inclusion criteria. Median age at diagnosis was 72 years, 61% were male, 67% Medicare, and 34% were treated in the relapsed setting. Outpatient cost, including chemotherapy cost, was the biggest cost driver (83% of the overall costs). Hospitalization and ER costs represented 12% and 5% of overall costs, respectively. The mean overall monthly cost in first-line CLL was $5,969 compared to $6,649 in the relapsed setting. Mean monthly outpatient costs ranged from $5,160 in first-line to $5,664 in the relapsed setting. Mean cost per hospitalization ranged from $11,956 in first-line to $12,345 in the relapsed setting, while mean cost per ER visit ranged from $3,170 in first-line to $3,141 in relapse. Twenty-nine percent of first-line patients and 40% of relapsed patients were hospitalized. Among those hospitalized, patients averaged 1.6 hospitalizations in first-line and 2.0 hospitalizations in relapse. A total of 32% of first-line patients and 40% of relapsed patients had ER visits. Among those with ER visits, patients averaged 2.0 visits in first line and 2.1 visits in relapse.

**CONCLUSION:** This retrospective cost of illness study in CLL established that relapse treatment costs are higher than first-line treatment costs, and outpatient costs are the largest component of the direct medical costs observed in CLL. This study provides important insight into the current economic landscape of CLL treatment. New and emerging therapies may potentially impact the cost of care in CLL by influencing both outpatient and inpatient costs.

**SPONSORSHIP:** Janssen Scientific Affairs, LLC.

**C21 Comparative Outcomes of Patients Newly Initiating First-Generation Versus Second-Generation Tyrosine Kinase Inhibitors for Chronic Myeloid Leukemia**

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**BACKGROUND:** Imatinib, a first-generation tyrosine kinase inhibitor (1GTKI), nilotinib and dasatinib, two second-generation TKIs (2GTKI), are approved by the FDA as first-line therapy for chronic myeloid leukemia (CML). Guidelines recommend first-line therapy with any of these agents, but no consensus exists for determining which agent should be used first.

**OBJECTIVE:** To examine the association between initiation of 1GTKI vs. 2GTKI and the following outcomes: treatment patterns, medication adherence, health services utilization, and direct health care costs.

**METHODS:** This was a retrospective cohort study of commercial and Medicare patients newly initiating 1GTKI or 2GTKI therapy for CML between June 1, 2010 and December 31, 2011. Treatment interruption and regimen changes were compared between patients initiating therapy with 1GTKI and 2GTKI using multivariable Cox proportional hazard regression models. Multivariate logistic regression was used to investigate the association between TKI therapy and adherence, defined as proportion of days covered ≥ 0.85. Multivariable logistic regression and generalized linear models (GLMs) were used to examine the association between TKI therapies and health services utilization and direct health care costs (plan and patient paid). All outcomes were assessed over 1 year.

**RESULTS:** Of the 368 patients included, 64% initiated therapy with a 1GTKI. 2GTKI use was associated with a higher risk of treatment interruption (hazard ratio: 1.48, 95% confidence interval [CI] 1.08-2.02). There was no difference in adherence between patients initiating a 1GTKI compared to a 2GTKI (odds ratio = 0.88, 95% CI 0.55-1.40). Outpatient visits were the most frequently used health service by both treatment groups, and were more common in the 2GTKI cohort (incidence rate ratio = 1.12, 95% CI 1.06-1.20). There were no statistically significant differences in emergency room visits or inpatient visits between patients initiating a 1GTKI versus 2GTKI. Total costs were 1.3 times higher for 2GTKI initiators versus 1GTKI initiators ($86,509 vs. $66,443, P = 0.001), and were attributed pharmacy costs.

**CONCLUSION:** Although treatment interruptions and outpatient visits were more common among patients initiating therapy with a 2GTKI, there were no differences in adherence among patients newly initiating 1GTKI versus 2GTKI. Patients initiating a 2GTKI incurred a higher TKI pharmacy and total costs than patients initiating a 1GTKI, which is likely to increase substantially with the impending release of generic imatinib.

**SPONSORSHIP:** This work was funded by the PhRMA Foundation. The funding organization had no role in the collection, interpretation, or reporting of the data and results. Humana, Inc., provided the data for the research.

**C22 Learnings from a Large Chart-Based Evaluation of Early Versus Advanced Breast Cancer as Identified Using Administrative Claims Data**

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**BACKGROUND:** Administrative claims databases typically lack tumor stage and many studies use secondary malignant neoplasm ICD-9 codes to identify early stage and metastatic disease from claims data. Accuracy of using a published claims-based algorithm for this purpose should be confirmed.

**OBJECTIVE:** Using tumor stage data obtained from medical records, confirm claims-based criteria used to impute staging of breast cancer.

**METHODS:** Patients were identified from 14 U.S. health plans between January 1, 2006-August 31, 2012 if they had ≥ 2 claims ≥ 30 days apart with codes for breast cancer (174.xx, 233.0x). Patients with lumpectomy or mastectomy claims and none for metastasis (196.0x-196.1x, 196.3x-196.5x, 196.8x, 197.0x-197.3x, 197.7x, 198.xx) were classified as early (eBC) and the remainder (with ≥ 2 claims metastasis
claims ≥ 30 days apart) as metastatic (mBC). Patients with < 6 months pre- and post-index plan eligibility, age < 18 and > 65 years, or other primary cancer were excluded. A randomly selected subsample from each group underwent medical record abstraction to obtain key clinical characteristics.

RESULTS: We identified 8,896 patients as eBC and 4,145 as mBC, mean ages, 50.5 and 50.9 years, respectively. Medical records were abstracted for 300 patients from each group. Tumor stage was documented in 74.3% of eBC and 75.3% of mBC patients. Among eBC, no patients had stage IV, 30.3% had stage I, 36.3% had stage II and 7.3% had stage III. Among mBC, 15% of patients had stage IV, 4.3% stage I, 33.7% stage II and 21.3% stage III. Clinical review of a randomly selected subset (n = 30) of the charts from the mBC group was followed by a claims-level review of mBC patients whose charts showed no metastasis. Claims showed that false positives included the ICD-9 code 196.3. Of 300 mBC patients with data from medical record abstraction, 102 were identified without the 196.3 code and 33% of those had stage IV disease.

CONCLUSION: Chart review of patients classified as early or late stage breast cancer from claims showed that exclusion of standard metastasis codes and inclusion of lumpectomy/mastectomy codes was a successful algorithm for identifying early stage. ICD-9 code 196.3 is typically included in claims-based analyses to identify late stage cancer. Breast cancer is unique since tumor involvement of axillary lymph nodes may represent earlier stage disease. The code 196.3 is challenging because it includes axillary and more distant upper extremity lymph node involvement. Exclusion of eBC patients and inclusion of metastatic claims only is not sufficient to identify patients with late disease, even when excluding the 196.3 code.

SPONSORSHIP: Genentech, Inc.

A Comparison of Annual Treatment Costs of rFIX Versus rFIX-Fc in the U.S.

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BACKGROUND: Two novel therapies (recombinant factor IX (rFIX), Rixubis and rFIX-Fc, Alprolix) were recently approved in the U.S. for the treatment of hemophilia B and have demonstrated similar efficacy and safety in clinical trials (Wynnyka, 2014; Powell, 2013). Therefore, an analysis of the cost of treatment between these therapeutic options for hemophilia B is warranted.

OBJECTIVE: To assess the annual treatment cost for hemophilia B patients prescribed prophylaxis or on-demand treatment with rFIX or rFIX-Fc.

METHODS: A model was developed to analyze the yearly cost of treatment for a hemophilia B patient prescribed a rFIX or rFIX-Fc. Costs for prophylaxis treatment were derived using the average dose recommended in both pivotal trials. For on-demand treatment of minor, moderate, and major bleeding episodes, costs were calculated using the average recommended dose in each product label as well as the number of infusions required to treat a bleeding episode in each product’s pivotal trial.

RESULTS: Annual prophylaxis treatment cost for rFIX-Fc once weekly was similar to that of rFIX twice weekly ($7,435 vs. $7,305 per kg/year, respectively). However, rFIX-Fc prescribed every 10 days was 43% more expensive than rFIX twice weekly ($10,410 per kg/year). When treating on-demand, rFIX-Fc was 166%, 78% and 77% more expensive than rFIX twice weekly for minor, moderate, and major bleeding episodes, respectively. The total annual cost savings with rFIX relative to rFIX-Fc for the patient treated on-demand was magnified as bleeding episodes occurred throughout the year.

CONCLUSION: This analysis suggests that rFIX may be a more cost-saving than rFIX-Fc when following labeled dosing recommendations for both products and considering similar median annual bleed rates reported in both pivotal trials. Further analysis is encouraged to understand how total treatment costs may vary when considering prescribing differences in real-world practice for the hemophilia B population.

D4 Real-World Dosing of Factor VIII in Hemophilia A Patients

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BACKGROUND: Regular replacement of coagulation factor VIII to prevent bleeding is the standard of care in hemophilia A and requires frequent intravenous infusions. Real-world data describing prophylactic dosing regimens of recombinant FVIII are limited.

OBJECTIVE: To analyze real-world FVIII dosing and treatment interval patterns in patients with hemophilia A and to compare the observed dosing patterns with the dosing regimens for rFVIII and rFVIIIFc evaluated in clinical studies.

METHODS: A retrospective analysis was conducted using aggregate Specialty Pharmacy Provider (SPP) records from November 2013 through March 2014. SPP data included 63 different attributes for each prescription, including NDC, drug quantity shipped, prescribed infusion dose, days supplied, and dose frequency. Patients were considered eligible if they received a shipment of any FVIII product. Patients were excluded from the analysis if they were being treated episodically, for immune tolerance induction, or their pharmacy records did not specify a prescribed infusion dose. Patients with missing or extremely abnormal weights were also excluded. The patient’s weekly consumption was calculated for each shipment record by multiplying the prescribed infusion dose by the dose frequency and dividing the product by the patient’s weight, resulting in the patient’s average weekly prescribed dose (IU/kg/week).

RESULTS: The analysis included 520 hemophilia A patients with a median age of 18 and median weight of 63.5 kg. Pharmacy dispensing records represented 277 distinct prescribers across 43 states. FVIII therapies evaluated included Advate, Recombinate, Helixate FS, Kogenate, Hemofil and Xyntha. The average weekly consumption across all therapies was 108.0 IU/kg/week (95% CI, 104.6-111.5). Dosing frequency ranged from once-daily to once-weekly with three times/week and every other day as the most common dosing intervals, representing 81.3% of patient records. For patients dosing thrice-weekly, the average infusion dose was 35.1 IU/Kg. Only 13.4% of the population was dosing ≤ two times per week. Clinical trials for Advate report weekly consumption of 110.3 IU/kg (31.4 IU/kg administered QOD). Two prophylactic regimens were evaluated for rFVIIIFc in A-LONG. The median weekly consumption was 77.7 IU/kg for the individualized prophylaxis and the median weekly dose of 63.5 IU/kg for the prophylactic prophylaxis regimen.

CONCLUSION: Pharmacy dispensing records support the clinical trial dosing intervals of rFVIII products currently requiring every other day or thrice-weekly dosing, however, real-world dosing of current therapies (IU/kg/week) may be greater.

SPONSORSHIP: Biogen Idec, Inc.

E1 Clinical Utilization of Anti-VEGFs in the Treatment of Diabetic Macular Edema: A Claims-Based Analysis

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BACKGROUND: Previous research has reported vascular endothelial growth factor antagonist (anti-VEGF) utilization patterns in diabetic macular edema (DME) patients initiating treatment in the years 2008-2010 to be significantly lower in clinical practice than the monthly dosing utilized in most randomized clinical trial (RCT) protocols. Patients initiating anti-VEGF therapy for DME in 2010 had a mean of 3.6 injections over 12 months and less than 6% of patients received 10 or more injections over 12 months. More recent data are needed to examine if anti-VEGF utilization patterns have changed significantly with time.

OBJECTIVE: To update previous analyses and estimate the utilization of anti-VEGF therapy in patients with DME in clinical practice.

METHODS: This administrative claims analysis used the Truven Health Analytics MarketScan Commercial Claims and Medicare Supplemental data and included adult patients newly diagnosed with DME treated with anti-VEGF intravitreal injection therapy initiated
between January 1, 2009 and December 31, 2011. The patient’s first DME diagnosis (index diagnosis) was required to be within 12 months before the first anti-VEGF injection (index drug event). Patients were required to have a follow-up period of at least 12 months from the index drug event. Overall and specific anti-VEGF (bevacizumab or ranibizumab) utilization was assessed by year of first injection. The main outcome measure was mean annual numbers of injections.

RESULTS: A total of 3,002 DME patients treated with anti-VEGFs met the eligibility criteria. The average age of the cohort was 60 years with 40% of patients aged between 55 and 64 years. Males comprised 54% of the cohort. Across the 2009, 2010, and 2011 initiation cohorts, mean annual numbers of anti-VEGF injections increased but remained low (2.8, 3.7, 4.0, respectively; overall mean = 3.7 injections). Approximately 63% of patients received ≤ 3 injections in 12 months, while 7% received 10 or more injections.

CONCLUSION: The current analysis provides updated utilization estimates for anti-VEGF use in the treatment of DME that are consistent with earlier trends. Patients receive fewer anti-VEGF injections than in major clinical trials of ranibizumab.

SPONSORSHIP: None.

E3 The Impact of Sitagliptin Prior Authorization on Hemoglobin A1c Values in Type 2 Diabetes Mellitus
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BACKGROUND: Health plans regularly implement management strategies such as prior authorizations to aid in appropriate drug use and help control drug expense; however, the impact of these strategies on clinical outcomes are often unknown. The management of type 2 diabetes mellitus (T2DM) requires treatment regimens to be based on patient- and agent-specific characteristics as well as drug cost. Prior authorizations can limit immediate access to a particular drug until coverage criteria are met and this may hinder achieving treatment objectives.

OBJECTIVE: To evaluate the relationship between sitagliptin prior authorization and Hgb A1c values in T2DM.

METHODS: A retrospective cohort study of commercial members was conducted using pharmacy and laboratory claims data. Members were required to have a coverage request for sitagliptin between January 2012 and July 2012 and been continuously enrolled in the health plan 12 months before and after the coverage request. Two cohorts were identified: (1) coverage request approved and (2) coverage criteria not met. The primary endpoint evaluated the change in A1c values before and after coverage request for each cohort. The secondary endpoints evaluated drug compliance and drug therapy in members who did not meet coverage criteria and in members who did not fill a prescription for sitagliptin following its approval.

RESULTS: There were 206 members included with 120 members (58.3%) in the approval cohort. At baseline, the cohort of members who did not meet coverage criteria had more members with an A1c greater than 9% (29% vs. 19%) and less members receiving insulin therapy (6% vs. 15%) compared to the approval cohort (0.1% reduction). In members where coverage criteria was not met, the most commonly added drugs were thiazolidinediones (18%) and sulfonylureas (18%) while 45% of members did not receive another anti-diabetic agent. There were 27% of members in the approval cohort that did not fill a prescription for sitagliptin following its approval.

CONCLUSION: Sitagliptan prior authorization did not appear to negatively impact Hgb A1c values in T2DM members. Members who did not meet coverage criteria saw a greater reduction in Hgb A1c values following the coverage request compared to those in the approval cohort. Further investigation is needed to determine clinical outcomes beyond Hgb A1c values when management strategies are implemented.

SPONSORSHIP: None.
Simulation Study of Switching Among Diabetes Medications Associated with Differential Adherence: Impact on Prescription Drug Plan Rankings for Medicare Star Ratings Measure D13—Medication Adherence for Diabetes Medications

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BACKGROUND: The Centers for Medicare & Medicaid Services uses a series of measures related to quality of care and service, known as the Star Ratings system, to assist consumers with comparing Medicare health and prescription drug plans (PDPs). Measure D13-Medication Adherence for Diabetes Medications (MD13) evaluates PDPs on the proportion of members who fill their oral diabetes prescriptions often enough to cover ≥80% of days over 12 months. MD13 is calculated across biguanides, sulfonylureas (SUs), thiazolidinediones (TZDs), and dipeptidyl peptidase-4 inhibitors (DPP-4is). Recently published data showed that patients with type 2 diabetes mellitus taking DPP-4is were significantly (P < 0.05) more likely to achieve this 80% threshold than those taking SUs or TZDs (by 12% points and 11% points, respectively). Among DPP-4is, those taking saxagliptin were significantly (P < 0.05) more likely to achieve the threshold than those taking sitagliptin (by 4.5% points).

OBJECTIVE: The present study simulated changes in plan rankings for MD13 that may result from switching patients from SUs, TZDs, and DPP-4 is to either sitagliptin or saxagliptin; for DPP-4 is, patients switch from sitagliptin to saxagliptin or vice versa.

METHODS: Data included the 2013 Medicare PDPs % values and rankings for MD13, diabetes medication market share in Medicare, and the aforementioned data on adherence differences. For each PDP, the baseline 2013 value for MD13 was used to calculate a new value under the assumption that all patients treated with an SU, TDZ, or DPP-4i were switched to either sitagliptin or saxagliptin. Estimated changes in the values for MD13 were proportional to medication market shares and the difference in the probability of patients achieving the 80% threshold between the medications.

RESULTS: Among 547 PDPs with available 2013 MD13 data, the mean (median, standard deviation [SD]) MD13 value was 75% (76%, 6%). PDPs were highly concentrated at the center of the distribution, with 123 PDPs ranking from 74% to 76%. In simulations of switching to sitagliptin, MD13 values increased by 3.7% points, resulting in a mean (median, SD) increase in MD13 rankings of 95 (103, 45) ranks; simulations for saxagliptin yielded even larger increases of 5.8% points and 140 (151, 67) ranks.

CONCLUSION: Modest differences in adherence may substantially impact PDP rankings for MD13. This simulation, which assumes causal inference, underscores a unique benefit of the use of diabetes medications that are associated with the greatest levels of adherence.

SPONSORSHIP: None.

Discontinuation and Adherence for Sitagliptin Versus Sulfonylurea as Add-On to Metformin

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BACKGROUND: Limited data exist on medication discontinuation and adherence for dipeptidyl peptidase-4 (DPP-4) inhibitors compared to other oral antihyperglycemic agents (OAHAs).

OBJECTIVE: To our knowledge this is the only U.S. study evaluating discontinuation and adherence with sitagliptin (SITA) vs. sulfonylurea (SU) as add-on to metformin (MET).

METHODS: This was a retrospective cohort study using a U.S. health-care claims database (MarketScan 2009-11). Eligible T2DM patients were age ≥18 years, with continuous enrollment for ≥12 months (baseline) prior to first SITA or SU script date (index date), with ≤45 days gap in MET coverage within 90 days before the index date and ≥1 MET script within 90 days after the index date, not pregnant, without moderate/severe renal impairment and had no other OAHAs at baseline. SITA and SU users were matched on length of follow-up and then propensity score matched on age, gender, proportion of days covered (PDC) for baseline MET use, concomitant medications and comorbidities. Differences in time to discontinuation (from index date up to 51 months) between SITA and SU users were assessed using Kaplan-Meier (KM) curves and Cox regression accounting for cluster-
ing due to matching. A linear regression with generalized estimating equation and conditional logistic regression examined the PDC and % adherent (PDC≥80%), respectively in each of years 1-3 post index. All models adjusted for copays (out-of-pocket expenses) made for SITA and SU prescriptions.

RESULTS: 14,886 pairs of SITA or SU users were matched with mean (SD) age 56.2 (10.6) years, 54.7% male, and mean baseline MET PDC 80% (20%). Median time to discontinuation was ~100 days shorter for SU (885 days) vs. SITA (984 days). SITA patients were less likely to discontinue compared to SU patients based on survival analysis (HR: 0.84, 95% CI: 0.81-0.88). PDC was 4.8%, 4.2%, 4.0% greater for SITA vs. SU in each of years 1-3 post index (all P<0.001). SITA users were significantly more likely to be adherent (adjusted odds ratio [aOR]: 1.39, 95% CI: 1.29-1.50; [aOR]: 1.38, 95% CI: 1.24-1.54; [aOR]: 1.34, 95% CI: 1.13-1.58) compared to SU users in each of years 1-3 post index.

CONCLUSION: In conclusion, patients on SU as add-on to MET discontinued sooner and had lower treatment adherence than patients on SITA as add-on to MET. Further research is needed to assess the clinical impact of these observed differences and reasons for discontinuation.

SPONSORSHIP: Merck & Co., Inc.
E10 Demographic and Clinical Characteristics of Type 2 Diabetes Mellitus Patients Initiating Canagliflozin in a U.S. Managed Care Population

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BACKGROUND: Canagliflozin is the first sodium glucose co-transporter 2 (SGLT2) inhibitor—a new class of oral antidiabetic (OAD) medication—approved for the treatment of type 2 diabetes mellitus (T2DM) in the U.S. Little is known about the utilization of canagliflozin in a real-world environment.

OBJECTIVE: To investigate demographic and clinical factors of patients initiating canagliflozin therapy in a large commercially insured U.S. population.

METHODS: A retrospective claims study was conducted on adult patients identified from the HealthCore Integrated Research Database. Patients with ≥1 medical claim indicating a diagnosis of T2DM and ≥1 pharmacy claim for canagliflozin between January 1, 2011 and September 30, 2013 were included. Index date was set as the date of the first SGLT2 claim, and patients were required to have ≥12 months of health plan enrollment pre-index date (baseline period). Patient demographics and clinical characteristics were assessed descriptively using ICD-9-CM codes. HbA1c measurements at baseline were available for a subgroup of patients.

RESULTS: We identified N=1,566 patients with claims for canagliflozin. Mean age (SD) was 54.0 (8.51) years and 62% of patients were male. The prescribing physicians were mostly endocrinologists (41%) followed by primary care physicians (29%). At baseline, 70% of patients were receiving ≥1 other OAD, primarily metformin (64%), sulfonylureas (46%) and DPP-4 inhibitors (25%), while 25% of patients had fills for insulin and 31% for GLP-1 receptor agonists. Dyslipidemia (74% of patients with ≥1 fill) and antihypertensives (73%). Of the patients with HbA1c results available at baseline (N=521), 80% had HbA1c <7% with a mean (SD) HbA1c of 8.5% (1.65).

CONCLUSION: In this sample of commercially insured patients associated with a large managed care plan, canagliflozin was often initiated as a second- or third-line therapy, with a relatively high share of patients receiving concomitant antidiabetic injectables. These patients also had higher HbA1c levels prior to initiation and were frequently diagnosed with other metabolic syndrome conditions. Future research is needed to examine changes in real-world clinical outcomes after canagliflozin initiation.

SPONSORSHIP: Eli Lilly and Company

E11EM Understanding Clinical Pharmacists’ Roles in Seeing Patients with Controlled Diabetes: A Retrospective Decision-Tree Model Approach

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BACKGROUND: Numerous studies have found favorable therapeutic results when incorporating pharmacist-provided direct care in the management of type 2 diabetes mellitus (T2DM). Pharmacists, however, are an expensive resource and it is imperative that their services be used in a cost-effective manner.

OBJECTIVE: To determine pharmacist’s intervention in patients with controlled and uncontrolled diabetes, with an objective to identify and improve clinical pharmacy resource allocation

METHODS: 572 eligible patients with diabetes (defined as having their first visit with a pharmacist between January 1, 2011 to June 30, 2011) were selected from the University of Michigan Health System Patient-Center Medical Home (PCMH) clinics. These patients were categorized as well-controlled (HbA1c ≤8%) or poor-controlled (HbA1c >8%). Clinical pharmacists’ interventions (therapeutic interventions, medication reconciliation, and other interventions) were quantified from the PharmD Intervention Checklist and a decision tree model was created for patients with well-controlled diabetes. The decision tree considered these individuals based on the number of pharmacist visits, comparing individuals with one visit versus multiple visits.

RESULTS: Among the eligible PCMH patients (N=572), 321 had an index HbA1c value. Of the 321 patients, 52.0% (N=167) had controlled HbA1c and 48.0% (N=154) had uncontrolled HbA1c. Patients with uncontrolled diabetes received more therapeutic and patient education interventions (P<0.001). Using the decision model of patients with controlled diabetes, 67.1% (N=112) had multiple visits and 32.9% (N=55) had one visit. Among these patients, 1.8% and 19.6% received any hypertension interventions (one visit versus multiple visits, P=0.001), and 0% and 10.7% received any hyperlipidemia interventions (one visit versus multiple visits, P=0.007). The multiple visits group had a higher number of total non-therapeutic interventions compared to patients with one visit (9.33 versus 1.20, P<0.001), this finding was driven by patient education services. Only 3.0% (N=5) of patients with controlled HbA1c received unknown interventions.

CONCLUSION: Overall, patients with uncontrolled diabetes compared to controlled diabetes received more therapeutic and patient education interventions. PCMH clinical pharmacy services were efficiently allocated among patients with controlled diabetes, as they received other clinically meaningful interventions. Pharmacists may provide important interventions to individuals with controlled diabetes.

SPONSORSHIP: This research was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number 2TL1TR000435.

E12 A Personalized-Medicine Approach to Evaluate Real-World Treatment Benefits of Patients with Type 2 Diabetes Mellitus (T2DM) Initiating Different Injectable Therapies

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BACKGROUND: In real-world studies it is difficult to determine how much of the difference in outcomes between alternative therapies is due to treatment effects or to differences in patients’ baseline (BL) characteristics.

OBJECTIVE: Decomposition, a statistical methodology that addresses this issue, was applied in the Initiation of New Injectable Treatment Introduced after Anti-diabetic Therapy with Oral-only Regimens (INITIATOR) study.

METHODS: Healthcare claims were extracted from databases affiliated with 2 national health insurers (Optum and HealthCore) and were linked to medical chart data. Adult patients with type 2 diabetes mellitus (T2DM) were identified who were previously on oral drugs (OADs) only, had hemoglobin A1c (A1C) ≥7%, initiated insulin glargine via disposable pen (GLA) or the glucagon-like peptide-1 receptor agonist...
liraglutide (LIRA) between April 1, 2010 and March 31, 2012, and had healthcare coverage during the 6 months before (BL) and 1 year after initiation. One-year reduction (Δ) in AIC from BL and treatment persistence were modeled; differences in outcomes between GLA and LIRA were decomposed into the “explained” part due to differences in BL characteristics and the “unexplained” part due to differences in treatment effects.

RESULTS: A total of 3,773 patients were included (women 43.9%; mean age 52.5 years; mean OAD count 2). At 1-year follow-up, ΔAIC was higher in patients on GLA by 0.65% (GLA -1.39%; LIRA -0.74%). Decomposition analysis showed that this was largely due to differences in BL characteristics (-0.73%; P<0.001) rather than differences in treatment effects (0.09%; P=0.434). However, heterogeneity in treatment effects was found: patients with BL AIC ≥9% or mental illness had higher ΔAIC when on GLA, while those with polypharmacy of 6-10 classes or BL hypoglycemia had higher ΔAIC when on LIRA. One-year treatment persistence was also higher in GLA by 16.1% (GLA 64.8%; LIRA 48.7%). Decomposition analysis showed that this was largely due to differences in treatment effects (17.9%; P<0.001) rather than BL characteristics (-1.8%; P=0.215). Heterogeneity in treatment effects was found such that patients who were older, had BL AIC ≥9%, had 3 BL OADs, or had polypharmacy >10 classes were more persistent if on GLA, while those who were younger or had BL AIC <8% were more persistent if on LIRA.

CONCLUSION: This study showed the feasibility of using decomposition analysis to identify factors that influence response to treatment and to explore personalized medicine via heterogeneity in treatment effects in observational studies.

SPONSORSHIP: Study funding and editorial support provided by Sanofi U.S., Inc.
CONCLUSION: These findings suggest that T2DM patients initiating GLA or LIRA in the managed-care setting had clinically and statistically significant differences in their BL characteristics and follow-up outcomes. This highlights challenges when one uses randomized clinical trial results for real-world healthcare decision making.

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

Impact of Switching Basal Insulin Analogs on Clinical and Economic Outcomes in Patients with Type 2 Diabetes in a National Managed Care Plan Setting

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BACKGROUND: Few studies have examined switching between basal insulin analogs among patients with type 2 diabetes mellitus (T2DM).

OBJECTIVE: To evaluate real-world treatment patterns and compare outcomes of patients with T2DM switching between insulin glargine (GLA) and detemir (DET).

METHODS: We examined 2 cohorts of adult (≥18 years) T2DM patients from the ClinformaticsM DataMart database, affiliated with a national managed care plan, between 2006 and 2013. Patients in Cohort 1 received GLA and then either continued GLA (GLA-C) or switched to DET (DET-S). Patients in Cohort 2 received DET and then either continued DET (DET-C) or switched to GLA (GLA-S). The index date was the first day of the switch for switching patients, and a randomly selected index insulin claim date for continuing patients. Patients had continuous health-plan enrollment ≥6 months before (baseline) and ≥12 months after (follow-up) the index date, and had baseline hemoglobin Alc (A1C) data available. One-year follow-up outcomes included insulin treatment persistence/compliance, A1C, hypoglycemia events, and healthcare costs. Selection bias was minimized by: 1. up to 5 (Cohort 1) or 1: up to 2 (Cohort 2) propensity score matching (PSM).

RESULTS: Overall, 2,193 patients (Cohort 1: n = 1,705; Cohort 2: n = 488) were included (46.5% women; mean baseline age 53 years; A1C 8.7%). After PSM, baseline characteristics within each cohort were balanced between groups. At 1-year follow-up, GLA patients were more persistent and compliant than DET patients whether continuing on GLA or switching from DET (persistence: GLA-C 59.8% vs. DET-S 46.7%, P = 0.005; DET-C 47.6% vs. GLA-S 57.9%, P = 0.031; compliance (adjusted medication possession ratio): GLA-C 0.76 vs. DET-S 0.66, P < 0.001; DET-C 0.70 vs. GLA-S 0.79, P = 0.002), had higher A1C reduction (GLA-C -0.60% vs. DET-S -0.11%, P = 0.1535; DET-C -0.27% vs. GLA-S -0.78%, P = 0.009), and similar hypoglycemia rate and healthcare costs. In addition, GLA-C patients had lower daily dose and rapid-acting insulin use than DET-S patients (46.9 vs. 52.7 U/day, P = 0.02; 52.5% vs. 61.3%, P = 0.006, respectively). In Cohort 1, 28.6% of DET-S patients switched back to GLA; in Cohort 2, 15.2% of GLA-S patients switched back to DET.

CONCLUSION: This real-world study of T2DM patients in a national managed care plan showed that GLA users, whether continuing on GLA or switching from DET, were more persistent and compliant than DET users and had improved clinical outcomes. It is suggested future pragmatic clinical studies be conducted to test the therapeutic exchangeability of GLA and DET.

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

E15 Maintenance Therapy Adherence Rates as a Function of Distribution Channel in a Medicare Population

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BACKGROUND: Regular use of maintenance medications for chronic medical conditions has the potential to decrease medical costs and reduce avoidable hospitalizations.

OBJECTIVE: This study investigates whether member-selected distribution channel (mail order-only vs. retail-only) is associated with higher medication adherence.

METHODS: Orally administered maintenance medication therapies for diabetes, hypertension, and hyperlipidemia were measured using proportion of days covered (PDC). The study was conducted using the pharmacy claims for the Humana Medicare members enrolled in the plan in 2011-2012 with at least two fills for the same maintenance therapy medication during the calendar year 2012 and having at least 6 months of continuous enrollment before and after the first fill. Members were self-assigned to mail-only or retail-only based on the distribution channel they selected to use to fill their prescriptions.

RESULTS: Members who relied solely on mail order pharmacies had higher adherence (PDC ≥ 80% = fully adherent) across all three therapeutic classes compared to the members who relied solely retail pharmacies (diabetes: 90.0 vs. 68.8%; hypertension: 91.4 vs. 75.7%; and hyperlipidemia: 89.5 vs. 71.3%, respectively, P ≤ 0.05). The groups were then matched on their demographic characteristics using propensity score matching but the differences between the two groups on adherence rates remained (diabetes: 90.0 vs. 69.5%; hypertension: 91.4 vs. 76.2%; and hyperlipidemia: 89.5 vs. 71.0%, respectively, P ≤ 0.05).

CONCLUSION: These findings suggest that the distribution channel for maintenance therapies impact adherence rates. The mail-order channel generated more adherent members than the retail channel.

SPONSORSHIP: Comprehensive Health Insights and Humana, Inc.

E16 Association of Pharmacy Dispensing Channel with the Use of Renin Angiotensin System Antagonist Among Medicare Part D Patients Having Diabetes and Hypertension

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BACKGROUND: Diabetes treatment is one of the Part D safety star rating measures used by the Centers for Medicare & Medicaid Services (CMS) for evaluation of the quality of care received from Part D plans. This measure recommends that Medicare patients using antidiabetics and antihypertensives should also receive renin angiotensin system (RAS) antagonists. Efforts to improve the quality of care merit exploring solutions that provide greater alignment with recommended guidelines for Medicare patients.

OBJECTIVE: Examine association of pharmacy dispensing channel (home delivery or retail) with being a RAS antagonist user among Medicare Part D patients on antidiabetics and antihypertensives; controlling for various confounders.

METHODS: A retrospective analysis using de-identified pharmacy claims data from a large national pharmacy benefits manager between January 1, 2013 and December 31, 2013. Continuously eligible Medicare Part D patients (MAPD and PDP) aged 65 years or older who had at least one prescription claim for an antidiabetic and an antihypertensive in 2013 were identified. Patients who received at least one
**CONCLUSION:**

Using retail channels to obtain their prescriptions.

The adjusted odds of being a RAS antagonist user for patients using home delivery was 1.30 [CI = 1.26-1.34] higher compared to patients using retail channels depending on where they filled at least 66.7% of their 30-day adjusted prescriptions for antidiabetics and antihypertensives and the rest were assigned mixed group. Multivariate logistic regression was used to evaluate the association between dispensing channel and utilization of RAS antagonists in 2013 controlling for differences in demographics, low income subsidy status, out-of-pocket cost burden, number of 30-day adjusted prescriptions for antidiabetics and non-RAS antagonist antihypertensives, geographic region and plan type.

**RESULTS:**

The final analytical sample consisted of 548,605 patients. The adjusted odds of being a RAS antagonist user for patients using home delivery was 1.30 [CI = 1.26-1.34] higher compared to patients using retail channels to obtain their prescriptions.

**CONCLUSION:**

Medicare Part D patients on antidiabetics and antihypertensives who used home delivery had greater likelihood (adjusted) of being a RAS antagonist user than patients who filled their prescriptions at retail. Managed care stakeholders looking to implement solutions that improve quality of care should consider the use of home delivery to ensure the use of appropriate blood pressure medications for patients with diabetes.

**SPONSORSHIP:** Pfizer, Inc.

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**E18 Incremental Healthcare Resource Utilization and Costs in U.S. Patients with Cushing’s Disease Compared with Diabetes and Population Controls**

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**BACKGROUND:**

Painful diabetic peripheral neuropathy (pDPN) is a costly chronic neuropathic pain condition affecting 10-26% of diabetes patients.

**OBJECTIVE:**

To compare medical and pharmacy healthcare utilization and costs for pDPN patients whose treatment was adherent versus non-adherent to pain management guidelines.

**METHODS:**

This retrospective cohort study used MarketScan claims databases (commercial and Medicare insurance) to identify patients age ≥ 18 treated and newly diagnosed with pDPN from July 1, 2010-June 30, 2012. The index date was the first pDPN diagnosis claim in combination with the first prescription pain medication, with continuous enrollment 12 months before and after index. Patients’ treatment was categorized into three levels of adherence to recommended pharmacologic pain management guidelines (adherent, non-adherent, unsure) during the post-index period, by designating pain medications as first line, later line, and not recommended. Medical and pharmacy utilization and costs were compared between the adherent and non-adherent populations by implementing descriptive statistics with t-tests and chi-square tests.

**RESULTS:**

Of 10,645 pDPN patients, 6,338 (60%) were treated in a manner adherent to guidelines, 3,713 (35%) non-adherent, and 594 (5%) unsure. Overall, mean age was 62.2 years, 50.1% were male, and the majority (63.3%) commercially insured. A significantly higher proportion of adherent patients were treated with antidepressants (61.3% vs. 41.7%), antiepileptic drugs (80.7% vs. 29.5%) and a lower proportion used an opioid (71.5% vs. 96.1; all P < 0.001). Mean total healthcare costs in adherent patients were $44,045 [$64,073] compared with $55,662 [$83,694] for patients non-adherent to guidelines (P < 0.001), driven primarily by inpatient admissions costs (adherent cohort $17,888 [41,885]; non-adherent $26,217 [55,680]; P < 0.001). Mean pain-related pharmacologic costs were more than twice as high in the adherent population versus the non-adherent group ($1,586 [$5,183] vs. $735 [$2,352]), driven by higher mean numbers of prescriptions (12.0 [8.6] vs. 8.0 [7.1]), yet lower for opioids (5.4 [6.6] vs. 6.2 [6.2]), all P < 0.001.

**CONCLUSION:**

For pDPN patients, adherence to pain management guidelines is associated with lower total healthcare costs in spite of higher utilization of pain medications (other than opioids) compared with patients whose treatment does not follow the treatment guidelines. These data suggest potential cost savings and lower opioid utilization may occur with better adherence to the treatment guidelines recommendations.

**SPONSORSHIP:** Pfizer, Inc.

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**E19 Comparison of Medical and Pharmacy Costs Between Adherence and Non-Adherence to Pain Management Guidelines for Patients with Painful Diabetic Peripheral Neuropathy**

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**BACKGROUND:**

Painful diabetic peripheral neuropathy (pDPN) is a costly chronic neuropathic pain condition affecting 10-26% of diabetes patients.

**OBJECTIVE:**

To compare medical and pharmacy healthcare utilization and costs for pDPN patients whose treatment was adherent versus non-adherent to pain management guidelines.

**METHODS:**

This retrospective cohort study used MarketScan claims databases (commercial and Medicare insurance) to identify patients age ≥ 18 treated and newly diagnosed with pDPN from January 1, 2008 to December 31, 2012, matching CD patients to DM patients and population controls by age, gender, region, and review year in a 1:2 ratio each. We examined healthcare utilization (i.e., total number of hospitalizations, emergency department [ED] visits, physician office visits, and prescription fills) and costs during a 1-year timespan for each patient.

**RESULTS:**

There were 1,852 CD patients in this study, with 3,704 matched DM patients and 3,704 matched controls. Mean age was 42.9 years and 78.2% were female. CD patients were hospitalized significantly more frequently (19.3%) than DM patients (11.0%, P < 0.001) or controls (5.6%, P < 0.001). CD patients also visited the ED significantly more often (25.4%) than DM patients (21.1%, P < 0.001) or controls (14.3%, P < 0.001). CD patients had a mean 19.1 office visits, more than DM patients (10.7, P < 0.001) or controls (7.1, P < 0.001). CD patients filled 51.7 prescriptions on average, more than DM patients (42.7, P < 0.001) or controls (20.5, P < 0.001). Mean total healthcare costs for CD patients were $26,269, versus $12,282 for DM patients (P < 0.001) and $5,869 for controls (P < 0.001).

**CONCLUSION:**

CD patients had significantly higher annual rates of healthcare resource utilization compared to matched DM patients and population controls without CD, including more hospitalizations, ED visits, office visits, and filled prescriptions. Moreover, the costs of CD patient care were double that for DM patient care and quadruple that for controls. This study puts into context the additional burdens of
CD over DM, a common, chronic endocrine condition which may also affect multiple organ systems, and population controls.

**SPONSORSHIP:** Novartis Pharmaceuticals Corporation.

**E21** Daily Maintenance Dose of Topical Testosterone Agents Among Hypogonadal Men in Commercial and Medicare Setting

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**BACKGROUND:** Topical testosterone agents (TTAs) are commonly used to raise low levels of serum testosterone in Hypogonadal (HG) men. A recent study estimated real-world maintenance dose of TTAs in commercially insured population.

**OBJECTIVE:** Confirm findings from a previous study on daily maintenance dose of TTAs in a larger commercially insured HG men cohort and expand the study to Medicare Supplemental population.

**METHODS:** Adult men with HG-associated diagnoses initiated at a recommended starting dose (RSD) with Axiron (Lilly USA, LLC; 60 mg per day; N=2602), AndroGel 1% (50 mg per day; N=3847), AndroGel 1.62% (40.5 mg per day; N=5521), Testim (50 mg per day; N=2873), or Fortesta (40 mg per day; N=992) between June 1, 2011 and June 30, 2012 were identified in an insurance claims database. Patients were required to have continuous eligibility and no claims of the index therapy in 12 months prior to and at least 6 months of continuous eligibility following initiation. Baseline demographic characteristics and comorbidities were compared among TTAs using a chi-squared test for categorical and a one-way analysis of variance for continuous variables. Mean dose was calculated per-person per-day (PPPD). Risk-adjusted dose PPPD was estimated from a general linear model, adjusting for treatment cohorts, and statistically significant baseline characteristics and comorbidities.

**RESULTS:** A majority of the study population (N=14,482, 91.5%) were insured commercially. Patient mean age and health status was comparable across cohorts. Maintenance dose was defined at month 4 by previous research. In commercially insured HG men at month 4, mean dose PPPD was 64.9 mg, 54.7 mg, 48.5 mg, 56.7 mg, 43.1 mg, and the risk-adjusted dose PPPD was 98.0%, 101.0%, 119.7%, 104.6%, 110.5% of RSD for Axiron, AndroGel 1%, AndroGel 1.62%, Testim, and Fortesta (P=0.155, P<0.001, P=0.105 vs. Axiron, respectively. In Medicare Supplemental HG men at month 4, mean dose PPPD was 63.0 mg, 55.4 mg, 46.1 mg, 53.8 mg, 42.6 mg, and the risk-adjusted dose PPPD was 98.7%, 109.7%, 119.1%, 104.7%, 113.0% of RSD for Axiron, AndroGel 1%, AndroGel 1.62%, Testim, and Fortesta (P=0.201, P=0.061, P=0.983, P=0.957 vs. Axiron), respectively.

**CONCLUSION:** This real-world study confirmed maintenance dose as a proportion of RSD was the least among Axiron patients in commercially insured HG men. The similar trend was observed in Medicare Supplemental population. Small sample size reduced statistical power in the Medicare sample.

**SPONSORSHIP:** Eli Lilly and Company.

**E22** The Economics of Anti-Obesity Treatment: Evaluating the Budget Impact to Payers in the United States Associated with New and Existing Anti-Obesity Medications

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**BACKGROUND:** An understanding of the formulary cost implications associated with the addition of new anti-obesity treatments is important to health plans in judging whether new treatments are affordable.

**OBJECTIVE:** The objective of this study was to evaluate formulary cost implications associated with the addition of naltrexone/bupropion (NB) for the treatment of obesity in the U.S.

**METHODS:** A pharmacy budget impact model was developed to estimate the net budget impact associated with the addition of NB to a formulary (calculated as the difference in cumulative costs for each year with and without NB) over 1, 2 and 3 years for a plan with 375,000 members. Estimation of the number of patients eligible for anti-obesity treatment was derived from the U.S. National Health and Wellness Survey (NHWS) (January-September 2013). NB’s share of the market was assumed to be 5.4%, 7.7% and 8.6% in years 1, 2, and 3, respectively. NB’s market share was sourced proportionally based on existing market shares of phentermine (80%); lorcaserin (54%); phentermine/topiramate (6.7%); and 7.0% from other products on the market. The annual acquisition cost ($USD) of phentermine was based on a current wholesale acquisition cost of $128 ($0.35/day), lorcaserin, phentermine/topiramate, and other products were priced at $2,394 (=199.50/month), and NB was priced at parity with lorcaserin, phentermine/topiramate, and other products ($199.50/month) based on a supply of 70 tablets in month 1 and 120 tablets in each subsequent month ($2,311/year). Patients were assumed to be treated for a duration of one year.

**RESULTS:** The number of patients estimated to receive an anti-obesity medication was 1,260 in year 1, and was projected to grow by 9.6% in year 2 (1,381 patients) and 11.3% in year 3 (1,537 patients). The net total budget impact to a plan size of 375,000 was estimated to be $121,053, $317,225 and $564,226 in years 1, 2 and 3 respectively. The corresponding per member per month (PMPM) cost was between $0.03 and $0.04. Assuming a 50% increase in NB market share, the net total budget impact to a plan size of 375,000 was estimated to be $181,579, $475,837 and $846,340 in years 1, 2 and 3, respectively.

**CONCLUSION:** The addition of NB to a formulary was generally associated with a PMPM cost of less than $0.05. There may be additional relevant costs to a health plan that have not been captured in this analysis, including cost-offsets from fewer health complications as a result of weight loss from anti-obesity medications.

**SPONSORSHIP:** This research was funded by an unrestricted educational grant from Takeda Pharmaceuticals.

**E23** Clinical and Financial Impacts of a Real-Time, Risk Score-Driven Authorization for Statin Therapy

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**BACKGROUND:** Previous literature has identified the burden utilization management (UM) approaches, such as prior authorization (PA), places on patients, prescribers, PBMs, and pharmacists. The ability to leverage integrated data sets and relevant customer health data at the point of care could be invaluable in facilitating pharmacy claims adjudication that are normally subject to UM rules.

**OBJECTIVE:** The objective of this study was to quantify the clinical and financial impacts of an automated, risk-driven authorization for statin therapy has had on these stakeholders since implementation in January 2014.
METHODS: Within a large, commercially insured population, beneficiaries initiating statin therapy from July 2013 to June 2014 were included in the study. Descriptive statistics were compared between the baseline and post-implementation cohorts for average time to statin therapy, utilization of branded statins, statin PA volumes, and point-of-sale (POS) statin rejection volumes.

RESULTS: Beneficiaries initiating therapy between July 2013 and December 2013 were assigned to the baseline population (n = 16,442), and those initiating in between January 2014 and June 2014 were assigned to the post-implementation group (n = 14,275). In the first 6 months post-implementation of the risk score driven authorization, the average time to UM-required statin therapy for patients requesting initial therapy decreased by 12.6% as compared to baseline. Overall, the utilization of UM-required statins across the statin using population increased 0.2% in the post-implementation period, however this change was not statistically significant (P > 0.05). Incoming PA volume to the PBM related to statin initiation decreased between January and June 2014 as compared to baseline. Subsequently, POS rejections related to UM-required statin initiation decreased significantly in the post-implementation period as compared to baseline (-37.3%, P < 0.05).

CONCLUSION: The use of predictive risk modeling to more efficiently apply UM protocols across populations is an extension of efforts to automate PA and reduce the burden on patients, providers, and payers. Although still in the early stages of implementation, this proactive approach to UM appears to offer distinct clinical benefits to statin patients and administrative benefits to providers, while having minimal impact on the overall utilization of a branded medication with generic therapeutic alternatives.

SPONSORSHIP: Cigna.

E24 Opportunities and Challenges in Providing Face-to-Face and Telephonic MTM Services to a Commercially Insured Population

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BACKGROUND: Medication therapy management (MTM) programs are designed to improve patient outcomes and decrease costs. We conducted a feasibility study of MTM interventions for a commercially-insured population of patients with dyslipidemia and/or diabetes, whose prescriptions were dispensed at Jewel-Osco pharmacies, a large regional chain in greater Chicago.

OBJECTIVE: To describe pharmacist-reported opportunities and challenges and compare characteristics of commercially-insured patients who agreed or declined to participate in face-to-face or telephonic MTM services provision.

METHODS: Patient data were extracted from claims data provided by Comprehensive Health Insights. Eligibility criteria included Humana plan enrollment, prescription fills by Jewel-Osco, and ages 18 to 89 excluding Medicare prescription drug coverage. As assigned, eligible patients were contacted by telephone, with a maximum of three attempts, and invited to receive comprehensive MTM services free of charge (either face-to-face by clinical pharmacists at Jewel-Osco or telephonically by clinical pharmacists at Humana RxMentor). Census data, geocoded by zip code, were used to analyze socioeconomic variables. Telephone interviews on opportunities and challenges were conducted in a semi-structured format with pharmacists providing MTM services for the enrolled sample. Research procedures were approved by the local institutional review board and Humana ethics committee.

RESULTS: Out of 3,207 eligible patients, 1,456 (45.4%) could not be reached via telephone, 1,497 (46.7%) declined MTM participation, and 254 (7.9%) consented. Differences between reachable and unreachable groups included age and neighborhood household income, health insurance status, race, and education (P ≤ 0.005). People accepting or refusing MTM services differed with regard to age, prescription costs, and neighborhood income and race variables (P ≤ 0.01). A total of 15/27 (55.9%) pharmacists that provided MTM services for participants was interviewed. Qualitative analysis showed positive and negative lessons learned across major thematic areas—perceived patient need, communications, MTM setup logistics, data collection, care coordination, time involvement, insurance concerns, comparisons with Medicare MTM population, and patient education.

CONCLUSION: The 8% of eligible commercially insured who participated is lower than the typical 13% for Part D MTM programs. Findings showed potential opportunities to target innovative MTM programs for patients ~60 to 64 years old with complex or expensive medication regimens, as well as patients with lower income and/or minorities.

SPONSORSHIP: Pharmacy Quality Alliance, Inc. (PQA), Humana RxMentor (in-kind support), and study data for MTM intervention summaries were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at the University of Illinois at Chicago via support of UIC Institute for Health Research and Policy Center for Clinical and Translational Science (CCTS) grant UL1RR029879.

E25 Academic Detailing: An Effective Tool for Positive Change

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BACKGROUND: Academic detailing is proven to assist clinicians in making optimal treatment decisions. Recently, the Atrius Health Clinical Pharmacy Program identified a topic to evaluate the impact of its Academic Detailing Service (ADS). In 2012, the FDA concluded that serious liver injury associated with statin use is rare and unpredictable, and routine monitoring of liver enzymes (e.g., ALT) does not improve its detection or prevention. Clinical pharmacists were the sole organized communicators of this update to nearly all Atrius internists via ADS meetings.

OBJECTIVE: To retrospectively measure the impact of face-to-face academic detailing by clinical pharmacists on the number of ALT tests ordered in patients on statins.

METHODS: Clinical pharmacists integrated into the Internal Medicine departments provide drug information, nonpreferred drug switches, and patient consultations. They also deliver interactive academic detailing via face-to-face communication of evidence-based clinical information. ADS meetings are conducted in brief 1:1 or small group (< 4 clinicians) meetings to approximately 385 prescribers each fiscal quarter. During ADS meetings, clinical pharmacists educate on topics including prescribing tools, cost-effective prescribing, new drugs, or the practical use of the most recent clinical guidelines. The Atrius Health ADS is a unique and widely accepted forum to engage directly with clinicians to change prescribing behaviors. The message to avoid routine ALT testing in patients taking statins was delivered in ADS meetings during the second quarter of 2012.

RESULTS: Claims data were reviewed for patients > 18 on a statin who received an ALT during Q1 2012 and Q1 2013. The overall number of patients on statins was similar during both periods. By comparison, similar data were reviewed for the newest Atrius Health medical group, which does not have an ADS (FDA’s update was communicated by a global e-mail to clinicians).
CONCLUSION: Clinicians in the ADS arm ordered 61% less ALTs in Q1 2013 (2,761 tests) as compared to Q1 2012 (7,112 tests). In the control group, a 14% decrease in ALT testing was found in this same population and time period (740 vs. 547 tests). This clinical message resulted in a $100,000 reduction in overall healthcare waste over one year. The Atrius Health ADS provided by clinical pharmacists serves as a model to other organizations on the impact of individualized clinician education in reducing healthcare costs.


F00-F99 Mental and Behavioral Disorders (i.e., Depression, Antipsychotics, Schizophrenia, Bipolar Disorder)
BACKGROUND: Abuse potential is an important consideration for prescribers selecting analgesics.

OBJECTIVE: To compare the abuse liability of extended-release oxycodone/acetaminophen (ER OC/APAP) and immediate-release (IR) OC/APAP.

METHODS: In a randomized, double-blind, double-dummy, active-and placebo-controlled 7-way crossover study, healthy, non-dependent recreational opioid users were assigned to receive each of 7 treatments: low-dose ER OC/APAP (15 mg OC/650 mg APAP), high-dose ER OC/APAP (30 mg OC/1300 mg APAP), low-dose IR OC/APAP (15 mg OC/650 mg APAP), high-dose IR OC/APAP (30 mg OC/1300 mg APAP), crushed high-dose ER OC/APAP, crushed high-dose IR OC/APAP, or placebo. Between 0-12 hours postdose, measurements were obtained for 3 subjective pharmacodynamic (PD) effects (drug liking, drug high, and good drug effects), objective PD effects (pupillometry), and OC/APAP pharmacokinetic (PK) parameters. Adverse events were recorded.

RESULTS: Fifty-five of 61 subjects completed all treatments. Oxycodone maximum concentration (Cmax) was lower and median time to Cmax (tmax) was longer after intact ER OC/APAP vs. IR OC/APAP. Area under the concentration-time curve, 0-infinity (AUC0-inf) was generally greater after IR OC/APAP than intact or crushed ER OC/APAP and lower after crushed than intact ER OC/APAP. Oxycodone maximum concentration (Cmax) was similar for intact and crushed high-dose ER OC/APAP, but median tmax was delayed for crushed ER OC/APAP (3.6 vs. 2.1 hours), and AUCtmax was greater for intact ER OC/APAP (36.7 vs. 17.3 ng∙h/mL). Drug liking, drug high, and good drug effects were generally greater after inter IR OC/APAP than intact or crushed ER OC/APAP and lower after crushed than intact ER OC/APAP. Emax (peak PD effect) vs. Cmax and area under the drug-effect curve, 0-time of measurement (AUEC0-τ) vs. AUC0-τ were correlated for each subjective drug effect (R² = 0.711-0.997). The mean abuse quotient (AQ, geometric mean Cmax/median tmax) was lower for low-dose (4.54) and high-dose ER OC/APAP (14.66) than for low-dose (30.38) or high-dose (58.33) IR OC/APAP. Emax correlated significantly (P < 0.0001) with AQ for drug liking (R² = 0.8716), drug high (R² = 0.8869), and good drug effects (R² = 0.8874). For all subjective effects, Emax correlated more strongly with Cmax than with AQ. Pupillometry showed corroboration with Cmax and subjective PD measures for ER OC/APAP and IR OC/APAP.

CONCLUSION: For ER OC/APAP and IR OC/APAP, subjective and objective PD effects correlated with PK parameter estimates (Cmax, tmax, and AQ) for OC. Crushing ER OC/APAP slowed the release of oxycodone, delayed tmax, decreased Cmax, and produced less intense subjective effects than intact ER OC/APAP. These data suggest that ER OC/APAP has lower liability for abuse than IR OC/APAP.

SPONSORSHIP: This study was funded by Mallinckrodt Pharmaceuticals.

The Impact of Implementing a Prior Authorization Program to Restrict the Use of Buprenorphine Products for Opioid Dependence

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BACKGROUND: Many buprenorphine products are indicated for the short-term treatment of opioid dependence in an outpatient setting. The goal of treating opioid dependence is to help the patient decrease or eliminate opioid use through medically supervised opioid withdrawal. In 2007 the estimated cost of treating opioid drug abuse was $83.7 billion. Increasingly, buprenorphine agents have been used off-label in the treatment of chronic pain and for maintenance treatment of opioid dependence. There are appropriate alternative therapies available for treating such conditions, such as methadone and less expensive traditional therapy options to treat chronic pain.

OBJECTIVE: To describe the economic and utilization impact from the implementation of a prior authorization program designed to limit the use of buprenorphine products for the short-term treatment of opioid dependence.

METHODS: Beginning July 1, 2013, a prior authorization program was implemented on buprenorphine products. The program required the medication be used for opioid dependence with a lifetime maximum treatment duration of 6 months. Patients were also required to have psychological counseling, be enrolled in a drug addiction recovery program and their physicians had to provide detailed treatment plans following evidence-based taper schedules that were provided. Pharmacy claims data were analyzed between July 2012 and June 2014—one year pre-implementation (PRI) to one year post-implementation (PSI). The PSI and PRI groups were compared using descriptive statistics by evaluating the number of members who filled prescriptions, the number of paid claims, and the total drug cost (including both member and plan paid).

RESULTS: Overall costs from the PRI group to the PSI group were reduced by $81,033 ($189,778 and $108,745, respectively; P < 0.02). When adjusted for current drug pricing, overall savings would be $126,330. In the PSI group, it was also found that 277 fewer claims

Prescription of Extended Release and Long Acting (ERLA) Opioid Analgesics for Acute Pain

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BACKGROUND: Despite the availability of numerous analgesic options, the optimal management of acute pain is not fully understood.

OBJECTIVE: To estimate the prevalence of prescribing ERLA opioids for adults (age ≥ 18 years) with acute pain.

METHODS: Data for these analyses were derived from IMS LRX longitudinal patient data for > 150 million patients covering approximately 65% of retail prescriptions filled in the U.S. Opioids included the ERLA formulations of fentanyl, hydromorphone, methadone, morphine, oxymorphone and tapentadol. Acute pain patients were defined as individuals who were prescribed opioids for up to a 30 day-supply between April 1, 2012 and March 31, 2013, with no opioid prescriptions for a year before their first dose or a year after their last dose.

RESULTS: 17.6 million patients (46.0% male, mean age 45.0 years, SD 17.6, range 18-88) were prescribed opioids for acute pain, accounting for 20 million prescriptions. ERLA opioids were prescribed alone for 0.4% of the sample and with regular-release opioids for 0.4% of persons. Oxycodone CR (32.9%), transdermal fentanyl (19.0%), and extended-release morphine (21.9%) were the most commonly prescribed ERLA opioids. General practice (34.7%), orthopedic surgeons (14.0%) and pain management physicians (13.1%) were the most prevalent prescribers of ERLA opioids for acute pain.

CONCLUSION: Although ERLA opioids were prescribed for acute pain for a small proportion of people who received opioids, a significant number of individuals were represented. General practice physicians and orthopedic surgeons accounted for more than half of ERLA prescribing in this group. 74% of ERLA prescribing for acute pain was accounted for by three drugs.

SPONSORSHIP: This study was funded by Mallinckrodt Pharmaceuticals.
were processed (512 vs. 789), 16 fewer patients received prescriptions (98 vs. 114), 20,881 fewer drug units were filled (17,076 vs. 38,857), and 9,639 less days supply were filled (10,255 vs. 19,894).

CONCLUSION: A prior authorization program to limit the use of buprenorphine led to a significant reduction in total drugs costs within the first year after implementation. The savings captured by this program can largely be attributed to reductions in the number of prescriptions, drug units filled and days supply filled. Future analysis will also look at opioid consumption among the groups analyzed.

SPONSORSHIP: No external funding was received to conduct this research.

F10 An Examination of Clinical Pathways Among a Sample of Patients with Schizophrenia Treated with Antipsychotic Medication: A Retrospective Analysis of Commercial Health Plan Claims Data

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BACKGROUND: Low adherence with antipsychotic (AP) medication in patients with schizophrenia may lead to elevated relapse rates, resource utilization, and poor prognosis. Therefore, treatment objectives focus on improvement of AP adherence and reduction of symptoms and relapse. Administrative claims are increasingly utilized to investigate patient treatment history and characteristics.

OBJECTIVE: To utilize claims data to identify medication treatment choices and outcomes for patients with schizophrenia taking APs in order to identify a claims-based algorithm to assign patients to the most effective AP medication regimens.

METHODS: Medical and pharmacy claims for Aetna members with a diagnosis of schizophrenia (ICD-9 CM 295.x) were analyzed for calendar years 2010-2013. Members were assigned to mutually exclusive groups by medication regimen: long-acting injectable (LAI) group (use of LAI), unstable oral 1 (oral AP switch), unstable oral 2 (concurrent AP use), or stable oral (at least two fills for the same oral AP without a refill gap). Members were required to have one year of medical and pharmacy eligibility prior to the index event, defined as the earliest prescription or medication switch. Patient Instability Events (PIEs) included AP medication possession ratio ≤0.8, hospitalization, AP switch, AP dose escalation, use of additional psychiatric medication, and psychiatric emergency room visits. PIEs were summed for each quarter of the pre-period and served as the primary dependent variables. A repeated measures general linear model was utilized to effectively model the longitudinal relationship between PIEs and the 4 study groups.

RESULTS: A significant time effect was observed on the total number of PIEs, and also a group by time interaction effect (P<0.05). Group means displayed over time present a trend of increasing patient instability during the pre-period for the LAI group and both oral unstable groups. In an examination of the fourth quarter during the pre-index year, one-way ANOVA revealed that the LAI and both Oral Unstable groups had a greater number of PIEs compared to the Oral Stable group (P<0.01). Trajectories of PIEs prior to the index event differed between the 4 defined study groups.

CONCLUSION: The PIE events identified here may be useful in the development of case finding tools to facilitate matching patients to the most effective and efficient treatment available. The next phases of these analyses will focus on post-index patient outcomes.

SPONSORSHIP: The current research was supported by funding from H. Lundbeck A/S and Otsuka America Pharmaceutical, Inc.

F12 Aripiprazole Is Associated with a Reduction in Hospital Readmission Rates Among Medicaid Patients with Schizophrenia Compared with Other Atypical Antipsychotics

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BACKGROUND: Some meta-analyses of clinical trials suggest that there may be marginal differences in efficacy among commonly used atypical antipsychotics. However, it is important to understand the comparative effectiveness of atypical antipsychotics in the real-world clinical practice setting.

OBJECTIVE: To examine the comparative effectiveness of aripiprazole versus other atypical antipsychotics on hospital readmission rates in the real-world setting.

METHODS: This was a retrospective cohort analysis of patients with schizophrenia (ICD-9 CM 295.xx) aged 18-65 years (at 6 months prior to index hospitalization) identified from the Truven MarketScan Multi-State Medicaid database from 2007 to 2012. Patients had an index mental health-related hospitalization and were categorized into different treatment groups based on prescription claims for an oral atypical antipsychotic between the dates of discharge from the index hospitalization and subsequent all-cause hospital readmission or the end of follow-up of 365 days, whichever occurred first. The main outcome of interest was the likelihood of hospital readmission rates during the follow-up period and was calculated at 30, 60, and 90 days. Readmission rates were compared between aripiprazole (reference) and other commonly used atypical antipsychotics. Multivariate logit regression was used to adjust for baseline differences between treatment groups and switching among atypical antipsychotics.

RESULTS: 15,556 patients with schizophrenia were identified. Hospital readmission rates in the aripiprazole group were 21.9% at 30 days, 30.8% at 60 days, and 38.8% at 90 days. Compared with aripiprazole, the odds of readmission within 30 days were greater for paliperidone (odds ratio [OR], 1.15; P<0.05), risperidone (OR, 1.21; P<0.01), olanzapine (OR, 1.33; P<0.01), and clozapine (OR, 1.23; P<0.05). These results were supported by similar findings at 60 and 90 days of follow-up post index hospitalization.

CONCLUSION: These findings suggest that in Medicaid-insured schizophrenia patients, treatment with aripiprazole was associated with a significantly lower risk of hospital readmission compared with many other oral atypical antipsychotic agents. Results indicate that commonly used atypical antipsychotic treatments have distinct effectiveness profiles in the real-world setting and should not be viewed as interchangeable therapeutic options for the treatment of schizophrenia.

SPONSORSHIP: Otsuka America Pharmaceutical, Inc., and H. Lundbeck A/S.

F13 Predictors and Costs of Treatment-Resistant Schizophrenia: An Assessment of State Medicaid Programs

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BACKGROUND: Schizophrenia (SCZ) is associated with significant economic burden, but little is known about the prevalence and economic impact of treatment resistant schizophrenia (TRS).

OBJECTIVE: To examine the predictors of treatment-resistant schizophrenia among Medicaid enrollees.

METHODS: This was a retrospective cohort analysis of patients with schizophrenia (ICD-9 CM 295.x) aged 18-65 years (at 6 months prior to index hospitalization) identified from the Truven MarketScan Multi-State Medicaid database from 2007 to 2012. Patients had an index mental health-related hospitalization and were categorized into different treatment groups based on prescription claims for an oral atypical antipsychotic between the dates of discharge from the index hospitalization and subsequent all-cause hospital readmission or the end of follow-up of 365 days, whichever occurred first. The main outcome of interest was the likelihood of hospital readmission rates during the follow-up period and was calculated at 30, 60, and 90 days. Readmission rates were compared between aripiprazole (reference) and other commonly used atypical antipsychotics. Multivariate logit regression was used to adjust for baseline differences between treatment groups and switching among atypical antipsychotics.
OBJECTIVE: To estimate (1) the extent of TRS among Medicaid beneficiaries diagnosed with SCZ, (2) predictors of TRS, and (3) economic outcomes associated with TRS.

METHODS: Data were obtained from Medicaid programs of 43 states, and District of Columbia, for ambulatory beneficiaries with SCZ (ICD-9-CM codes 295.00–295.99). TRS was defined as ≥ 3 prescription claims for antipsychotics from at least two different chemical classes with ≤ 30-day gaps between them. Patient-level data from 2008-2012, were divided into two cohorts: those with TRS and those with SCZ but not TRS. Time-frames for analyses were: (1) “index date”, defined as date of first claim for initial antipsychotic medication; (2) “pre-period”, documenting no use of antipsychotics 6 months prior to index date; and (3) “post-period”, documenting use of antipsychotics for at least 12 months after index date. SAS (v 9.2), and STATA (v 12) were used for analysis. The a priori level of statistical significance for all tests was set at P<0.05. Economic results reflect SCZ-related outlays in 2012 U.S. dollars.

RESULTS: Of the 296,417 patients with SCZ in the 5-year period, 107,852 met criteria for having antipsychotic claims with at least 6 months without treatment prior to index and at least 12 months of treatment post index. 31% of these treated SCZ patients had TRS (33,434/107,852). Female gender (OR = 0.84, 95% CI = 0.73-0.97; P<0.05) and white race (OR = 0.83, 95% CI = 0.77-0.96; P<0.05) were associated with a decreased probability of TRS. A gap in pharmacotherapy of ≥ 30 days (OR = 1.18, 95% CI = 1.07-1.32; P<0.05), SCZ-related admission to hospital after initiation of antipsychotic treatment (OR = 1.23, 95% CI = 1.11-1.44; P<0.05), and concomitant psychiatric illness (OR = 1.15, 95% CI = 1.02-1.33; P<0.05) were associated with an increased probability of TRS. For TRS patients, physician service expenditures increased by $358 per capita per year (P<0.05; a 14% differential); hospital/laboratory increased by $890 (P<0.05; a 26% differential); pharmacotherapy increased by $648 (P<0.05; a 11% differential); and total SCZ-related health service expenditures increased by $1,896 per capita per year (P=0.05; a 19% differential), relative to those with SCZ, but no TRS.

CONCLUSION: TRS is exhibited by a large proportion of Medicaid beneficiaries with SCZ, and is associated with an increase in SCZ-related health service expenditures.

SPONSORSHIP: This analysis was supported by Jazz Pharmaceuticals.

S15 Savings from Implementing a Tablet Splitting Criteria for Aripiprazole in a State Medicaid Program
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BACKGROUND: When different strengths of agents are parity priced by manufacturers, that is the per unit cost is the same regardless of the strength, tablet splitting can be a means of reducing program costs while not limiting access. The Mississippi Division of Medicaid (MDOM) identified aripiprazole as a good candidate for a tablet splitting policy. The MDOM consulted with psychiatrists to assess the feasibility and to identify potential difficulties with a tablet splitting policy for aripiprazole. Potential issues identified that made programming for electronic prior authorization (EPA) difficult included labeling indicates QD dosing but BID dosing is sometimes used for tolerability reasons, and the daily dose computed from quantity dispensed and days supply on claims does not always result in a reasonable daily dose. MDOM implemented the aripiprazole tablet splitting criteria through EPA at the end of February 2013.

OBJECTIVE: The goal of a tablet splitting criteria is to reduce total program costs without restricting beneficiary access to treatment options. The research objectives were to evaluate the impact of a tablet splitting policy for aripiprazole on access to care and pharmacy costs.

METHODS: A retrospective analysis was conducted of the MDOM prescription claims for February 2013-April 2014. All aripiprazole prescriptions were extracted and daily consumption (DACKON) was computed by dividing the number of tablets dispensed by the days supply. Tablet splitting rates and the number of beneficiaries taking aripiprazole were computed for each month. Saving were computed based on the average cost of goods paid for each tablet strength and the number of tablets that would have been dispensed without tablet splitting for the period January-June 2014.
Patient Characteristics and Dosing Patterns in Bipolar Disorder Patients Treated with Lurasidone

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BACKGROUND: Lurasidone is an approved treatment for bipolar depression in adults as monotherapy and adjunctive therapy with mood stabilizer. Lurasidone dosing patterns for bipolar disorder patients have not previously been studied in naturalistic settings.

OBJECTIVE: To describe real-world lurasidone dosing patterns and their relationship with patient characteristics.

METHODS: This LifeLink Pharmetrics-Plus database analysis included adult (≥18 years) bipolar disorder patients who initiated lurasidone between November 1, 2010-December 31, 2012 with ≥6 months of continuous enrollment before/after lurasidone initiation. Patients were grouped by starting lurasidone daily dose: 20, 40, 60-80 and 120-160 mg (60-80 and 120-160 combined due to sample size). Cochran-Armitage tests for trends were used to compare dichotomous baseline demographics, treatment history, and clinical characteristics across dose groups.

RESULTS: Of 1,119 lurasidone patients (mean age 40.6 years; 70.7% female; 17% comorbid substance abuse, 18% hypertension), 80 (7.1%) initiated on 20 mg, 695 (62.1%) on 40 mg, 14 (1.2%) on 60 mg, 307 (27.0%) on 80 mg and 23 (2.1%) on 120-160 mg daily. Mean daily starting lurasidone dose was 51.9 (SD 23.4; median 40) mg. Over 6-months post-index, mean daily dose was 55.2 (SD 22.9; median 40) mg. At baseline, patients with bipolar mania (13.8% [20 mg], 25.5% [40 mg], 28.7% [60-80 mg], 34.8% [120-160 mg]) and mixed bipolar (27.5% [20 mg], 30.9% [40 mg], 35.2% [60-80 mg], 47.8% [120-160 mg]) were significantly more likely to have higher starting lurasidone doses. A dose-trend association was observed for bipolar depression (36.3% [20 mg], 33.4% [40 mg], 38.6% [60-80 mg], 47.8% [120-160 mg]; P = 0.11). Patients with comorbid substance abuse, obesity, and a history of prior antipsychotics (first- and second-generation) were significantly more likely to be initiated on a higher starting dose (P<0.05).

CONCLUSION: These analyses of real-world data show that patients with bipolar mania or mixed, prior antipsychotic use, comorbid substance abuse and obesity were more likely to be prescribed higher starting lurasidone doses.

SPONSORSHIP: This study was sponsored by Sunovion Pharmaceuticals Inc.
**METHODS:** A retrospective cross-sectional, claims-based study of patients aged 18-64, with a MS diagnosis (ICD-9 340) between January 1, 2010 and December 31, 2011 was conducted, using the Truven Health MarketScan database. Two groups without dementia were identified: MS patients with a CD diagnosis code (ICD-9 331.7, 331.89, 331.9) (CD) and MS patients without a CD diagnosis code (non-CD). The index year was based on year of CD diagnosis for the CD group and year of MS diagnosis for the non-CD group. Findings were reported using descriptive statistics with their 95% confidence intervals (CI).

**RESULTS:** Of the 44,903 MS patients who met the study criteria, only 296 (0.66%) had a CD diagnosis. The average age of patients between the two groups was similar, but a larger proportion of CD patients (38%) were between ages 55-64 vs. non-CD patients (29.6%). CD patients had a greater percentage of MS symptoms than non-CD patients: pain (75.7% vs. 64.1%), walking, balance and coordination problems (37.8% vs. 17.8%), fatigue (35.8% vs. 23.9%), numbness (27.4% vs. 19.8%), muscle weakness/spasticity (24.3% vs. 13.6%) and bladder dysfunction (21.3% vs. 12.8%), respectively. Healthcare resource utilization (HCRU) was high among the CD group; 5.4% of patients: pain (75.7% vs. 64.1%), walking, balance and coordination problems, and bladder dysfunction (21.3% vs. 12.8%), respectively. Healthcare resource utilization (HCRU) was high among the CD group; 5.4% of CD patients were treated for a relapse at an inpatient facility vs. 2.4% of non-CD patients. The percentage of MS-related hospitalizations was also higher in the CD group (5.7% vs. 2.6%). The majority of CD patients had an MRI (92.2%) with an average number of MRIs of 1.5 (SD = 1.2, 95% CI [1.4-1.6] while only half of non-CD patients had an MRI (54.8%), mean number of MRIs was 0.8 SD = 1.0, 95% CI [0.8-0.8]). On average, all-cause annual medical costs for CD patients were $20,203.50 and $10,684.96 for non-CD patients.

**CONCLUSION:** Based on existing clinical knowledge, brain atrophy in MS patients occurs 2-3 times the rate observed in healthy controls. In this study, only a few MS patients received an ICD-9 code of CD which could reflect a lack of brain atrophy awareness or an accepted brain atrophy treatment algorithm. MS patients with a diagnosis of CD exhibit high MS symptomatology, particularly walking, balance and coordination problems, and high HCRU and medical costs.

**SPONSORSHIP:** Novartis Pharmaceuticals Corporation.

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**G8EM**

**Cost-Effectiveness Analysis of Peginterferon Beta-1a Compared with Other Disease Modifying Therapies in the Treatment of Relapsing-Remitting Multiple Sclerosis in the United States**

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**BACKGROUND:** Peginterferon beta-1a (PEG-IFN; 125 µg administered subcutaneously [SC] every 2 weeks) is an investigational disease modifying therapy (DMT) for relapsing-remitting multiple sclerosis (RRMS) that may improve treatment (Tx) adherence by reducing the frequency of administration. The pivotal ADVANCE trial has shown benefits of PEG-IFN vs. placebo on relapses and disability progression, but its long-term clinical and economic consequences vs. other DMTs are still unknown.

**OBJECTIVE:** To assess the cost-effectiveness of PEG-IFN vs. two injectable DMTs, interferon beta-1a (IFN-beta; 44 µg SC 3 times/week) and glatiramer acetate (GA; 20 mg SC daily), in the Tx of RRMS from the U.S. payer perspective.

**METHODS:** An economic model, published and reviewed by health technology assessment authorities, was adapted for this analysis. The model, using a Markov cohort approach, predicts disability progression (measured by the Expanded Disability Status Scale [EDSS]) and occurrence of relapses and adverse events (AEs) according to the Tx received, and translates them into quality-adjusted life years (QALYs) and costs. The natural history data were obtained from the placebo arm of the ADVANCE trial extrapolated with data from the London Ontario database for EDSS transition probabilities and from a large population-based MS survey for relapse rates. A network meta-analysis was conducted to estimate the comparative efficacy of each Tx vs. placebo. Costs (in 2014 U.S. dollars) of drug acquisition, disease management, relapses, and AEs were from public databases and literature. The analysis assumed the same risk of discontinuation for all Txs. Clinical and economic outcomes were projected over 30 years and discounted at 3% per year.
RESULTS: Preliminary results suggested that over 30 years, per patient, PEG-IFN yielded greater clinical benefits, with 0.32 and 0.43 additional QALYs gained compared with IFN-beta and GA, respectively. Probabilistic sensitivity analysis indicated that the incremental cost per QALY gained for PEG-IFN compared with IFN-beta and GA was below a willingness-to-pay threshold of $50,000 per QALY in 81% and 57% of 1,000 replications, respectively.

CONCLUSION: The preliminary analysis suggests that PEG-IFN could be a cost-effective Tx for RMRS in the U.S., and would be a valuable addition to managed care formularies.

SPONSORSHIP: Evidera received funding from Biogen Idec, Inc., to conduct this study.

G13EM Budget Impact Model of Eslicarbazepine Acetate for Refractory Partial-Onset Epilepsy in a U.S. Health Insurance Plan

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BACKGROUND: Approximately two million people in the U.S. suffer from epilepsy, accounting for $15.5 billion in direct and indirect costs annually. Patients with refractory partial-onset seizures experience higher seizure burden compared to well-controlled patients and are in need of additional treatment options.

OBJECTIVE: To estimate the pharmacy budget impact of eslicarbazepine acetate for adjunctive use in adult patients with refractory partial-onset epilepsy.

METHODS: A 1-year pharmacy budget impact model, reflecting a U.S. payer perspective, was developed to estimate the difference in health plan costs with and without eslicarbazepine acetate adjunctive treatment for patients with refractory partial-onset seizures who are currently receiving a branded antiepileptic drug (perampanel, oxcarbazepine XR, ezogabine, lacosamide, levetiracetam XR). A 1,000,000-member health plan was assumed and inputs for epilepsy prevalence (1%), percentage of patients with partial-onset seizures (60%), percentage of patients adjunctively treated (18%), and percentage of refractory patients treated with branded antiepileptics (50%) were obtained from various sources. Costs of treatment were calculated based on the weighted average cost by product strength (utilization and daily average consumption were obtained from IMS Health and product unit costs were obtained from Red Book), and a $25 copay was assumed for all products. Current market shares were based on utilization data from IMS Health (perampanel 0.23%, oxcarbazepine XR 4.16%, ezogabine 1.35%, lacosamide 82.68%, levetiracetam XR 11.58%). New market share estimates were based on eslicarbazepine acetate obtaining an assumed 1% market share acquired from all existing products in proportion to the current market share.

RESULTS: Over a 1-year period, it was estimated that there would be approximately 540 patients with refractory partial-onset epilepsy treated with branded antiepileptics in a hypothetical plan with 1,000,000 members. Adoption of eslicarbazepine acetate would result in an overall minimal budget impact to the health plan, with a total cost of $2,959, per patient per year cost of $5.48, and a per member per month cost of less than $0.001.

CONCLUSION: In this budget impact model of pharmacy costs, adjunctive treatment with eslicarbazepine acetate compared to other branded antiepileptic drugs may result in a minimal budget impact to a U.S. health plan over 1 year. Eslicarbazepine acetate offers another adjunctive treatment option for adult patients with refractory partial-onset seizures.

SPONSORSHIP: This research was supported by Sunovion Pharmaceuticals Inc.

G16 Resource Use, Productivity Loss and Economic Burden of Narcolepsy: Results from the National Health and Wellness Survey

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BACKGROUND: Narcolepsy, a chronic sleep disorder characterized by excessive daytime sleepiness (EDS), is associated with significant functional impairment. This cross-sectional study aimed to provide a comprehensive understanding of the economic burden of narcolepsy, including direct and indirect costs, resource use, and patient productivity loss in the U.S.

METHODS: The study used a U.S.-specific healthcare perspective to estimate the total incremental direct cost and productivity loss of treating narcolepsy over a 1-year period. Healthcare claims data from several sources were used to estimate resource utilization and associated costs, including physician visits, medications, hospitalizations, and transportation. Productivity loss was estimated by calculating the number of hours lost due to EDS and related impairments. The study also included a survey of patients with narcolepsy to gather patient-reported outcomes and healthcare resource use.

RESULTS: The estimated total incremental direct cost of treating narcolepsy over a 1-year period was $3.6 billion, with $2.9 billion attributed to health services and $0.7 billion to non-health services. The productivity loss due to EDS and related impairments was estimated at 2.4 million lost work hours, equating to $1.8 billion in lost productivity. The survey results indicated that patients with narcolepsy experienced significant impairment in work productivity, with 42% reporting difficulty staying awake at work.

CONCLUSION: The study provides comprehensive insights into the economic burden of narcolepsy, highlighting the significant direct and indirect costs associated with the disease. Further research is needed to develop effective treatment strategies that can mitigate these burdens.
BACKGROUND: Narcolepsy is a neurological disorder characterized by excessive daytime sleepiness and other symptoms that can include cataplexy, in which laughing or sudden emotion precipitates transient loss of muscle strength. Symptoms are often controlled but not eliminated by appropriate medications. These symptoms could broadly impact other aspects of health, work, and well-being, but few population-based data have been available to assess this possibility.

OBJECTIVE: To examine the burden of narcolepsy in terms of resource use, work productivity, and associated costs.

METHODS: Data were from the 2011-2013 U.S. National Health and Wellness Survey (NHWS), an annual, representative, cross-sectional general health survey (2011 NHWS N = 75,000; 2012 N = 71,157; 2013 N = 75,000). Respondents who reported ever having received a diagnosis of narcolepsy by a physician were matched 1:2 with controls on demographics and health risk behaviors (e.g., smoking status) via propensity score matching. Analyses examined differences between patients with and without narcolepsy on resource use, work and activity impairment, and associated costs.

RESULTS: Respondents with narcolepsy (N = 437), compared to 874 matched controls, reported significantly higher numbers of hospitalizations (Mean = 1.02 vs. M = 0.27), ER visits (M = 1.22 vs. M = 0.40), traditional healthcare provider visits (M = 10.25 vs. M = 4.08), and visits to other specialists (e.g. psychiatrists M = 0.72 vs. M = 0.28) in the past 6 months than controls (one-way ANOVAs, P < 0.001 for all comparisons). Those with narcolepsy reported significantly higher percentage of time missed from work in the last week (absenteeism, M = 17.4% vs. M = 5.6%), percentage of productivity loss while at work (presenteeism, M = 40.2% vs. M = 17.5%), percentage of overall work impairment (M = 45.5% vs. M = 20.1%), and activity impairment (M = 50.9% vs. M = 25.9%) in the past week than matched controls (one-way ANOVAs, P < 0.001 for all). Individuals with narcolepsy compared to controls had significantly higher indirect (M = $19,852 vs. M = $9,125, P < 0.001) and direct costs (M = $54,136 vs. M = $18,586, P < 0.001).

CONCLUSION: These data show that narcolepsy is associated with substantially increased resource use, work and activity impairment, and higher associated costs. Further analyses are needed to distinguish the impact of medical comorbidities as well as treatment on these outcomes.

SPONSORSHIP: This analysis was funded by Jazz Pharmaceuticals.

G18 Therapeutic Class Management: A Multidisciplinary Process with a Continuous Quality Improvement Approach

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BACKGROUND: Opioid analgesic management involves all areas of healthcare. Challenges include opioid-specific problems, measurement of goals and resistance to change. Transforming quality improvement into a continuous dynamic process requires collaboration and process integration.

OBJECTIVE: The purpose is to (a) describe the process of member selection to a disease-state multidisciplinary workgroup, (b) describe the workgroup function, (c) define outcome measures to project effective strategies (d) adjust policies/protocol based-on outcome results and (e) review lessons learned.

METHODS: The workgroup includes members selected from multiple disciplines reflecting the drug class’s multifaceted nature. An internal data evaluation and external literature review was conducted to identify problem scope and possible success measures. Workgroup members interact with various groups and external stakeholders, including operational and clinical pharmacists, nurses, prescribers, disease experts, care management and behavioral health programs, and community resources. Bi-weekly workgroup meetings, daily committee case reviews and subsequent prescriber outreach allow for continuous quality improvement. An extensive bi-annual data collection and review guided internal policy guideline changes and new initiatives, which completed the cycle.

RESULTS: The team comprised clinical pharmacists, pharmacy operations supervisor, practicing physician and disease management nurse. The team worked to foster collaboration, improve the quality of services provided and create a detailed guideline addressing appropriate and best practice for opioid prescribing, as well as prior authorization criteria and appendix to aid the assessment of clinical documentation. Thorough training of pharmacists and staff was critical to aligning...
goals. Committee stakeholder meetings to hear concerns of prescribers were effective in fostering solid relationships. The workgroup used the referral process to engage other collaborators and link members to appropriate care. Results included high prescriber satisfaction, clear understanding of organizational goals and innovative ways to improve the management of fraud, abuse and misuse, without affecting access to pain management.

CONCLUSION: The process and implementation cycle is continuous with constant focus on next steps and goals. Frequent and consistent policy revisions through updated clinical practice data validate results. The successful multidisciplinary process can be extrapolated to any area of healthcare.

SPONSORSHIP: None.

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

A Retrospective Cohort Study to Identify Medicare Members at Risk of Low Adherence to Glaucoma Medication

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BACKGROUND: Reported non-adherence rates with topical glaucoma medications range from 5% to 80%. As intra-ocular pressure (IOP) reduction slows the progression of visual field loss in glaucoma, targeting non-adherent patients is crucial to effective disease management.

OBJECTIVE: To identify patient characteristics and other factors related to non-adherence with topical prescription glaucoma medications, and to create a predictive model incorporating these variables.

METHODS: This retrospective cohort study analyzed data from Humana’s administrative claims database. Patients aged 65-89 years enrolled in a Medicare Advantage Prescription Drug Plan (MAPD), medical and pharmacy benefits) or a Medicare Prescription Drug Plan (PDP, pharmacy benefits only), and with ≥1 topical IOP-lowering medication claims between January 2011 and September 2012 were identified. Patients had to have ≥12 months’ continuous enrollment before and after the initial (index) IOP prescription claim. Adherence was defined as the proportion of days covered (PDC) with drug supply (calculated from the number of drops/bottle and dose) over the first year after the index IOP prescription. Patients with PDC ≥80% were considered adherent, in accordance with the Centers for Medicare and Medicaid Services (CMS) Star Rating definition. Multivariate logistic regression was used to construct predictive models of non-adherence using the MAPD and PDP datasets.

RESULTS: 178,404 patients were included in the study (73,256 MAPD and 105,148 PDP); most (72%) were continuing IOP medication users. Predictive models for non-adherence in the MAPD and PDP populations were of similar age, gender ratio and income status. Adherence rates (PDC≥80%) over the first post-index year were similar in the MAPD (51%) and PDP (52%) populations. Predictive models for non-adherence common to the MAPD and PDP populations were constructed using 10 and 9 variables, respectively; the two models had similar performance (area under the curve ≥0.70). Predictors of non-adherence common to the MAPD and PDP populations were mail-order prescription filling (index script), being a new user, and male gender. Predictors of adherence common to both populations included advanced age, higher pharmacy costs during the pre-index period, and low income subsidy.

CONCLUSION: Non-adherence to topical glaucoma medication can be adequately predicted with ≤10 commonly available demographic and claims-based variables. The predictive models appear to be robust and applicable to other patient populations, and can be used to target interventions to improve glaucoma medication adherence.

SPONSORSHIP: This analysis was funded by Allergan Inc., Irvine, CA.

100-I99 Diseases of the Circulatory System (i.e., Atrial Fibrillation, ACS, Pulmonary Hypertension)

11 Impacting Generic Dispensing, Formulary Compliance and Drug Spend through the Implementation of an Electronic Prescribing Program

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BACKGROUND: Electronic prescribing (e-Prescribing) enables providers to electronically submit prescriptions directly to pharmacies. One of the benefits of an integrated e-Prescribing offering is the ability for the provider to access member’s medication history, pharmacy benefits, and formulary information from their pharmacy benefit manager or payer to make more informed decisions at the time of prescribing. Use of e-Prescribing has grown steadily in recent years and now represents 58% of all prescriptions filled. Electronic prescribing is incorporated into the Affordable Care Act with specific minimum utilization requirements. Greater utilization of e-Prescribing has been shown to reduce medication errors, adverse drug events, increase generic utilization and formulary compliance.

OBJECTIVE: To investigate the differences in generic dispensing rates (GDR) and formulary compliance rates and corresponding drug costs for payers with and without a comprehensive electronic prescribing program at a large nationwide pharmacy benefit manager.

METHODS: Pharmacy plan members from commercial clients who had claims between January 1, 2014 and March 31, 2014 were included in the analysis. Members were classified based on whether their prescriber had access to comprehensive e-Prescribing services to promote formulary compliance and generic dispensing or whether their prescriber utilized standard prescribing tools. A generalized linear model was created in order to assess the differences in GDR and formulary compliance while adjusting for the effects of age, gender, distribution channel, drug class, medication abuse potential, member cost share, line of business, state of residence, and pharmacy chain.

RESULTS: Compared to clients that did not have comprehensive e-Prescribing services, clients that did experienced a 1.7% (P<0.0001) higher GDR and a 3.3% (P=0.00001) higher formulary compliance rate after adjusting for the effects of the potential confounders. In addition, clients that provided formulary and eligibility information to their providers that electronically prescribed experienced a 3.4% lower overall drug spend.

CONCLUSION: A comprehensive formalized e-Prescribing program allows payers to achieve significantly higher GDR, formulary compliance rates and favorable drug spend.

SPONSORSHIP: Catamaran.

12 Assessment of LDL-C in High-Risk Coronary Heart Disease Patients with Hyperlipidemia in the United States.

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BACKGROUND: Coronary heart disease (CHD) is the most common type of heart disease responsible for nearly 380,000 deaths annually in the U.S. Elevated low density lipoprotein cholesterol (LDL-C) is one
of the major risk factors for CHD and has been a primary target for lipid lowering therapy.

**OBJECTIVE:** This study evaluated LDL-C status in high risk CHD and CHD risk-equivalent (CHD RE) patients with hyperlipidemia.

**METHODS:** A retrospective cohort study utilizing the Truven Analytics MarketScan database was conducted. Patients were ≥18 years with hyperlipidemia or on lipid-lowering therapy, and continuously enrolled for ≥24 months prior to index date and up to 12 months (CHD) or 24 months (CHD RE) after index date. Enrollment occurred between January 1, 2007 and December 31, 2011 (CHD) or December 31, 2010 (CHD RE). Per Adult Treatment Panel (ATP) III guidelines, a CHD event was defined as: myocardial infarction, angina, coronary artery bypass graft, percutaneous coronary intervention, other chronic ischemic heart disease and a CHD RE diagnosis was defined as: type 2 diabetes, peripheral vascular disease, stroke, abdominal aortic aneurysm, transient ischemic attack. Patients with rhabdomyolysis, chronic kidney disease, CHD, or CHD RE diagnosis any time prior to the index date were excluded. The number of lipid panel tests per patient and with LDL-C ≥100 mg/dL was captured within 30 days prior to index date and at 30-day intervals after the index date up to one year.

**RESULTS:** There were 711 CHD and 324 CHD RE patients with LDL-C values available one year after index date. Mean ages (standard deviation) were 58.0 ± 10.6 years (CHD) and 56.5 ± 12.4 years (CHD RE); 17.2% and 17.0% were ≥65 years; 67.7% and 46.9% were male, respectively. There were 63.0% (CHD) and 54.7% (CHD RE) of patients with LDL-C ≥100 mg/dL within 30 days before index date and 33.9% (CHD) and 49.8% (CHD RE) of patients with LDL-C ≥100 mg/dL within 30 days after index date. At the end of one year, 29.3% (CHD) and 45.8% (CHD RE) of patients had LDL-C ≥100 mg/dL.

**CONCLUSION:** A higher proportion of CHD RE patients compared to those with CHD had LDL-C ≥100 mg/dL after one year of follow-up. While there is a decline in number of patients with LDL-C >100 mg/dL one year after CHD event or CHD RE diagnosis, 29-46% of high risk patients continue to have elevated levels of LDL-C, indicating opportunities for better lipid management.

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

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**13 Work Absenteeism, Short-Term Disability and Related Indirect Costs Associated with Cardiovascular Events and Related Clinical Procedures**

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**BACKGROUND:** Cardiovascular (CV) disease accounts for 17% of direct medical costs in the U.S. The indirect cost of CV disease is projected to reach $276 billion in 2030.

**OBJECTIVE:** To quantify work absenteeism (WA) and short-term disability (STD) hours and related indirect costs associated with CV events and related clinical procedures [CVERP; myocardial infarction, ischemic stroke, unstable angina, revascularization, heart failure, transient ischemic attack] in U.S. employees.

**METHODS:** Full-time employees aged 18-64, eligible for WA or STD benefits and with hyperlipidemia or lipid-lowering therapy in 2003-2011 were extracted from the MarketScan Commercial and Health and Productivity Management Databases. For patients with CVERP, the index date was the date of the first CVERP claim, for patients without a CVERP, an index date was randomly assigned based on the distribution of index dates in the CVERP cohort. Patients with data for ≥1 year pre- and ≥1 month post-index were followed up to 3 years. Patients with and without CVERP were matched on demographics and comorbidities using propensity score matching. Per patient per month (PPPM) WA and STD hours were measured during the acute period (1 month post-CVERP), and during longer-term periods (years 1, 2, and 3) post-index for eligible patients. Indirect costs associated with these hours were calculated based on the Bureau of Labor Statistics wage rates and adjusted to 2013 dollars.

**RESULTS:** A total of 5,803 WA and 21,074 STD eligible CVERP patients were matched to patients with no CVERP. Their characteristics were well balanced (mean age 52-53, male 82-86%, Charlson comorbidity index 0.6-0.7). For all time periods, patients with CVERP had significantly higher mean WA and STD hours and indirect costs than those without. All differences were statistically significant (P<0.001) and were most pronounced in year 1, especially in the acute period post-CVERP; CVERP patients had 24.7 more WA hours and 54.5 more STD hours PPPM, equivalent to indirect costs of $720 and $942 PPPM. During the first year, the mean corresponding increases were 44 hours, 13.9 hours, $133, and $240 PPPM. During the third year, the differences were 1.2 hours, 2.1 hours, $34, and $35 PPPM respectively.

**CONCLUSION:** CVERP are associated with significant work loss and related indirect costs, especially in the acute period following the CVERP. Prevention or reduction of CVERP could result in substantial WA and STD related cost savings for employers.

**SPONSORSHIP:** This study was funded by Amgen.
Medication Burden in Patients with Acute Coronary Syndromes: A Retrospective Cohort Analysis Using Electronic Health Records

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BACKGROUND: Medication adherence is directly related to medication burden and the prescribing patterns of cardiovascular (CV) medications upon admission and discharge among a cohort of patients with ACS.

OBJECTIVE: We aimed to describe and contrast the extent of overall medication burden and the prescribing patterns of cardiovascular (CV) medications upon admission and discharge among a cohort of patients with ACS.

METHODS: We conducted a retrospective descriptive analysis of patients with an ACS event admitted to two large, predominately rural hospitals over a 4-year period from 2008 through 2012. Patients included in the study cohort were >18 and <90 years of age and discharged from the hospital with a principal diagnosis of ACS. We quantified medication use at two different points during the timeline of care; admission and at the time of discharge. All medications except vitamins and alternative products were included in the analysis. Frequencies of dosing intervals were determined for orally administered scheduled medications only.

RESULTS: A total of 4,767 patients were included in our study cohort. Medication totals increased from a median of 7 to 10 with over 68% of admission and 95% of discharge taking 5 or more medications. Whereas 35% of patients were taking a medication only once a day or less at the time of admission, by discharge 90% were taking at least twice daily medications and 24% were taking at least thrice daily medications. Use of recommended CV medications increased from admission to discharge. This was largest with P2Y12 use (increase from 16% to 64%), but was notable across all recommended cardiac classes (aspirin or warfarin from 52% to 92%, statin from 52% to 90%, beta-blockers from 48% to 89%, and ACEI/ARB from 44% to 57%). A majority of patients discharged were not taking all live recommended cardiac medication classes (5% at admission and 35% at discharge).

CONCLUSION: The burden of medication use among an ACS patient population is large, complex, and easily underappreciated. Understanding that the majority of patients with an ACS will be discharged on a substantially more complicated medical regimen than they were admitted with, including the majority taking over 10 different medications daily with a frequency of oral medications of at least twice a day in nearly all, can help guide measures to improve long term adherence.

SPONSORSHIP: Merck & Co, Inc.

Profiling of Charges Among Atherothrombotic Patients with a History of Prior Myocardial Infarction: Implications for Managed Care

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BACKGROUND: Atherothrombotic patients with a history of a prior myocardial infarction (MI) are at high risk for major adverse cardiovascular events (MACE).

OBJECTIVE: To profile prior MI managed care patients based on their real-world charges to determine if there are patterns associated with resource use and/or costs.

METHODS: Patients ≥18 years old with a primary discharge or outpatient diagnosis of MI enrolled in the Humana database from January 1, 2008 to January 1, 2011 were identified. The earliest date of a drug record of a P2Y12 anti-platelet agent ≥90 days from the MI diagnosis was the index date and a period of 1-year pre- and 3 years post-index was the study time frame. MI patients with unknown age or sex on the index date, a history of thrombocytopenia, coagulation disorders or non-atherogenic etiologies for MI were excluded. Pre-index charge distributions of MI-related and all-cause charges of these prior MI patients were generated and patients were stratified into low (LC), medium (MC) and high charge (HC) strata based on MI-related charges. Descriptive statistics comparing patient demographics, comorbidities, medical resource utilization, and charges were generated.

RESULTS: A total of 6,374 patients (64.9% male, with a mean age [±SD] of 65.9 ± 7.2 years) were selected. The mean (SD) total pre-index MI-related and all-cause charges were $7,551 ($12,249) and $21,496 ($18,807) respectively. The pre-index MI-related charge (all-cause charge) breakdown was; HC ($19,852 [$28,304]), MC ($2,140 [$16,518]) and LC ($664 [$19,686]). HC MI patients were more likely to be male (68.5% vs. 63.8% vs. 62.4%; P < 0.0001) and younger (65.4 vs. 66.1 vs. 66.2; P = 0.026) than MC and LC MI patients. HC MI patients had significantly higher pre-index rates of CAD (97.9% vs. 89.2% vs. 27.7% [MC] vs. 31.8% [LC]; P < 0.0001). In the post-index, patients in both the LC and MC had higher MI-related annualized charges ($2,253 vs. $2,830 vs. $1,966; P < 0.0001) and higher post-index all-cause annualized charges ($18,392 vs. $19,580 vs. $13,832; P < 0.0001) than the HC MI cohort. The main charge driver in the post-index MI and all-cause charges was significantly higher pharmaceutical expenditures.

CONCLUSION: Increasing expenditures in pharmaceuticals post-MI have not been offset by charge decreases in inpatient or outpatient charges, primarily in the LC and MC charge cohorts.

SPONSORSHIP: AstraZeneca.
BACKGROUND: Individuals with previous coronary heart disease (CHD) have an increased risk for recurrent major adverse coronary events (MACE). Despite control of modifiable “traditional” CHD risk factors (e.g., smoking, HTN, DM), a significant proportion of patients have recurrent MACE. Examining the association of “non-traditional” risk factors (NTRFs) in proximity to a recurrent MACE may reveal novel associations.

OBJECTIVE: The purpose of this study was to evaluate the association of potential NTRFs prior to a first recurrent MACE.

METHODS: This matched case-control study was conducted at Kaiser Permanente Colorado. Cases were defined as patients with an incident coronary event occurring between January 1, 2005 and December 31, 2010 and a first recurrent coronary event occurring at least 270 days after the incident event. Controls were defined as patients with an incident coronary event occurring between the same time period but without a recurrent coronary event. The NTRFs evaluated included depression, anxiety, insomnia, pulmonary disease, prediabetes, atrial fibrillation/flutter, congestive heart failure, erectile dysfunction, anti-psychotic medication use, hormone replacement therapy, socioeconomic status, and a wellness visit one year prior to recurrent event. The NTRFs were reviewed 180 days prior to the occurrence of the first recurrent coronary event for any potential association. Cases were matched 1:5 to control patients. Patient characteristics and outcomes were compared using chi-square tests of association/Fisher’s exact test and independent sample t-tests/Wilcoxon rank sum tests for categorical and continuous variables, respectively. Multivariate analysis was performed using conditional logistic regression.

RESULTS: There were 3,291 controls matched to 402 cases. The overall mean age was 66.1 years and 33.8% were female. Baseline characteristics were similar between groups except cases were more likely to have diabetes mellitus (31.3% of cases vs. 21.9% of controls, P < 0.001). A higher chronic disease score was associated with MACE (OR = 1.10, CI: 1.04-1.16). The presence of anxiety/depression (OR = 1.44, CI: 1.06-1.97) heart failure (OR = 1.46, CI: 1.05-2.03), and renal disorder (OR = 1.47, CI: 1.10-1.98) were associated with a first recurrent MACE.

CONCLUSION: High chronic disease score, anxiety/depression, heart failure and renal disorder were associated with a first recurrent MACE. Addressing these NTRFs may help reduce risk of future recurrent MACE. Future research should investigate interventions targeting modifiable NTRFs.

SPONSORSHIP: Kaiser Permanente Colorado.

Quality Assessment and Risk Evaluation for Commercial Members of a Regional Health Plan with Nonvalvular Atrial Fibrillation

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BACKGROUND: Patients with nonvalvular atrial fibrillation (NVAF) are at increased risk for stroke. Nationally recognized guidelines for managing NVAF provide drug therapy recommendations based on the CHA2DS2 VA5c, a stroke risk stratification scoring system. For patients with a CHA2DS2 VA5c >2, oral anticoagulation with warfarin or target specific oral anticoagulants (TSAOAs) is recommended. The HAS-BLED score helps identify patients with NVAF at high risk for major bleeding, a potential risk of anticoagulation therapy. Despite the clear benefit, gaps remain between guideline recommendations and clinical practice.

OBJECTIVE: For members with a diagnosis of NVAF compare prescribed antithrombotic drug therapy to the 2014 AHA/ACC/HRS Atrial Fibrillation Guidelines.

METHODS: A retrospective review was conducted at a regional health plan associated with a local integrated delivery system (IDS). Commercially insured members >18 years of age who were active members as of September 1, 2013 with a diagnosis of NVAF (ICD-9 code 427.31, 427.3) within the previous two years were reviewed. Target drugs reviewed were warfarin, clopidogrel and TSOAs if prescribed since January 2, 2012. If a member was not prescribed warfarin but had >3 INR within the past year, the member was considered to be taking warfarin. Members with valvular heart disease were excluded. The analysis focused on members considered to be at high risk for stroke with a CHA2DS2VA5c>2.

RESULTS: Of the 1,158 members reviewed, 569 (49.1%) did not have a prescription claim for antithrombotic therapy. Of the 569 members, 308 (54.1%) had a CHA2DS2VA5c score>2. Due to the integration of the health plan and health system, HAS-BLED scores and aspirin doses were available for 43 (14%) of the 308 members. Of the 43 first-admission. Secondary outcomes were the potential risk factors associated with death and first admission. Cox proportional hazards and logistic regression models were used for primary outcomes and secondary outcomes, respectively.

RESULTS: Of 1,274 eligible patients, 779 met inclusion criteria. Patients were predominantly male (98.5%) with the mean age of 74 (SD = 11). The average duration of therapy was 1806 days (SD = 860) [4-95 years]. After adjusting for the demographic, diagnostic and medication variables, there was a statistical significant association between duration of clopidogrel therapy and time-to-all-cause-mortality to age and admission (hazard ratio [HR], 0.98 [95% CI: 0.97-0.99] and HR, 0.60 [0.49-0.73]), respectively. The impact of age disappeared in the model when assessing the association between duration of clopidogrel therapy and time-to-first-admission (HR, 0.99 [0.99-1.00]). Cardiovascular diagnoses did not show any statistical significant associations with the events. Several medications were identified to also have protective effects. They were proton pump inhibitors (PPI), histamine-2 receptor antagonists (H2RA), aspirin, and non-steroidal anti-inflammatory drugs (NSAIDs).

CONCLUSION: Clopidogrel therapy beyond two years in patients treated for cardiovascular indications seemed to have protective effects for death and admission when combined with concurrent use of PPI or H2RA or aspirin or NSAIDs. The results of this study go against the conventional belief that long-term treatment with clopidogrel may cause harm.

SPONSORSHIP: None.

An Evaluation of the Chronic Use of Clopidogrel in the Veteran Population

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BACKGROUND: Clopidogrel is approved for various indications, but the duration of therapy differs. Currently, there are little and conflicting evidence available on whether prolonged use is associated with increased risk of adverse effects or improved outcomes.

OBJECTIVE: We aimed to evaluate the real-life harm of chronic clopidogrel therapy (>2 years) for cardiovascular indications.

METHODS: This is a retrospective chart review study. Eligible patients were from the Veteran Affairs Long Beach Healthcare System who received clopidogrel therapy between January 1, 2000 and December 31, 2012 for at least two years and had a cardiovascular diagnosis. Patients were excluded if they were on clopidogrel for cerebrovascular-related indications, or if there were missing data on baseline parameters. Primary outcomes were time-to-all-cause-death and time-to-death and first-admission. Secondary outcomes were the potential risk factors associated with death and first admission. Cox proportional hazards and logistic regression models were used for primary outcomes and secondary outcomes, respectively.
members, 34 (79%) had a HAS-BLED score < 2; 13 were prescribed no therapy, while 21 reported taking a daily aspirin. The results indicate many members with NVAF at high risk for stroke and not at high risk for major bleed were not receiving recommended antithrombotic therapy.

CONCLUSION: The health plan will contact the prescribers of the 265 members for whom HAS-BLED scores were unavailable and those of the 34 who had HAS-BLED scores ≤ 2 and were prescribed no therapy or aspirin alone. The results will be shared with the IDS and local physician community and an educational intervention and monitoring program will be developed.

SPONSORSHIP: Health New England and Pfizer, Inc. (nonfunded).

113 Comparative Assessment of Medical Resource Use and Costs Associated with Patients with Symptomatic Peripheral Artery Disease Versus a Matched Control Patient Population

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BACKGROUND: A better understanding of the potential economic impact of symptomatic peripheral artery disease (SPAD) relative to a matched control population may help improve care management in these patients.

OBJECTIVE: To evaluate and compare the economic impact associated with symptomatic PAD patients and a well-matched control patient population.

METHODS: SPAD was defined as having evidence of intermittent claudication (IC) and/or critical limb ischemia (CLI) requiring percutaneous revascularization (PRV). Both SPAD and control patients ≥18 years old enrolled in the MarketScan Commercial and Encounters database (MCED) from January 1, 2005 to June 30, 2013 were identified using an exact match based on age, sex, index year and Charlson Comorbidity Score (CCS). SPAD patients were selected using an algorithm comprising a combination of PAD related ICD-9 diagnostic and DRG codes, PRV CPT-4 procedure codes, and IC medication NDC codes. A final 1:1 control population with an exact match based on age, sex, index year and CCS was identified. The earliest date of a record of SPAD was the index date and a period of 1 year pre- and 3 years post-index was the study time frame. SPAD patients with stroke/TIA, with bleeding complications and contraindications to anti-platelet therapy were excluded. Descriptive statistics comparing patient demographics, clinical characteristics, medication utilization, medical resource utilization, and cost outcomes were generated.

RESULTS: 3,965 SPAD and 3,965 control patients were matched on a 1:1 ratio. In both cohorts, 54.7% were male, with a mean age (± SD) of 69.0 ± 12.9 years and a CCS score of 1.32 ± 0.9. SPAD patients had more CV comorbidities than control patients (27.7% vs. 12.6% CAD, 27.1% vs. 15.9% hyperlipidemia, 49.8% vs. 28.2% hypertension) in the pre-index. 17.8% SPAD vs. 6.6% control patients were on clopidogrel in the pre-index. Post-index rates of ischemic stroke, NSTEMI, unstable angina, and CV or PAD-related procedures (PCI, CABG, limb amputations and PRV) were higher among SPAD patients versus control patients. All-cause annualized inpatient admissions (0.46 vs. 0.22 admissions); ER days (0.27 vs. 0.22 days) and office visit days (12.5 vs. 10.2 days) were higher among SPAD vs. control patients in the post-index. Inpatient costs ($8,494 vs. $3,778), outpatient costs ($8,459 vs. $5,692), and total costs ($20,880 vs. $12,501) were higher among SPAD versus control patients in the post-index.

CONCLUSION: SPAD patients have significantly higher medical resource use and costs when compared to a well matched control population.

SPONSORSHIP: Merck & Co., Inc.
**114EM** Cost-Effectiveness of Apixaban Versus Dabigatran for Thromboprophylaxis in Total Knee Replacement Surgery in the United States

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**OBJECTIVE:** To assess the cost-effectiveness of apixaban versus dabigatran as thromboprophylaxis agent for the prevention of venous thromboembolism (VTE) and bleeding episode after total knee replacement (TKR) surgery.

**METHODS:** A decision-tree model was developed to compare the cost-effectiveness of apixaban versus dabigatran for TKR from U.S. Medicare perspective. The analysis was conducted over 6-month of surgical and post-operative time horizon. Treatment efficacy and safety data (probabilities of distal and proximal deep vein thrombosis, symptomatic pulmonary embolism, and major bleeding) were derived from published literature including systematic reviews and clinical trials. Costs were based on estimates from published studies; old costs were inflated and adjusted to constant dollars for year 2013. Medication costs were estimated from Redbook 2013. Cost of diagnostic measures for VTE were derived using the current procedure terminology (CPT) for the year 2013. The diagnosis code-related Medicare payments were extracted for disease conditions such as DVT, PE and major/minor bleeding episodes and inflated to year 2013. To account for future values of costs and events, a discount rate of 3% was applied in the base-case analysis.

**RESULTS:** The cost of medication for the guideline-consistent prophylaxis treatment regimen were $340 for apixaban and $423 for dabigatran. Cost of treatment of bleeding episode and VTE were $14,820 and $14,379, respectively. Apixaban had lower rates of major bleeding episodes while higher rates of VTE as compared to dabigatran. Prophylaxis treatment with apixaban was $874 less than dabigatran for prevention of VTE and bleeding episode in patient undergoing TKR.

**CONCLUSION:** From U.S. Medicare perspective, dabigatran has higher efficacy rate but also higher cost of treatment for thromboprophylaxis for patients undergoing TKR compared to apixaban.

**SPONSORSHIP:** None.

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**116EM** Impact of Reduction in Falls for Patients with Neurogenic Orthostatic Hypotension (NOH) Associated with Parkinson’s Disease (PD): Post-Hoc Economic Analyses of Phase III Clinical Trial Data on Droxidopa

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**BACKGROUND:** A consequence of autonomic failure, NOH results in inadequate noradrenergic response to postural change. Studies suggest NOH is a substantial risk factor for falls in patients with PD. Droxidopa is an oral norepinephrine pro-drug recently approved by the FDA for treatment of symptomatic NOH caused by primary autonomic failure.

**OBJECTIVE:** The objective was to estimate a decrease in costs associated with a reduction in number of falls experienced by patients with PD and NOH.

**METHODS:** We used a retrospective, piggyback design of RCT data on droxidopa, as well as data in the literature, to estimate the cost offset by reduction in falls. Patients with PD in a Phase III study underwent ≤ 2 weeks of double-blind titration with droxidopa, followed by 8-week maintenance therapy (100-600 mg TID) or placebo. Falls were recorded daily via electronic diaries; 92 droxidopa patients reported...
308 falls, and 105 placebo patients reported 908 falls. The difference in numbers of falls between therapy and placebo, although significant, was found to be non-normally distributed. Post-hoc analyses found a good fit to a Poisson Inverse Gaussian (PIG) distribution in PD-related research on falls. With normalization for falls/patient/week, droxidopa led to significantly fewer falls than did placebo (0.40 vs. 1.05, P = 0.018, PIG). The percentage of patients with fall-related injuries was lower for droxidopa (16.7%) than for placebo (26.9%). Fall-related injuries were evaluated using predefined adverse event types (e.g., contusion). With data in the literature on probability of falls and costs related to falls, we calculated average cost/fall/treatment, to estimate the potential cost reduction during 8 weeks of droxidopa therapy and placebo.

RESULTS: Using probability of fall to be fatal or non-fatal, fall requiring or not medical care, and costs from a systematic review of falls data, we estimated average cost of fall/patient to be $4,573 for droxidopa vs. $11,813 for placebo over 8 weeks. A reduction in cost due to falls of $7,239 could be expected. Sensitivity analyses with more conservative estimates of cost of falls or number of falls decreased the savings to $3,467 and $2,651, respectively.

CONCLUSION: This simple model indicates droxidopa could reduce cost due to falls for PD patients with NOH, with potential savings ≤$7,239 over 8 weeks.

SPONSORSHIP: Lundbeck LLC, Deerfield, IL.

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

J3 Tolerability of 5-grass sublingual tablet in Subjects with Grass Pollen-Induced Allergic Rhinoconjunctivitis: Results of a Pooled Analysis

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BACKGROUND: Efficacy and safety of the 5-grass tablet have been demonstrated in subjects with grass pollen-induced allergic rhinoconjunctivitis. Knowledge of the tolerability profile helps prescribers provide appropriate patient care and educate patients.

OBJECTIVE: Using pooled data across the development program for 5-grass tablet, to report the time to onset of adverse reactions (i.e., events considered related to the treatment) that led to study discontinuation.

METHODS: Subjects (age 5-65 years) with medically confirmed grass pollen-induced allergic rhinoconjunctivitis for at least 2 years were included in 8 double-blind, placebo-controlled studies. All subjects who received at least one dose of the 5-grass tablet during the single treatment period or the first treatment period of the long-term study were included in the analysis. Adverse events were monitored throughout the studies.

RESULTS: Among the 1,514 subjects receiving active treatment, 50 of 1,360 adults (4%) and 6 of 154 children/adolescents (4%) permanently discontinued as a result of adverse reactions. Of these 56 subjects, 43 (77%) reported events consistent with application site reactions (oral pruritus, pharyngeal edema or throat irritation). The other subjects reported skin reactions such as urticaria (4 subjects), episodes of chest discomfort (3 subjects), respiratory events such as cough or dyspnea (2 subjects), conjunctivitis (2 subjects), liver disorder (1 subject) or vomiting (1 subject). Among all adults receiving active treatment, 9 (0.7%) discontinued on Day 1, 22 (1.6%) from Day 2 to 15 and 9 (0.7%) from Day 16 to 30. Overall, 80% of the adults stopping treatment discontinued within the first month of treatment initiation. The 6 children/adolescents who withdrew did so within the first two weeks of treatment.

CONCLUSION: Across the development program for 5-grass sublingual tablet, approximately 4% of subjects who received active treatment withdrew from the studies because of adverse reactions. Most were application site reactions which began soon after treatment initiation.

SPONSORSHIP: Stallergenes S.A.

J5EM Budget Impact Model of Oralair for the Treatment of Grass Pollen-Induced Allergic Rhinoconjunctivitis in Adults and Children

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BACKGROUND: Allergic rhinoconjunctivitis (AR) is a chronic condition with substantial economic burden and reduced quality of life of the patients. AR is estimated to affect up to 40% of the U.S. population and to lead to a range of related co-morbidities.

OBJECTIVE: The aim was to estimate the third party payer budget impact (BI) of Oralair, a recently approved sublingual immunotherapy tablet indicated as immunotherapy for patients (aged 10-65 years) with grass-pollen induced AR.

METHODS: Pharmacy, medical, and total BIs (2013 USD) were estimated for the first three years of ORALAIR market entry. The target population was patients (aged 10-65) with grass-pollen AR and was estimated using published epidemiological data. Without ORALAIR, patients were assumed to be treated with all possible combinations of subcutaneous immunotherapy (SCIT), intranasal steroids, ophthalmic anti-allergic drops, oral antihistamines, and leukotriene modifiers, or over-the-counter treatments. Market share without ORALAIR was obtained from analysis of de-identified claims of privately insured patients (aged 10-64) with AR due to pollen (ICD-9-CM: 477.0) from April 1, 2012-March 31, 2013. Patients allergic only to grass-pollen were assumed to replace their current treatment with ORALAIR, whereas polysensitized patients would use ORALAIR as an addition. After ORALAIR entry, the market share of existing treatment was assumed to be reduced in proportion to the treatment's market share without ORALAIR entry. Components of pharmacy costs were obtained from the claims analysis and literature. Treatment resource utilization (RU) was obtained from the literature, while the cost of each RU component was calculated from the claims analysis. The total BI and per member per month (PMPM) BI was estimated from a U.S. third-party payer's perspective. One-way sensitivity analyses of key parameters were conducted.

RESULTS: In a hypothetical health plan with 1 million members, the estimated target population size in the first year after ORALAIR entry was 26,320 persons. After ORALAIR entry, the pharmacy costs increased by $0.36, $0.44, and $0.51 PMPM while the total costs (after medical cost offsets) increased by $0.15, $0.18, $0.22 PMPM in the first, second, and third year, respectively. Sensitivity analyses showed that results were most sensitive to ORALAIR's compliance rate and treatment duration.

CONCLUSION: Use of ORALAIR for grass-pollen induced AR is expected to increase pharmacy budgets, but the increase is offset in part by lower medical budgets due to reduced frequency of medical visits compared with symptomatic treatments and SCIT.

SPONSORSHIP: Greer Laboratories, Inc.
Allergy Immunotherapy for Allergic Rhinitis Is Associated with Significantly Reduced Outpatient Services Use for Chronic Conditions of the Upper Respiratory Tract: A Large-Scale, Retrospective, Matched Cohort Study

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BACKGROUND: Published data show that allergy immunotherapy (AIT) for the treatment of allergic rhinitis (AR) is associated with significantly reduced health services use and costs.

OBJECTIVE: To examine types of outpatient services and degree of benefit associated with AIT for the treatment of AR.

METHODS: Data obtained from computerized, Health Insurance Portability and Accountability Act-compliant Florida Medicaid (July 1, 1997-June 30, 2009) paid claims. International Classification of Diseases, Ninth Revision codes identified AR (477.X), asthma (493.X), atopic dermatitis (691.8); conjunctivitis (372.X), chronic diseases of the upper respiratory tract (CC-URT, 471-476, 478). Current Procedural Terminology codes identified outpatient- (99201-15, 99354-5, 99241-5) and AIT-related (95115, 95117, 95120, 95125, 95144, 95165, 95180, 95199) services. “Index AR diagnosis” = first AR claim; “newly-diagnosed AR” = index AR diagnosis preceded by 1 year without AR; “de novo AIT” ≥ 2 AIT claims following newly-diagnosed AR, and non-AIT-related services=CPTs not classified as AIT-related. Matched (1:1 on demographics, Charlson Comorbidity Index, asthma, atopic dermatitis, and conjunctivitis) AR controls never received AIT. Chi-square tests compared within- and between-group differences for rates of non-AIT-related service use at 6, 12 and 18 months pre-versus post-AIT initiation.

RESULTS: Matched were 4,967 AIT-treated patients to 4,967 controls. At the 6-month post-period, the AIT group had significantly reduced non-AIT-related outpatient services use by 14.3% (P<0.0001); controls had significantly increased use by 1.0% (P=0.02). Compared to controls, by the 18-month post-period, the AIT group was 3 times more likely to reduce use of outpatient services for CC-URT (95% CI: 2.4, P<0.0001). Specifically, compared to controls, the likelihood that the AIT group would reduce outpatient services for CC-URT-related diagnoses by 18 months was 35 times greater for nasal polyposis (95% CI: 2-600, P=0.0159); 31 times greater for other diseases of the respiratory tract (95% CI: 2-573, P=0.02); 8 times greater for chronic pharyngitis and nasopharyngitis (95% CI: 5-11, P<0.0001); 4 times greater for chronic disease of the tonsils and adenoids (95% CI: 2-7, P<0.0001); and 2 times greater for chronic sinusitis (95% CI: 1-2, P<0.0001).

CONCLUSION: Throughout the 18-month study, compared with controls, the AIT group experienced a significant reduction in the rates of non-AIT-related outpatient services use in general and CC-URT outpatient services use specifically.

SPONSORSHIP: Funding provided by Stallergenes and grants from the American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma, and Immunology; and the Joint Council of Allergy, Asthma and Immunology.

Factors Associated with Non-Treatment of COPD: A Cross-Sectional Analysis of the National Health and Wellness Survey Data


BACKGROUND: In the U.S., it is estimated that >26 million people have chronic obstructive pulmonary disease (COPD). Previous research suggests that a substantial proportion of COPD patients remain untreated; however there is limited evidence that identifies the factors accounting for this lack of COPD treatment.

OBJECTIVE: To assess the factors associated with non-treatment of COPD in patients with self-reported diagnosis of COPD.

METHODS: A cross-sectional analysis of the U.S. National Health and Wellness Survey Data (NHWS) from 2010-2012 was performed. The NHWS is an annual, self-administered, Internet-based, survey of U.S. adults and includes information on >70,000 individuals each year. From this sample, all adults over the age of 40 who self-reported experiencing COPD and confirmed their COPD had been diagnosed by a physician were included. Two cohorts (Treated COPD and Untreated COPD) were formed based on patient-reported current use of a prescription medication to treat COPD. Univariate statistical comparisons (t-tests and chi-square tests) were performed to assess the differences in patient demographic and clinical factors between the two cohorts. A multivariate logistic regression model was used to assess the factors associated with non-treatment of COPD.

RESULTS: A total of 9,344 patients were included. Of these, 38.9% were Treated COPD patients while 61.1% were Untreated COPD patients. Untreated COPD patients were younger (39.8 years vs. 63.4 years, P<0.0001) and more likely to be female (55.8% vs. 49.0%, P<0.001) than Treated COPD patients. Multivariate analysis showed factors that were most strongly associated with non-treatment of COPD include COPD severity, the need for oral steroids, medication coverage status and smoking status. Compared to patients with severe COPD, patients with mild COPD were 5.4 times more likely (Odds Ratio [95% Confidence Intervals]: 5.37 [4.31, 6.69]) and patients with moderate COPD were 2.1 times more likely to be untreated 2.08 [1.68, 2.57]. Patients not needing oral steroids were 2.8 times more likely to be untreated (2.78 [2.27, 3.45]). Patients without medication coverage were 1.8 times more likely to be untreated (1.82 [1.59, 2.08]). Lastly, compared to former smokers, non-smokers were 1.8 times more likely to be untreated (1.75 [1.52, 2.04]).

CONCLUSION: A large proportion of COPD patients reported that they were not currently treating their COPD. Non-treatment of COPD may be strongly influenced by factors such as COPD severity, medication coverage status and smoking status.

SPONSORSHIP: Funding for this study was provided by Boehringer Ingelheim Pharmaceuticals Inc.
best-worst scaling (BWS) questions. The PASAPQ includes a Performance and Convenience domain. Twelve inhaler attribute definitions were developed based on the PASAPQ items. The BWS questions asked respondents to select the most and least important of these attributes for achieving satisfaction with an inhaler. Two types of analyses were conducted: descriptive statistics of the PASAPQ responses and a random-parameters logit model of BWS responses.

RESULTS: The survey was completed by 503 participants. The majority were female (57.3%), white (88.5%), and 51 to 70 years old (67.6%). Of the participants, 46.9% reported a diagnosis of chronic obstructive pulmonary disease, 21.9% asthma, 8.2% other lung disease, and 23.1% more than one lung disease. PASAPQ item responses indicated that the majority of participants were satisfied or very satisfied (ranging from 61% to 75%), fewer than 20% reported being somewhat dissatisfied to very dissatisfied. Based on the PASAPQ scores, up to 72% of participants reported being satisfied or very satisfied on the three most important attributes. The three most important device attributes were Feeling that your medicine gets into your lungs, Inhaler works reliably, and Inhaler makes inhaling your medicine easy. The importance weight for the most important attribute was statistically significantly greater than the importance weight of the second most important attribute. The BWS results revealed that the most important attributes corresponded to six of the seven items in the PASAPQ Performance domain.

CONCLUSION: Based on the PASAPQ, the majority of participants reported satisfaction with the Combivent Respimat device. Performance attributes are of greater importance for achieving satisfaction than convenience attributes.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

J12 Guideline-Based Therapeutic Recommendations: Rates of Commission and Omission

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BACKGROUND: SinfonyRx and the Medication Management Center (MMC), provide Medication Therapy Management (MTM) for over 5 million patients nationwide. Patient prescription claims are analyzed against clinical algorithms for more than 300 therapeutic recommendations. Although ongoing updates are made, the algorithms have not undergone a full review since their development. Errors were presented to the Clinical Committee for review and adaptation into clinical algorithms following approval. Given the vast number of patients impacted by the services at the MMC/SinfonyRx, it is essential that their database be updated and remain current.

OBJECTIVE: In this quality improvement project, we sought to improve patient safety by identifying clinical algorithms that are not relevant and should be removed (errors of commission) as well as those that should be included but are not (errors of omission).

METHODS: The project utilized four databases to assess the appropriateness of SinfonyRx’s clinical algorithms for three guideline-based therapeutic recommendations (congestive heart failure add beta-blocker, pain add proton pump inhibitor and asthma add inhaled corticosteroid). Errors were presented to the Clinical Committee for review and adaptation into clinical algorithms following approval. Error rates between therapeutic recommendations were compared using a chi-square with an alpha level of 0.05.

RESULTS: No significant difference was found between groups with regards to errors of commission (P=0.110), but there was a significant difference between groups with regards to errors of omission (P=0.0024).

CONCLUSION: The results are important because they suggest that the clinical algorithms necessitate review and that doing so will lead to safe and appropriate therapeutic recommendations for patients.

SPONSORSHIP: University of Arizona College of Pharmacy and SinfonyRx.

J13 Outcome Evaluation of the Texas Adult Potentially Preventable Initiative on Asthma in Older Adults and Chronic Obstructive Pulmonary Disease

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BACKGROUND: The 82nd Texas Legislature appropriated $2 million for the Texas Department of State Health Services (DHS) to implement an initiative to reduce potentially preventable hospitalizations in 2012 and 2013. Potentially preventable hospitalizations (PPHs) are hospitalizations that would likely not occur if the conditions had been successfully managed in an outpatient setting. Counties could choose any of the 8 conditions associated with potentially preventable hospitalizations; angina, bacterial pneumonia, congestive heart failure, chronic obstructive pulmonary disease (COPD) and adult asthma, dehydration, diabetes complications, hypertension, and urinary tract infection.

OBJECTIVE: To examine the impact of PPHs initiative on hospital admissions and total charges resulting from adult asthma/COPD in Ector county.

METHODS: DHS contracted ($62,500 annually) with Ector county hospital district to implement the initiative. The services provided were based on a needs assessment that is conducted during the visits and they include: smoking cessation counseling, medication and medical services support, patient education, healthcare provider education, community education and case management. Nurses review a hospitalization daily readmit report from the medical center health hospital to determine the readmission cause. The nurses visit or call the patients in the hospital and then follow up with them after discharge on days 14, 21 and 30. In addition to the hospital readmit report, the initiative receives patient referrals from coalition members and other area hospitals.

RESULTS: In 2012, Ector county provided smoking cessation services to 126 people and patient education to 308 patients. The target goal was to reduce hospital admissions and charges by 15%. Hospital admissions and charges from adult asthma/COPD in Ector county decreased by 23.2% and 11.5%, respectively between 2011 and 2013. Hospital admissions for adult asthma/COPD in counties that did not receive funding decreased by 10% while the hospital charges increased by 9.1% between 2011 and 2013.

CONCLUSION: Services provided through the initiative resulted in reduced hospital admissions and total hospital charges from adult asthma/COPD. The overall decreases in hospital admissions and charges were greater in counties that received initiative funding as compared to counties that did not. In addition to monetary savings, the Ector county community also benefited from greater health awareness as a result of the initiative.

SPONSORSHIP: This study was conducted without any external funding.
Real-World Analysis of the Economic Impact of Infliximab Utilization by Site of Care and Medical Diagnosis Within Two Regional Health Plans

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BACKGROUND: Past research has demonstrated consistently higher costs per claim of medical benefit specialty drugs at hospital outpatient facilities (HOP) compared to alternative sites of care (SOC). Infliximab, in particular, is used to treat a large variety of disease states and has been demonstrated to represent the largest overall spend among such drugs. Currently, there is limited understanding of the economic impact that medical diagnosis has on infliximab utilization within various SOC.

OBJECTIVE: To identify how utilization of infliximab differs by SOC and disease categories, and impacts financial expenditures within two regional health plans.

METHODS: Using two large regional health plans’ medical database (approximately 4 million lives), continuously enrolled patients who were administered infliximab between January 1, 2013 and December 31, 2013 were identified. Medical diagnosis, SOC, infliximab utilization, and cost were identified for each claim. Diagnoses were grouped into the following categories: rheumatoid/musculoskeletal, gastrointestinal (GI), dermatologic, ocular, oncology/hematology, and other. Results were analyzed using descriptive statistics.

RESULTS: A total of 3,161 unique patients were administered infliximab therapy representing 17,903 total claims and $88,032,179 in cost. Of the 17,903 claims, 6.3% were administered through home infusion and/or specialty pharmacy (H/P/S); 34.3% in a HOP, and 59.1% in a physician office, with average paid amounts of $4,293, $7,302, and $3,606 per claim, respectively. The total spend per disease category was $48,360,142 for GI with $32,515,633, $12,821,810, and $2,995,893 being accounted for by HOPs, physician offices, and H/P/S, respectively, and $35,096,887 for rheumatoid/musculoskeletal with $9,177,723, $24,140,500, and $1,778,664 being accounted for by HOPs, physician offices, and H/P/S, respectively. The total spend for all other disease groups were less than $5 million total.

CONCLUSION: Choice of SOC infusions can be associated with a high degree of unnecessary costs. The average claim cost from a HOP was 102% higher than the average claim cost from a physician office even though the average units per claim in the physician offices were 20% higher. Additionally, SOC utilization differs dramatically according to disease state. Approximately 67% of all infliximab spend for GI conditions are billed from HOPs compared to just 26% for rheumatoid/musculoskeletal conditions. Identifying disease categories with a high percentage of HOP utilization is one opportunity for managed care organizations to reduce unnecessary utilization and contain escalating SOC costs.

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

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BACKGROUND: Patient-reported treatment satisfaction in moderate-to-severe plaque psoriasis (PsO) have revolutionized treatment expectations.

OBJECTIVE: To describe how OIC affects pain management among chronic non-cancer pain patients and to describe the discordance in perception of OIC symptoms and management between patients and their healthcare providers (HCPs).

METHODS: Patients on daily opioids for ≥4 weeks for chronic non-cancer pain with OIC were recruited into a prospective longitudinal study of OIC burden. Laxative Inadequate Response (1xLIR) was defined as patients who had sufficient use of laxative (≥1 stool softer or laxative ≥4 times in past 2 weeks) but who had an inadequate response (defined as <3 bowel movements [BMs] or ≥1 Patient Assessment of Constipation Symptoms [PAC-SYM] symptom scored moderate, severe or very severe).

RESULTS: 238 U.S. patients completed the baseline survey (58% women, 73% white). Chronic back (86%) and joint pain (51%) were the most frequently reported pain conditions. Patients reported 1.3 spontaneous BMs/week; however, 87% reported a desire to have ≥1 BM/day. Prevalence of 1xLIR among sufficient laxative users was 97%. Although 79% of HCPs reported they discussed OIC symptoms/concerns with patients, only 57% of those HCPs were actually aware the patient met criteria for OIC. Moreover, for patients reporting OIC symptoms at ≥ moderate severity, the proportion of HCPs who had observed or discussed each symptom ranged from 2%-41%. In contrast, HCPs were well aware of patient’s pain severity, with patients and HCPs reporting an average pain rating of approximately 6 (6.4 and 6.7, respectively). Nevertheless, HCPs overestimated how well patients managed their pain and OIC concurrently. 52% of patients with OIC reported at least moderate interference with pain management vs. 33% of HCPs. HCPs were aware of patient’s laxative use status in only 42% of cases. 31% of HCPs suggested patients experienced a benefit when the patient indicated no benefit from laxative treatments.

CONCLUSION: A significant unmet need remains in the chronic, non-cancer pain population suffering from OIC, with nearly half of patients reporting moderate to complete interference with pain management as a result of OIC. The disparate perceptions between patients and their HCPs regarding the importance and severity of OIC complicating pain management demonstrate a need for greater communication. Clinical education and coordination of care by HCPs, including nursing professionals, may help to address the need to better appreciate and proactively manage the burden from which these patients suffer.

SPONSORSHIP: This work was sponsored by AstraZeneca.

K00-K93 Diseases of the Digestive System (i.e., Crohn’s Disease, IBD, IBS)

K1 Real-World Analysis of the Economic Impact of Infliximab Utilization by Site of Care and Medical Diagnosis Within Two Regional Health Plans

K2 Impact of Opioid-Induced Constipation (OIC) on Pain Management and the Discordance Between Patient and Healthcare Provider Reports of the Burden of OIC

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OBJECTIVE: To assess treatment satisfaction and factors affecting treatment choice, among PsO patients.

METHODS: Patients, identified in administrative claims, had ≥1 PsO diagnoses and ≥1 claims for methotrexate, cyclosporine, or injectable biologic (adalimumab, etanercept, or ustekinumab). Surveys were mailed to patients to assess satisfaction and rate the importance of

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

L1 Patient-Reported Treatment Satisfaction in Moderate-to-Severe Plaque Psoriasis

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‘Optum, Janssen Scientific Affairs, LLC, Janssen Biotech Services

BACKGROUND: Biologic therapies for plaque psoriasis (PsO) have revolutionized treatment expectations.

OBJECTIVE: To describe how OIC affects pain management among chronic non-cancer pain patients and to describe the discordance in perception of OIC symptoms and management between patients and their healthcare providers (HCPs).

METHODS: Patients on daily opioids for ≥4 weeks for chronic non-cancer pain with OIC were recruited into a prospective longitudinal study of OIC burden. Laxative Inadequate Response (1xLIR) was defined as patients who had sufficient use of laxative (≥1 stool softer or laxative ≥4 times in past 2 weeks) but who had an inadequate response (defined as <3 bowel movements [BMs] or ≥1 Patient Assessment of Constipation Symptoms [PAC-SYM] symptom scored moderate, severe or very severe).

RESULTS: 238 U.S. patients completed the baseline survey (58% women, 73% white). Chronic back (86%) and joint pain (51%) were the most frequently reported pain conditions. Patients reported 1.3 spontaneous BMs/week; however, 87% reported a desire to have ≥1 BM/day. Prevalence of 1xLIR among sufficient laxative users was 97%. Although 79% of HCPs reported they discussed OIC symptoms/concerns with patients, only 57% of those HCPs were actually aware the patient met criteria for OIC. Moreover, for patients reporting OIC symptoms at ≥ moderate severity, the proportion of HCPs who had observed or discussed each symptom ranged from 2%-41%. In contrast, HCPs were well aware of patient’s pain severity, with patients and HCPs reporting an average pain rating of approximately 6 (6.4 and 6.7, respectively). Nevertheless, HCPs overestimated how well patients managed their pain and OIC concurrently. 52% of patients with OIC reported at least moderate interference with pain management vs. 33% of HCPs. HCPs were aware of patient’s laxative use status in only 42% of cases. 31% of HCPs suggested patients experienced a benefit when the patient indicated no benefit from laxative treatments.

CONCLUSION: A significant unmet need remains in the chronic, non-cancer pain population suffering from OIC, with nearly half of patients reporting moderate to complete interference with pain management as a result of OIC. The disparate perceptions between patients and their HCPs regarding the importance and severity of OIC complicating pain management demonstrate a need for greater communication. Clinical education and coordination of care by HCPs, including nursing professionals, may help to address the need to better appreciate and proactively manage the burden from which these patients suffer.

SPONSORSHIP: This work was sponsored by AstraZeneca.
factors related to specific medication choice. Patients were identified as “biologic-experienced” based on either current or prior use of a biologic. One of the primary outcomes was the Treatment Satisfaction Questionnaire for Medication-9 scores. Each sample was weighted by the inverse probability of eligibility and survey completion, for point estimates and variability measures. Calculations were done using SAS/STAT 9.2 survey procedures for simple random sampling with stratification.

**RESULTS:** A total of 426 patients completed the survey: 263 biologic-experienced and 163 biologic-naïve. The percent of affected skin was higher among experienced than naïve (72% vs. 44%, respectively, P = 0.0002). Satisfaction scores (range 1-100) with convenience were similar between cohorts. Mean scores for effectiveness were higher for experienced [74 (Standard Error [SE]: 1.34); 95% confidence interval [CI]: 71.4, 76.7] than naïve (60 [1.74]; 95% CI: 56.3, 63.2) patients. Mean global satisfaction was higher for experienced (70 [1.33]; 95% CI: 67.1, 72.3) than naïve (56 [1.74]; 95% CI: 52.9, 59.7).

**CONCLUSION:** Satisfaction with current medications for PsO is higher among patients who have biologic treatment experience than patients who do not.

**SPONSORSHIP:** Janssen Scientific Affairs, LLC.

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**L3**

Association of Patient Cost-Cutting Behaviors with Health Status and Lost Work Productivity in Patients with Psoriatic Arthritis

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**BACKGROUND:** There has been a trend in managed care toward greater patient cost sharing. However, high costs may necessitate cost-cutting decisions by patients.

**OBJECTIVE:** This study seeks to quantify cost-cutting behaviors in patients with psoriatic arthritis (PsA) and assess the association of these behaviors with patient-reported health status and work productivity loss.

**METHODS:** Individuals aged ≥18 and reporting a PsA diagnosis completed a cross-sectional, self-administered, Internet-based questionnaire in 2012. Behaviors in the prior six months were classified as non-adherent cost-cutting behaviors (NACC), which include taking less medication, halving tablets, buying fewer tablets, not filling Rx, or filling less often, or adherent cost-cutting behaviors (ACC), which include generic use, sample use, multi-month mail order, coupons, and discount cards. Patients with NACC and ACC were compared with those who used no cost-cutting strategies (NCCS). Health status was assessed using the SF-36, and work productivity loss was assessed using the Work Productivity and Activity Impairment questionnaire.

**RESULTS:** Of 306 patients, 64.4% (n = 197) reported at least one cost-cutting behavior. The most frequently reported behaviors were asking for a generic (34.3%), asking for samples (29.1%), buying multiple months at a time through mail order (21.9%) and not filling a prescription because it was too expensive (19.3%). NACC behavior was associated with poorer health status than patients with ACC behavior and NCCS (SF-36 physical component summary: 38.7 vs. 41.3 and mental component summary: 39.1 vs. 46.9). Presenteeism (36.9 vs. 22.2), overall work impairment (37.9 vs. 23.1) and activity impairment (57.5 vs. 42.5) were also poorer in the NACC group compared to the group with ACC behavior and NCCS. The NACC behaviors patients also had more ER visits (41.2% vs. 19.5%) and hospital visits (35.3% vs. 11.3%, P < 0.05) than the ACC behavior group and NCCS group.

**CONCLUSION:** A substantial proportion of PsA patients engage in cost-cutting behaviors which are associated with worsening health status, decreased work productivity and more ER and hospital visits; however, due to the cross-sectional nature of the study, the direction of these associations cannot be determined.

**SPONSORSHIP:** Janssen Scientific Affairs, LLC.

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**L7EM**

Economic Evaluation of Sequencing Strategies in the Treatment of Moderate-to-Severe Psoriasis in the United States

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**BACKGROUND:** In the treatment of psoriasis, switching between alternative biologic treatments is common; however, little is known about the optimal cost-effective strategy in sequencing treatment.
OBJECTIVE: We assessed, from a U.S. payer perspective, the cost-effectiveness of placing apremilast, a new oral treatment, before biologics for moderate to severe plaque psoriasis patients.

METHODS: A 10-year Markov state transition cohort model was developed to compare 2 treatment sequences in the base-case: (1) apremilast followed by etanercept followed by adalimumab and (2) etanercept followed by adalimumab. Patients who failed adalimumab were assumed to receive best supportive care (BSC) as the last line of treatment. Response to therapy was assessed using the Psoriasis Area and Severity Index (PASI) at the end of the clinical trial periods, ranging from 12 to 16 weeks, depending on the study drug. Non-responders moved to the next line of therapy. A 20% annual dropout rate was assumed for each study drug. Treatment efficacy inputs were obtained from a published meta-analysis and trial results. Drug costs were sourced from 2014 Wholesale Acquisition Costs, and 3% annual discount rate was applied to costs and quality-adjusted life-years (QALYs). Costs for BSC were sourced from a previously published U.S.-based study. Apremilast was assumed to be priced at a discount compared with biologics. Utilities were estimated from PASI response using previously published economic evaluations.

RESULTS: The apremilast arm was estimated to provide an additional 0.74 years (5.00 vs. 4.26 years) in which patients achieved a 75% reduction from baseline PASI score (PASI-75) and an additional 0.14 QALYs (6.87 QALYs vs. 6.73 QALYs). Total time spent on the biologic was reduced by 0.56 years (4.26 vs. 4.82 years) and time spent in BSC was reduced by 1.04 years (3.96 vs. 5.00 years). Under base-case assumptions, placing apremilast before biologics was found to be dominant (lower costs, higher QALYs). Sensitivity analyses indicated that several parameters (e.g., utility gains by PASI response, BSC costs, discount rate for costs) influence the incremental cost-effectiveness ratio, with results ranging from dominant to cost-effective (< 50 k/QALY). Similar results were obtained when combinations of etanercept, adalimumab, and ustekinumab were used in the 2-drug sequence.

CONCLUSION: Placing apremilast before biologics results in more responders at Week 16 was $1,893,760 for apremilast, $3,594,220 for etanercept, $2,029,396 for adalimumab, $2,149,734 for ustekinumab 45 mg, and $39,857 for ustekinumab 90 mg. The cost per PASI-75 responder and the lowest cost to achieve 100 PASI-75 responders through 16 weeks in PsO patients as compared with etanercept, adalimumab, ustekinumab 45 mg, and ustekinumab 90 mg. SPONSORSHIP: This study was sponsored by Celgene Corporation.

L8EM Cost Per Responder of Apremilast Versus Etanercept, Adalimumab, and Ustekinumab in Patients with Moderate-to-Severe Psoriasis

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BACKGROUND: In the U.S., psoriasis (PsO) is estimated to cost $11 25B annually (Menter et al., 2008). It is becoming increasingly important to payers to investigate the value of new treatment options in the management of PsO.

OBJECTIVE: The purpose of this study was to estimate the cost per responder after 16 weeks of therapy for PsO patients treated with apremilast, etanercept, adalimumab, and ustekinumab in adults with PsO in the U.S.

METHODS: Comparative efficacy data were obtained from a Bayesian network meta-analysis of biologic and oral systemic drugs as of October 2013. The primary outcome was a ≥75% reduction in the Psoriasis Area Severity Index score (PASI-75) at the end of the trial period (12 or 16 weeks, depending on drug). Cost and efficacy comparisons were made at Week 16, and efficacy for drugs with a trial period of 12 weeks was assumed to be maintained through 16 weeks. U.S. wholesale acquisition cost as of July 2014 and approved labeled dosing for induction of PsO treatment were used to derive drug treatment costs.

RESULTS: At Week 16, the adjusted PASI-75 response rate was 31.9% for apremilast, 52.6% for etanercept, 65.9% for adalimumab, 68.6% for ustekinumab 45 mg, and 74.0% for ustekinumab 90 mg. The cost per PASI-75 responder at Week 16 was $18,938 for apremilast, $33,508 for etanercept, $20,294 for adalimumab, $21,497 for ustekinumab 45 mg, and $39,857 for ustekinumab 90 mg. The cost to achieve 100 responders at Week 16 was $1,893,760 for apremilast, $3,594,220 for etanercept, $2,029,396 for adalimumab, $2,149,734 for ustekinumab 45 mg, and $3,985,713 for ustekinumab 90 mg.

CONCLUSION: Apremilast had the lowest wholesale acquisition cost per PASI-75 responder and the lowest cost to achieve 100 PASI-75 responders through 16 weeks in PsO patients as compared with etanercept, adalimumab, ustekinumab 45 mg, and ustekinumab 90 mg.

SPONSORSHIP: This study was sponsored by Celgene Corporation.

L9 Treatment Patterns and Healthcare Resource Utilization in Patients with Actinic Keratosis: A U.S. Payer Perspective


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BACKGROUND: The prevalence estimates for actinic keratosis (AK) in the U.S. range between 11-26%. New therapies continue to emerge and current field-directed treatment options include the in-office therapy photodynamic therapy (PDT) and the patient-applied topical therapies imiquimod, 5-fluorouracil (5-FU), diclofenac, and the recently approved ingenol mebutate (IngMeb). IngMeb has shorter dosing duration (2 or 3 days) and clinical studies suggest milder adverse events than other topical therapies. However, real-world data on the use of IngMeb is limited.

OBJECTIVE: Compare healthcare resource utilization (HRU) (outpatient visits [OP] and prescriptions [Rx]) and treatment patterns in AK patients treated with IngMeb to other field-directed AK therapies.

METHODS: A retrospective cohort study was conducted using the IMS PharMetrics health plan claims database. AK patients (ICD-9 CM 702.0) receiving PDT or ≥1 Rx for a topical agent (imiquimod, 5-FU, diclofenac, or IngMeb) between January 1, 2012 and December 31, 2012 were identified (first AK treatment date was the index date). Patients were required to be ≥18 years of age on the index date and had continuous insurance enrollment for ≥6 months pre- and post-index. IngMeb patients were matched 1:1 with others using propensity scoring methods. Treatment refills/repeat, switching, augmentation and HRU were compared amongst the therapies over the 6-month post-index period.

RESULTS: Final sample consisted of five matched cohorts (n = 790-982 per cohort). Refill rates were similar except for imiquimod vs. IngMeb (15% vs. 9%, P < 0.0001). Repeat PDT treatments were significantly higher than IngMeb refill rates (20% vs. 10%, P < 0.0001). Topical agent switch/ augmentation rates were comparable. PDT had significantly higher switch rates than IngMeb (5% vs. 2%, P < 0.01). IngMeb patients had a significantly lower proportion of patients with ≥1 AK-related OP visit during the 6-month follow-up than any other cohort: vs. imiquimod (50% vs. 66%, P < 0.0001), vs. 5-FU (50% vs. 69%, P < 0.0001); vs. diclofenac (51% vs. 56%, P < 0.05); vs. PDT (50%
and age. Not understanding treatment or side effects, caregivers forgetfulness, prescribed medications. Some barriers to adherence for the acne patient approximately only half of patients affected by acne adhere to pre-
der affecting adults, adolescents and children too. Data reports that

**BACKGROUND:** Acne vulgaris is a chronic inflammatory skin disorder affecting adults, adolescents and children too. Data reports that approximately only half of patients affected by acne adhere to prescribed medications. Some barriers to adherence for the acne patient population include cost, dealing with the hassle of topical products, not understanding treatment or side effects, caregivers forgetfulness, and age.

**OBJECTIVE:** To evaluate and compare medication adherence associated with acne drugs in children (0-12 years) and adolescents (13-17 years) with acne.

**METHODS:** The MarketScan Medicaid Database was analyzed retrospectively. Data from enrollees with acne were included if patients were aged 6-17 years on the index date, had at least one acne-related medication claim, and were enrolled in Medicaid during January 2004 to December 2007. Adherence rate was measured using medication possession ratio (MPR, dichotomized to categorize patients as adherent (≥0.8) or nonadherent (<0.8). Descriptive statistics, t-test, chi-square tests, and multivariate logistic regressions were used for analyses.

**RESULTS:** Of 20,039 eligible patients, 2,860 were children, and 17,179 were adolescents. Approximately 6.96% of children and 16.75% of adolescents had at least one acne-related medication refill. MPR was 0.22 in children and 0.37 in adolescents. Only 3.71% of children were adolescents had at least one acne-related medication refill. After controlling for covariates using logistic regression, adolescents were 2.06 times more likely to get an acne-related medication refill and were 2.40 times more likely to be adherent to acne-related medication. The analyses also showed that acne-related medication adherence was associated with patients’ characteristics and acne medication type.

**CONCLUSION:** Medication adherence is an important aspect of pharmacy today. While neither patient population was considered adherent to acne-related medications, there was a significant difference between the two patient populations. Understanding the underlying cause of non-adherence for each group is especially important in order to correct the problem. This study revealed that medication type is a contributing factor towards adherence. Physicians should take this into account when prescribing medications for patients with acne. Also, as medication experts, pharmacists should not only educate patients on how to properly use acne-related medications, but explain the benefits of medication adherence in order to increase adherence to acne-related medications.

**SPONSORSHIP:** None.

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

**M1 Persistence with Osteoporosis Therapies Among Commercially Insured Women at High Risk for Fracture in the United States**

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**BACKGROUND:** Newer osteoporosis therapies with less frequent administration frequency and different route of administration have become available in recent years; however, limited real-world persistence data exist for these therapies, especially among osteoporotic patients at high risk for fracture.

**OBJECTIVE:** To evaluate 12-month persistence and compliance with osteoporosis therapies in women with osteoporosis at high risk for fracture enrolled in U.S. commercial health plans.

**METHODS:** Females 50 to 64 years of age at high risk for fracture newly initiating denosumab, raloxifene, teriparatide, or bisphosphonates (alendronate, ibandronate, or risedronate) between January 1 and March 31, 2012 were identified from the MarketScan Commercial database (index date = qualifying claim date). High risk for fracture was indicated by either having a pre-index fracture or pre-index use of osteoporosis therapy which was discontinued at least 3 months prior to index. Patients were required to have at least 24 months of pre-index and at least 12 months of post-index continuous enrollment with medical and pharmacy benefits. Propensity score weighting was used to adjust for differences in baseline demographic and clinical characteristics. Study outcomes assessed during the post-index 12-month period included: (1) persistence, defined as continuous use of the index therapy without a gap > 60 days; (2) medication coverage ratio (MCR), defined as the proportion of days covered by therapy; and (3) compliance, defined as an MCR ≥ 0.80.

**RESULTS:** A total of 1,882 women newly initiating osteoporosis medications (mean [SD] age: 58.9 [3.8] years) were identified. Propensity score weight-adjusted 12-month persistence rates were: 78.3% for teriparatide, 69.6% for denosumab, 46.3% for raloxifene, 39.2% for ibandronate, 35.9% for alendronate, and 27.8% for risedronate (P < 0.001). The adjusted mean (SD) MCR was highest among patients treated with denosumab (0.84 [0.20]), followed by teriparatide (0.73 [0.30]), raloxifene, (0.61 [0.33]), ibandronate (0.59 [0.32]), alendronate (0.52 [0.33]), and risedronate (0.47 [0.32]; P < 0.001). The adjusted compliance rates were 72.5% for denosumab, 62.5% for teriparatide, 44.5% for raloxifene, 34.4% for ibandronate, 32.1% for alendronate, and 24.5% for risedronate (P < 0.001).

**CONCLUSION:** In this analysis of women with osteoporosis aged 50 to 64 years at high risk for fracture, 12-month persistence was highest among teriparatide users, but 12-month compliance and MCR were highest among patients initiating denosumab.

**SPONSORSHIP:** Research funded by Amgen, USA.

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**M6 DMARD Treatment Patterns During the First 12 Months of Therapy in U.S. Patients with Rheumatoid Arthritis**


**BACKGROUND:** Rheumatoid arthritis (RA) is a chronic inflammatory disease associated with joint pain, stiffness and swelling,
Uncontrolled, RA can cause damage and deformity to the joints, resulting in disability and economic burden. Many patients with RA fail 1st line treatment and the majority fail to achieve remission with conventional and/or biologic disease modifying anti-rheumatic drugs (c/bDMARDs).

**OBJECTIVE:** To assess patterns of DMARD use during the first 12 months of treatment among patients with RA.

**METHODS:** A retrospective observational analysis of commercial claims data was conducted using the MarketScan database. A total of 4,689 DMARD naive patients with RA were identified, with at least 12 months pre and post index continuous enrollment between January 1, 2007 and December 31, 2009. Index date was the date of the first DMARD prescription. Patients were categorized as continuers, discontinuers, switchers, or augmenters (during the 12 months follow up post-index), based on changes to index therapy. Discontinuers were defined as having >90 day gap in therapy. Demographics were analyzed, and treatment patterns were categorized at end of each 6 month period, for 36 months.

**RESULTS:** A total of 4,054 (86.5%) patients initiated a cDMARD and 635 (13.5%) of patients initiated a bDMARDs. Of all the cDMARDs initiators, 1,927 (47.5%) continued and 2,127 (52.5%) changed therapy of which 1,599 (39.4%) discontinued, 375 (9.3%) augmented, and 153 (3.8%) switched. Among the bDMARDs initiators, 266 (41.9%) continued and 369 (58.1%) changed therapy of which 229 (36.1%) discontinued, 108 (17%) augmented, and 32 (5%) switched. Over 3-years, the proportion of patients on monotherapy decreased while the proportion on combination therapy increased. Of those with continuous enrollment at 36 months, 64% were on only cDMARDs, 28% were on cDMARDs and bDMARDs, and 6.7% remained on bDMARDs at the end of the 3 year post-index period.

**CONCLUSION:** The majority of patients initiated cDMARD, but a bDMARD was the initial treatment in a significant proportion of these U.S. RA patients between the years 2007 to 2009. Augmentation occurred more than switching during a 12 month follow-up. Patient use of cDMARD decreased over a 36 month period, with an increase in combination c/bDMARD therapy. Identifying real-world patterns of DMARD use and reasons for discontinuation are important in understanding factors that may drive outcomes in RA.

**SPONSORSHIP:** This research was funded by Eli Lilly and Company, Indianapolis, IN.

**M9** Evaluation of Tumor Necrosis Factor Inhibitor (TNFi) Use, Utilization Patterns, Concomitant Conventional DMARD (cDMARD) Therapy, and Associated Costs for RA-Related Healthcare Resource Use (HCRU) in a U.S. Claims Database

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**BACKGROUND:** 28-41% of RA patients using TNFi in RCTs fail to achieve 20% improvement in ACR scores (ACR20); inferior outcomes are generally observed without concomitant cDMARD.

**OBJECTIVE:** To evaluate TNFi treatment patterns, concomitant cDMARD use, and associated HCRU and costs in a U.S. claims database.

**METHODS:** Exploratory, retrospective cohort analysis of RA patients aged ≥18 years with ≥2 outpatient or 1 inpatient visit for RA (ICD-9 code: 714.xx) and newly initiating a TNFi in the Truven MarketScan Commercial Claims and Encounters and Medicare Supplemental Databases (2010-13). Patients were continuously enrolled ≥6 months before and 12 months after index TNFi claim. Patients with another inflammatory disease diagnosis, pre-index biologic or >1 biologic within 14 days were excluded. RA severity was evaluated using claims-based index of RA severity (CIRAS) scale (0 [low]-10 [high]). Treatment patterns were characterized by start of non-index biologic prescription (switchers, S); gap between index TNFi prescriptions of >180 days and no other biologic (discontinuers, D); or no gap >180 days in index TNFi and no other biologic (continuers, C). HCRU and costs were evaluated post-index. Multivariable analyses assessed predictors of continued TNFi therapy and RA-related direct costs.

**RESULTS:** 9,567 patients newly initiated a TNFi. 4,267 (45%) without a cDMARD. During follow up, 67% were C, 17% D, and 15% S (66% of S initiated non-index TNFi). Mean (SD) days between first and last prescription for the index TNFi was 267 (122): C, 342 (42); D, 79 (47);
and S, 150 (90). Mean baseline CIRAS scores were 4.4 (C), 4.1 (D) and 5.0 (S), mean Charlson comorbidity scores were 1.3 (C), 1.5 (D) and 1.4 (S). Patients with higher RA severity, more days between RA diagnosis and index TNFi, more pre-index cDMARD prescriptions or who were Capitation Point of Service plan members were significantly less likely to continue TNFi. The unadjusted 1-year mean (SD) RA-related cost was $24,319 ($20,078) after initiating TNFi: 74% due to prescriptions, 24% to office visits and 2% to inpatient visits. C and D had significantly (55% and 68%, respectively) lower RA-related costs vs. S.

CONCLUSION: Analysis indicated real-world TNFi discontinuation/switching of 33%, consistent with reported RCT response rates. Of patients initiating TNFi, 45% did not initiate cDMARD concurrently. Patients who switched from index TNFi to second biologic had increased RA-related costs vs. non-switchers.

SPONSORSHIP: This study was sponsored by Pfizer Inc.

M12 Effectiveness of Repeated Courses of Hyaluronic Acid Injections on the Time to Total Knee Replacement Surgery: Evidence from a Large U.S. Health Plan Claims Database

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BACKGROUND: Total knee replacement (TKR) is an effective surgical method to treat patients with osteoarthritis (OA) of the knee. However, TKR is an invasive procedure with potential risk for serious complications and high costs up to $70,000 in the U.S. Alternative lower risk therapies that can delay or obviate TKR are valuable to certain patients, particularly those who are poor candidates for surgery or wish to avoid TKR as long as possible. Hyaluronic acid (HA) injections are a safe and effective treatment to alleviate pain and improve joint function. Thus, HA has the potential to delay or even obviate TKR providing physicians with a valuable tool in providing high quality low cost care especially when compared to alternative surgical options such as TKR.

OBJECTIVE: To study the effect of repeated courses of HA on the time to TKR over a 3-year period using data from a large U.S. health plan administrative claims database.

METHODS: Retrospective analyses using IMS Health’s PharMetrics Plus Health Plan Claims Database were conducted by identifying knee OA patients with claims indicating initiation of HA at an index date during the selection period (2007-2010). Supartz/Hyalgan (shared HCPCS code), two multi-injection HA agents with similar applications, were selected for further investigation. The follow-up period was 36-months post-index date of initial HA injection. Patients who were continuously enrolled from 12-months pre-index to 36-months post-index date were evaluated. A Cox proportional hazards model (PHM) was used to model risk of TKR with covariates such as age, gender, comorbidities, and pre-index healthcare costs.

RESULTS: 18,217 patients received Supartz/Hyalgan for treatment of knee OA. 13,561 (74.4%) patients received a single course of treatment, 2,999 (16.5%) 2 courses, 1,012 (5.6%) 3 courses, 404 (2.2%) 4 courses, and 241 (1.3%) 5+ courses. Successive courses of Supartz/Hyalgan led to greater proportions of patients without TKR 3 years after treatment initiation. Multiple injections significantly decreased risk of TKR (96.3% without TKR for 5+ courses vs. 72.7% without TKR for 1 course, hazard ratio 0.113 [P<0.0001]).

CONCLUSION: After adjusting for baseline characteristics in multivariate statistical modeling, findings from a real-world database showed that repeated courses of treatment with Supartz/Hyalgan can successfully delay TKR for up to 3 years. Additional research is needed to evaluate the impact of repeated HA courses on delaying TKR beyond a 3-year time horizon.

SPONSORSHIP: This study was sponsored by Seikagaku Corporation.

M15 Association Between Gastrointestinal Events and Healthcare Resource Utilization Among Patients with Osteoporosis: Analysis of a Managed Care Population in the U.S.

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BACKGROUND: Occurrence of gastro-intestinal (GI) events among patients taking osteoporosis (OP) therapy may pose an incremental healthcare resource utilization (HCRU) burden. OBJECTIVE: The objective of this study was to examine the association of GI and HCRU in women who were taking oral bisphosphonates (BIS).

METHODS: This retrospective study using i3 InVision Data Mart identified women ≥55 years who were prescribed oral BIS during 2001-2011 and had no history of GI events 12 months prior to treatment initiation. Patients with medical claims for an upper GI event ≤ 4 months after treatment initiation were identified as cases; the remaining patients were controls. The date of the first upper GI event among cases and a randomly assigned date within the first 4 months after treatment initiation among controls was defined as the index date. Cases were matched 1:1 to controls using propensity scores which were calculated using logistic regression based on baseline patient characteristics including age, comorbidities, osteoporotic fracture history and medication use. Outcomes were all-cause and OP-related HCRU in the 6-month post-index period. Differences were assessed using McNemar’s test.

RESULTS: Of the 62,863 eligible patients, 4,735 (7.6%) women experienced an upper GI event within 4 months of treatment initiation (cases). 4,739 cases were matched with 4,739 controls. Cases had significantly higher rates of all-cause HCRU than controls (outpatient: 99.3% vs. 87.8%; inpatient: 20.2% vs. 6.4%; emergency room (ER): 12.5% vs. 7.4%; all P<0.001) as well as OP-related HCRU (outpatient: 24.6% vs. 18.2%; inpatient: 3.4% vs. 1.0%; ER: 0.7% vs. 0.4%; all P<0.05).

CONCLUSION: The rate of upper GI events was 7.6% within 4 months among patients taking BIS based on this study using claims data from a U.S. commercial plan. However, this study design reflects correlational relationships only and does not ascribe causality of GI symptoms and use of BIS. Prior studies have shown that the background rate of GI events prior to initiating BIS was similar to the rate seen after initiating BIS. Study results show that patients experiencing an upper GI diagnosis post treatment initiation with BIS were 1.5 times as likely to use outpatient OP related services, 3.5 times as likely to use inpatient OP related services and 1.9 times as likely to use OP related ER services compared to patients without an upper GI diagnosis post treatment initiation with BIS. Results from this study suggest that upper GI events may pose an incremental HCRU burden among patients with OP.

SPONSORSHIP: This research was conducted by Merck & Co., Inc., Whitehouse Station, NJ, without external funding.
N00-N99 Diseases of the Genitourinary System (i.e., ESRD)

N1 Evaluation of Outcomes in Patients with Overactive Bladder Within an Integrated Healthcare Delivery System Using a Treatment Patterns Analyzer
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BACKGROUND: More than 33 million adults in the U.S. suffer from overactive bladder (OAB). Medications commonly used to treat OAB include antimuscarinics (AMs), which may be considered inappropriate in the elderly. Inappropriate prescribing has clinical consequences and financial implications for payers when considering Medicare Star ratings and HEDIS measures. An OAB software tool has been developed to evaluate patients treated for OAB, including identifying anticholinergic burden (ACB) and potential quality improvement initiatives.

OBJECTIVE: The objective of this study was to identify gaps in care between recognized best practices and practice patterns in an integrated healthcare delivery system (IHDS) setting using the OAB software tool.

METHODS: De-identified pharmacy and medical claims from a mid-size IHDS were imported into the OAB tool and compared to nationally representative claims data. Patients with a diagnosis of OAB (based on an ICD-9-CM primary or secondary diagnosis), with or without current or prior OAB pharmacotherapy, were identified between January 1, 2009 to December 31, 2013. Index treatment, treatment changes, comorbidity burden, adherence, ACB, concomitant use with anticholinesterase (AC), costs, and healthcare resource utilization were compared.

RESULTS: Of 157,710 members in the plan population, a total of 7,309 patients met the study criteria; 84% of the patients were on no OAB medication and 15.6% had evidence of AM utilization. Of the 1,147 patients taking OAB medications, 15% achieved a PDC of ≥80%, and the 1-year overall discontinuation rate was 73%. Clinically relevant ACB was similar among branded (15%) and generic (16%) AMs. Concomitant use of ACs and an AM was seen in 3.4% of patients taking an OAB medication. Per-Utilizing-Member-Per-Month costs were $318.67. All-cause office visits, emergency room visits, and hospitalizations associated were in 81%, 6%, and 4% of the population.

CONCLUSION: The results of this analysis suggest that the majority of patients with OAB did not take medication for their disease. OAB medication adherence was poor and discontinuation was high. Patients in this population may experience elevated ACB, which can be challenging for older adults. Though deidentified, the IHDS, independently, can identify members for intervention and avoidance of poor outcomes and associated healthcare costs and utilization for quality improvement opportunities.

SPONSORSHIP: This study was sponsored by Astellas Scientific and Medical Affairs, Inc.

N2 Inpatient Antibiotic Utilization Patterns Among Patients with Complicated Urinary Tract Infections
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BACKGROUND: Understanding inpatient drug utilization for acute conditions like complicated urinary tract infections (cUTI), where a majority of patients are managed in an INPAT care setting is important.

OBJECTIVE: This study used a novel approach by linking the HealthCore Integrated Research Environment (HIRE) administrative claims data with the Premier Inpatient database (PID) to assess detailed INPAT drug utilization among patients with cUTI.

METHODS: For this retrospective analysis, patients with a cUTI (defined as treatment failure to first ambulatory (AMB) antibiotic [ABX] administration) related INPAT admission were identified using the HealthCore Integrated Research Environment (HIRE) database (2006-2013) and admission date defined the index date. Selected patients were required to have an UTI-related AMB visit and an ABX prescription within a 30-day prior to the index date. Using a deterministic matching approach, cUTI-related INPAT records for patients selected using the HIRE database were matched with INPAT records in the PID. Using the linked PID database records INPAT treatment patterns (e.g., initial ABX therapy, switching), comorbidity burden and INPAT costs were assessed. AMB treatment patterns for the 30-day period prior to the index date were assessed using the HIRE outpatient and pharmacy claims database. All analyses were descriptive in nature.

RESULTS: The study cohort included 1,118 patients (mean age: 62.4 years) with majority being females (77%) and ~68% enrolled in a PPO plan. The mean Deyo–Charlson comorbidity score was 1.8. Over 97% patients received an oral ABX and ~12% received IV ABXs during the 30-day period prior to the index date. During the INPAT stay 81% received an IV ABX and 29% received an oral ABX (19% were step down form IV ABX and 10 % have only oral ABX) Fluoroquinolones (67%) and cephalosporins (60%) were the most commonly used oral and IV ABX, respectively during the INPAT stay. The mean duration of IV ABX therapy during the INPAT stay was 3.0 days. Among those switched to a step down oral ABX therapy, IV-levofoxacin to oral-levofoxacin (13%) was the most common step-down sequence.

CONCLUSION: With antibiotic resistance being a global health concern, understanding current management practices and empirical ABX use among patients with cUTI and other infections is critical. Our study describes the current treatment patterns and provides an approach to address the gap of evaluating inpatient drug utilization for infectious diseases using the administrative claims data. In future, the outlined approach can be replicated for other chronic and acute conditions.

SPONSORSHIP: AstraZeneca, Gaithersburg, MD.

P00-P99 Certain Conditions Originating in the Perinatal Period (i.e., Birth Trauma and Disorders of the Fetus and Newborn)

P1 Safety of High-Dose Vancomycin in Neonatal Infections Treatment in a NICU
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BACKGROUND: Currently many physicians try to use high-dose vancomycin for neonates infection. The safety of high-dose vancomycin is not clear.

OBJECTIVE: To compare the incidence of nephrotoxicity between high-dose unlabeled use of vancomycin and routine dose normal use of vancomycin.

METHODS: Neonates who met the inclusion criteria from January 2009 to December 2012 in NICU in a hospital were included in this study. The neonates were divided into two groups according to trough concentration levels of vancomycin: group A (low vancomycin trough

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A total of 65 evaluable neonates were identified. In group A (72.31%) had low vancomycin trough concentrations meanwhile in group B (27.69%) had high trough concentrations. 20 cases (30.77%) in group C were given routine dose meanwhile 45 cases (69.23%) in group D were given high dose. (2) 13 neonates (20.0%) occurred vancomycin-related nephrotoxicity in all 65 cases, with 5 cases in group A (10.64%, 5/47) and 8 cases (44.44%, 8/18) in group B, or 3 cases in group C (15%, 3/20) and 10 cases in group D (22.22%, 10/45). (3) In group D, although 8 cases were given up to 100 mg/kg daily dose of vancomycin, their serum vancomycin trough concentrations were lower than 20 μg/ml with the minimum only 4.72 μg/ml.

**CONCLUSION:** Daily doses of vancomycin and trough concentrations had no good linear relationship. However, in general, neonates with higher trough concentrations and high dose in NICU were more likely to occur nephrotoxicity comparing to low trough concentrations and routine dose. Renal function of neonates who received vancomycin should be monitored carefully in NICU regardless of high dose or routine dose.

**SPONSORSHIP:** None.

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

**R1 Randomized Controlled Trial of an Emergency Department Care Coordination Program for Patients with Chronic Non-Cancer Pain: Analysis of Emergency Department Cost Savings**

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**BACKGROUND:** Patients utilize emergency departments (EDs) to manage chronic non-cancer pain (CNCP). Their use of community-based physicians to manage this condition would provide more continuous and affordable care. Care coordination programs (CCPs) are now being implemented to identify patients frequently utilizing EDs to manage CNCP and encourage physicians to refer patients to community-based providers for appropriate pain management. Evaluation of ED cost savings of CCPs has not yet been conducted.

**OBJECTIVE:** To evaluate the ED cost savings of a CCP designed to decrease the use of ED physicians for the management of CNCP.

**METHODS:** This study was conducted within a large metropolitan hospital system comprising 13 electronically linked EDs. An algorithm identified 41 frequent consumers of ED care for CNCP who were randomized to receive the CCP or usual care. Chi-square tests were used to identify any differences in baseline characteristics between study groups and t-tests were used to compare differences between study groups in the mean ED cost per visit, per patient, and per facility.

**RESULTS:** Baseline characteristics between the two groups, including mean ED cost per visit, were similar except for a difference in ethnic composition. Following exposure to the intervention, patients in the intervention group had a lower mean ED cost per patient ($1,094 vs. $1,305; P < 0.05) and a lower mean ED cost per facility ($14,420 vs. $17,321; P < 0.05) than did patients in the control group.

**CONCLUSION:** Implementation of a CCP to manage patients with CNCP at an ED can reduce the mean ED cost for the facility. However, EDs adopting CCPs should inform identified patients frequently using the ED to manage their CNCP that the ED remains available to manage their health concerns not related to CNCP.

**SPONSORSHIP:** This project was funded by the Centers for Disease Control and Prevention under contract #BAA 2011-N-13277. The content is solely the responsibility of the authors and does not necessarily represent the official views of the CDC.
statistically significant savings was realized in medical claims, while RX claims increased. These findings highlight the potential financial impact of comprehensive MTM services provided by a plan-sponsor pharmacist.

**SPONSORSHIP:** This research was conducted by Providence Health Plans, Portland, OR, without external funding.

**U00-U99 Codes for Special Purposes and AMCP Unclassified Abstracts (i.e., Care Management, Specialty Pharmacy, Rare Diseases, Star Ratings, Pharmacist Services, MTM, Med. Rec., Outcome Analyzers, Part D, Multidisease Studies, ACO, ACA)**

**U1 Impact of 2014 Essential Health Benefit Benchmark Plans on Pharmacy Coverage**

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**BACKGROUND:** Beginning in 2014, the Affordable Care Act requires new health plans to cover essential health benefits (EHB), including pharmaceutical products, according to the state level benchmark plans.

**OBJECTIVE:** The objectives of this analysis were to understand state level variations in design of plans, access to drugs and likely impact on patient choice and health outcomes.

**METHODS:** Benchmark plans for the top five states (i.e., FL, IL, NY, TX and CA), covering ~116 million lives, were obtained from the CMS. For each plan, the categories, classes and number of covered drugs was collected and pooled into one database. Analysis was conducted at the entire population level, state-level and for top classes of drugs. The comments from patient groups were reviewed to understand the impact of EHB on patient choice and health outcomes.

**RESULTS:** Benchmark plans for the top five states provide coverage of ~4215 drugs belonging to 138 classes as defined by USP. While four states (FL, IL, NY and TX) had a similar number of covered drugs (median of 892 drugs), CA had a significantly lower number of covered drugs, amounting to 28% less than the other four states. On average, 10% of the drugs were in the class called “No USP Class”, highlighting the limitation of CMS designated USP classification system for the new plans. In CA, FL, IL, NY and TX there were 18, 7, 8, 11 and 8 classes, respectively, for which only 1 was covered. In CA, top 8 classes were identified for which patients had a 75% lower choice than other states, and these included indications such as Anti-Diabetics and Pain medications.

**CONCLUSION:** Review of new benchmark plans shows some states can have a significantly lower patient choice of therapies. There is a need for new policy measures to ensure that all patients have equal access to new treatments.

**SPONSORSHIP:** None.

**U2 Impact of Medication Therapy Management (MTM) on Quality Outcomes in a Dual-Eligible Population**

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**BACKGROUND:** Medication Therapy Management (MTM) is a requirement of all Medicare Part D plans. Thus, there is an interest in evaluating the interventions that result from MTM and the potential impact on quality outcomes and cost. CalOptima OneCare is a Medicare Advantage Special Needs Plan for dual-eligible members. OneCare’s Clinical Pharmacists conduct in-house MTM face-to-face or by telephone, and send a comprehensive medication review (CMR) to providers. The CMR includes a reconciled medication list, clinical recommendations, and the status of select quality measures. The quality measures reported are among the compilation of standardized metrics known as HEDIS and Star measures.

**OBJECTIVE:** The primary objective was to assess the impact of MTM on select HEDIS and Star measures. The secondary objective was to characterize the MTM recommendation acceptance rates.

**METHODS:** All MTM eligible members in calendar year 2012 were identified (n = 2,278). Among them, 229 members were identified to have enrollment gaps and were excluded from the study. The members who completed one or more MTM sessions comprised the MTM group (n = 135), while those who did not complete an MTM session comprised the non-MTM group (n = 1914). Individual member performance on select HEDIS and Star measures were retrieved from an internal registry. MTM recommendation acceptance rates were inferred by analyzing pharmacy claims data approximately 120 days after the MTM session.

**RESULTS:** In the MTM group, all the pre-selected quality measures improved after the MTM session. Compared to the non-MTM group, the post-MTM group performed better on drug safety measures and LDL-control in diabetics. A total of 878 MTM recommendations were made and 25% of recommendations were accepted. The highest acceptance rate was for the therapeutic duplications category (50%), and the lowest acceptance rate was for the drug-age interactions category (14%). Cost savings from discontinued medications were $8,854.57 monthly and $65.59 per MTM member per month.

**CONCLUSION:** The MTM group had similar demographics with the non-MTM group. Although MTM recommendation acceptance rates were modest, MTM may have had a positive impact on some quality measures.

**SPONSORSHIP:** None.

**U6 Impact of Switching from Pregabalin to Generic Gabapentin in a Novel Pharmacy Benefit Design**

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**BACKGROUND:** Health plans have initiated pharmacy cost reduction programs to induce members to switch from retail branded medications to mail order or generics. One large U.S. health plan’s program requires members to switch from retail pregabalin to mail order or a less costly product to continue receiving pharmacy benefit cost sharing.

**OBJECTIVE:** To evaluate the impact of switching from retail pregabalin to generic gabapentin in this health plan.

**METHODS:** This retrospective study included commercial health plan members > 19 years old with ≥1 pharmacy claim for pregabalin and ≥1 inpatient or ≥2 outpatient medical claims with a diagnosis code of painful diabetic peripheral neuropathy (pDPN), fibromyalgia, postherpetic neuralgia or partial onset seizures. Index dates were the first retail pregabalin claim after start of the program. Members were continuously enrolled for 12 months before and after their index dates. Program and non-program cohorts were propensity score matched (1:1). Outcomes were measured during the 12-month post-index
CONCLUSION: More members in the program requiring pregabalin mail order or use of another product switched from retail pregabalin to gabapentin. Members who switched to gabapentin were more likely to have claims for opioids, TCA, and SSRI during the post-index period (all \( P < 0.05 \)). Members who switched to gabapentin were also more likely to have ≥1 short-acting opioid claim during the pre-index period (61% vs. 54%, \( P = 0.044 \)) but were not more likely to have a claim for a long-acting opioid, tricyclic antidepressant (TCA) or selective serotonin reuptake inhibitor (SSRI). In the post-index period, members who switched to gabapentin were more likely to have a claim for a short- or long-acting opioid, and more likely to have a claim for a TCA, or an SSRI (all \( P < 0.05 \)).

CONCLUSION: More members in the program requiring pregabalin mail order or use of another product switched from retail pregabalin to gabapentin. Members who switched to gabapentin were more likely to have claims for opioids, TCA, and SSRI during the post-index period than those who did not switch.

SPONSORSHIP: Pfizer Inc.

U9 Effect of a Comprehensive Medication Review for Medicare Members Enrolled in a Medication Therapy Management Program

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BACKGROUND: The Centers for Medicare and Medicaid Services (CMS) requires Medicare Part D prescription drug plans to implement a Medication Therapy Management (MTM) program. EmblemHealth’s MTM program is designed to ensure prescribed medications are used appropriately to optimize therapeutic outcomes. Pharmacists achieve this by performing a Comprehensive Medication Review (CMR) with members.

OBJECTIVE: To assess the effect of a telephonic MTM program by pharmacists in a managed care setting for Medicare members.

METHODS: During 2013, data was collected each quarter to identify members who met criteria per CMS requirements. This included Medicare Advantage Prescription Drug Plan (MAPD) members who had three of the five following medical diagnoses: diabetes, chronic obstructive pulmonary disease, chronic heart failure, dyslipidemia or rheumatoid arthritis and utilized ≥7 chronic prescription drugs and incurred annual costs for prescription drugs ≥$786.00 per quarter. Members were contacted through mail and telephone to participate in a medication phone consultation with a pharmacist. A proprietary database of claims data, lab values and demographic information was developed to facilitate CMR completion. Pharmacists ensured members understood their medicine’s indications and administration, and resolved medication-related problems. Members received a reconciled medication list and action plan in CMS-standardized format. The number of CMRs completed and reasons for non-completion were collected. The number of pharmacist recommendations made and acceptances by a physician as a result of the CMR review were collected.

RESULTS: A total of 3,640 members met criteria for inclusion. A CMR was completed with 1,734 (48%) members. A total of 346 recommendations to the physician were made and 109 (32%) of these were accepted. Of the accepted recommendations, 82 (75%) involved improving medication adherence, resolving duplicate therapy and recommending additional therapy. A total of 1,906 members (52%) did not complete the CMR review. Reasons for non-completion included: disenrollment 78 (4%), death 142 (7%), request not to participate 204 (11%), and unreachable members 1,482 (78%).

CONCLUSION: Of Medicare members, 48% completed the telephonic CMR. The majority of remaining members could not be reached. Additional outreach methods should be considered. Pharmacists have the most impact in making recommendations to physicians involving medication adherence, resolving duplicate therapy and recommending additional therapy. These should be emphasized in future programs.

SPONSORSHIP: This study was conducted with no outside funding.
U10 A Pharmacy Discharge Program Reduces Readmissions, Improves Patients’ Understanding of Their Role in Managing Their Health, and Increases Pharmacy Profits

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BACKGROUND: An unplanned hospital readmission within 30 days of discharge is considered a “ sentinel event” for poor quality, with per case costs over $7,000 and annual cost estimates from $15bn to $25bn in the U.S. Under value based purchasing, hospitals with above average readmission rates risk reductions in their Medicare reimbursements. Despite these incentives, hospital readmissions persist, with a significant proportion attributed to medication non-adherence. Our outpatient pharmacy introduced a Pharmacy Discharge Program (PDP) to partner with 11 medical-surgical units working with patients to ensure discharge prescriptions are filled before they leave the hospital.

OBJECTIVE: To investigate the impact of a PDP on readmissions, patient satisfaction and margin of the outpatient pharmacy.

METHODS: Pharmacy phased in PDP first in three and then an additional eight medical-surgical units at a 906-bed suburban hospital. The outpatient pharmacy worked closely with nursing staff to have them present the PDP to all patients during admission. Patients choosing to participate in the program who are discharged during pharmacy hours leave the hospital with all of their pharmaceutical prescriptions filled. Pharmacy hours: M-F, 7am-6pm & Sat, 9am-1pm. Evaluation period: Implementation through December 31, 2013.

RESULTS: During the evaluation period, 4,007 patients with 8,462 unique prescriptions participated in the PDP. The 30-day readmission rate was significantly lower for PDP participants, 7.5% compared to 13.1% (P<0.0001). Patient satisfaction measured by top box scores for the HCAHPS question “would you recommend this hospital to your friends and family?” was higher, but not significantly so, for PDP patients, P=0.567. However, top box scores for the statement “When I left the hospital, I had a good understanding of the things I was responsible for in managing my health” were significantly higher for PDP participants (37.6% responded definitely yes, n = 347) compared with the mean hospital score for the same time period (52% responded definitely yes, n=9,159), P=0.04. Gross profit directly attributable to the PDP using COGS was $198,665 during the evaluation period.

CONCLUSION: Implementation of a collaborative PDP significantly reduces hospital readmissions and improves patients’ understanding of their role in managing their health, while simultaneously increasing pharmacy profits.

SPONSORSHIP: None.

U12 Longitudinal Utilization and Cost Trends of Oncology Drugs Within the Pharmacy Benefit

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BACKGROUND: According to 2013 PBM reports, cancer was the third most costly condition to treat within the specialty drug categories. Recent trends in cancer treatment include increases in the number of new molecular entities (NMEs) approvals, expanded indications, and more oral agents and targeted drug therapies (TDT).

OBJECTIVE: To describe recent trends in oncology drug utilization and per member per month (PMPM) cost within the pharmacy benefit and to explore potential trend drivers including drug approvals.

METHODS: This was a descriptive analysis using pharmacy claims of participating commercial, Medicaid, Medicare Part D plans with MedImpact Healthcare Systems, Inc., during the measurement period of January 1, 2011-June 30, 2014. Trends in the prevalence of oncology drug utilization, average ingredient cost (AIC) per claim and PMPM costs were calculated on a quarterly and annual basis during the measurement period for each line of business. The indications, approval type (NME or new indication), orphan status, route of administration and mechanism of action of oncology drugs with approval dates from 2009 through 2013 were compiled. Oncology drugs approved for use in patients with specific genetic mutations were designated as TDT.

RESULTS: During 2011 through the first half of 2014, the annualized increase in utilizing members was 4.3% for commercial, 1.4% for Medicaid and 9.7% for Part D. The annual increase in AIC per claim was 16.2% for commercial, 18.0% for Medicaid and 15.7% for Part D. PMPM for plans within all lines of business started at $2.18 in 2011 and increased to $3.23 in the first half of 2014. The PMPM annual increase was 19.4% for commercial, 25.4% for Medicaid and 18.9% for Part D. The number of NMEs (n = 12) and new indication (n=6) approvals peaked in 2012. The proportion of NMEs that were oral agents increased from 40.0% in 2009 to 75.0% in 2013. The proportion of NMEs that were targeted therapies increased from 0% in 2009/2010 to 28.6% in 2011 and up to 50.0% in 2013. The proportion of indications that were granted orphan status increased from 66.7% in 2009 to 83.3% in 2013.

CONCLUSION: Oncology drug PMPM pharmacy costs have increased dramatically over the past 3.5 years. The greatest cost increases appear in Medicaid plans, followed by commercial then Part D. The increased costs appear to be primarily driven by increases in drug price with more modest increases in utilizing members. We observed more approvals for orphan indications, oral drugs and targeted therapies. If trends continue, pharmacy spend for oncology drugs may outpace treatments for other diseases.

SPONSORSHIP: None.

U13 The Current State of Patient-Reported Outcomes in Managed Care: Payor Perceptions of PROs and Other Measures of Benefit

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BACKGROUND: The importance of including the patient’s perspective in reporting treatment benefits has increased in recent years. Despite the publication of the Food and Drug Administration’s (FDA) guidelines on PRO development for inclusion in labeling claims and industry’s investment in PRO development, it is generally unknown whether payers value or utilize PROs in terms of decision making or in patient healthcare improvement initiatives.

OBJECTIVE: To survey managed care pharmacy and medical directors regarding their familiarity and perceptions about PROs versus other types of measures assessing treatment benefit, and to identify how payers utilize PROs in decision making.

METHODS: A survey was administered to pharmacy and medical directors within Xcenda’s Managed Care Network (MCN). The survey assessed payer perceptions of PROs, clinician-reported outcome (ClinROs), observer-reported outcome (ObsRO), and performance outcome (PerfO) measures.
RESULTS: 60 payers completed the survey, including pharmacy directors (53.3%), medical directors (38.3%), and others (8.3%) from both regional and national organizations. Payors represented managed care organizations (MCOs) (45%), integrated health delivery systems (IHDS) (12%), MCO/IHDS (20%), pharmaceutical benefit managers (PBMs) (12%), or other (11%). 58.3% of payers reported familiarity with PRO data, and fewer (33.3%) reported familiarity with the FDA’s Clinical Outcome Assessment Qualification Program. Payers perceived that ClinROs and PerfOs were the most credible outcome assessments, followed by PROs and ObsROs. A similar pattern was found for the perceived value of these outcome assessments. However, findings varied by disease state. In terms of tier placement or utilization management, 55%, 51.7%, 28.3%, and 16.7% of payers reported ClinROs, PerfOs, ObsROs, and PROs, respectively, have an impact on decision making.

CONCLUSION: Results indicate that the majority of payers are familiar with PROs and some perceive PROs to be credible and valuable; however, other outcome measures such as ClinROs have higher perceived credibility; value and impact on decision making. Future research should investigate the specific hurdles associated with payer adoption of PRO data into the decision making process. Findings also suggest that novel payer-industry-FDA collaborations may be necessary to heighten the relevance and importance of PROs.

SPONSORSHIP: Xcenda.

U16 Association of Pharmacy Dispensing Channel with the Use of High-Risk Medications Among Medicare Part D Patients

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BACKGROUND: High risk medications is one of the Part D safety star rating measures used by the Centers for Medicare & Medicaid Services (CMS) for evaluation of the quality of care provided by Part D plans. This measure recommends that Medicare patients 65 years or older should not be receiving prescriptions for certain drugs with a high risk of side effects when there may be safer drug choices. Efforts to improve adherence with recommended guidelines for Medicare patients. The adjusted odds of being a high risk medication user for patients using home delivery was 0.73 [CI=0.69-0.77] lower compared to patients using retail channels to obtain their prescriptions.

CONCLUSION: Medicare Part D who used home delivery had lower likelihood (adjusted) of being a high risk medication user than patients who filled their prescriptions at retail. Managed care stakeholders looking to implement solutions that improve quality of care should consider the use of home delivery to ensure the use of appropriate medications for elderly patients.

SPONSORSHIP: Express Scripts.

U18 Re-Evaluating Reference-Based Pricing (RBP) for Pharmaceuticals: Lessons Learned from RBP for Total Joint Replacement

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BACKGROUND: Reference-based pricing (RBP) is a benefit design which requires patients to pay the difference above a reimbursement ceiling, in order to encourage selection of high value healthcare via mechanisms of price transparency and payment incentives. RBP originated within the pharmaceutical industry in the 1980s and is used in European countries such as Germany. In the U.S. adoption of RBP has been more limited, perhaps due to concerns regarding the potential for a negative impact on satisfaction or quality. Recently RBP has expanded outside of pharmacy benefits to include services such as elective surgery, with favorable early cost and quality results. While these results are promising, a missing piece is to examine patient reported outcomes and establish whether patients understand and accept the benefit structure.

OBJECTIVE: This study compares functional status and satisfaction for patients with RBP benefits following total joint replacement (TJR) relative to a control group. We also examine factors contributing to the success of RBP that are applicable to pharmacy coverage.

METHODS: We conducted a survey study of Anthem Blue Cross California members post RBP implementation. We collected responses for TJR patients with RBP benefits and using RBP facilities, and compared them to TJR patients without RBP benefits. Metrics include functional scores using validated survey instruments (KOOS/HOOS) as well as satisfaction with the chosen facility and insurance coverage.

RESULTS: We analyzed results for 91 respondents, 35 in the RBP cohort and 56 in the non-RBP cohort. Patients in the RBP cohort reported equal or better outcomes for metrics such as hip and knee function (8-11% higher than non-RBP) and quality of life (6%-9% higher). The RBP and non-RBP cohorts reported similar satisfaction on questions related to hospital and staff (> 90% on most measures). Notably, patients subject to RBP reported higher satisfaction with plan coverage and benefit notification (16%-17% higher).

CONCLUSION: The patients with RBP benefits reported similar or higher levels of satisfaction with both care received and the level of health plan coverage relative to a control group. Factors related to the successful implementation for RBP included: patient perceptions that available options were equal or better quality to non-RBP options, perceptions that the insurance coverage under RBP was adequate, and a communication strategy that provided sufficient information to make decisions. These lessons learned apply to both medical and pharmacy benefit structures.

SPONSORSHIP: WellPoint, Inc.
**U19** Prevalence and Factors Associated with Self-Medication Practice Among Young Adults in Saudi Arabia: A Cross-Sectional Study

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**BACKGROUND:** Self-medication is a common practice worldwide. In Saudi Arabia, studies addressing this practice have been scarce.

**OBJECTIVE:** To assess the prevalence and identify correlates/determinants of self-medication practice in young adult population in Saudi Arabia.

**METHODS:** This is a cross-sectional descriptive study. The study tool was self-administered, web-based questionnaire developed in concordance with the available literature. Age, gender, educational background, health insurance status and medication knowledge were investigated for potential association with self-medication practice. Descriptive outcomes were expressed as frequencies, percentages, and means ± SD. Chi-square test and logistic regression were used to assess for statistical significance. A P value ≤ 0.05 was considered significant.

**RESULTS:** Mean age of respondents was 22 ± 4.8. Self-medication practice was reported by 74% of respondents in the past 6 months (n=608), with the most commonly used classes being headache relievers (84% of self-medicators) and antibiotics (53%). The most commonly reported reasons for self-medication were mild nature of illness and effectiveness in previous experiences followed by ease of accessibility in community pharmacies. We found significant association between self-medication and educational background as well as knowledge score. Those with medical background were more inclined to practicing self-medication than those from non-medical field (OR = 1.805, 95% CI = 1.253-2.600, P<0.01). Similarly, those with high-knowledge scores were more likely to self-medicate than low-knowledge scorers (OR = 2.409, 95% CI = 1.609-3.607, P<0.001). Interestingly, about two thirds of respondents reported having advised relatives and friends to use medications found to be effective in a field (OR = 1.663, 95% CI = 1.141-2.422, P = 0.01). No significant association was observed between self-medication practice and age, gender, chronic disease or health insurance status.

**CONCLUSION:** Self-medication is widely practiced by youth in Saudi Arabia. Medical background and high medication knowledge seems to be among the risk factors. With easy accessibility to medications, and the high level of self-medication established in this study, further research is needed to be in place to address relevant safety issues and assess potential implications of self-medication in Saudi Arabia.

**SPONSORSHIP:** This study was sponsored by The Boeing Company.

**OBJECTIVE:** This study aimed to estimate hospitalization rates and the costs of two common infections, pneumonia and bronchitis, among PID patients receiving IVIG treatment in real-world setting.

**METHODS:** Patients who had at least 1 inpatient (or Emergency Room–ER-) claim or at least 2 outpatient claims with a PID diagnosis (ICD-9 code 279.xx) and had at least 6 months of continuous IVIG claims were identified from the Truven MarketScan Database (years 2002-2013). Hospital admission rates for pneumonia and bronchitis were calculated for PID patients who contracted these infections. Total direct costs per episode for each of the two infection types were also calculated, with costs adjusted to 2013 dollars.

**RESULTS:** A total of 2,021 PID patients met the inclusion criteria. Among these patients, 1,182 pneumonia episodes were identified. Seventy-eight percent (917 out of 1,182 episodes) were treated in an outpatient setting and 265 (22%) resulted in hospital admissions. The average cost for pneumonia was $744 for episodes treated in an outpatient setting and $18,707 for inpatient treatment, with an overall average cost of $4,771 per episode. A total of 2,034 bronchitis episodes were identified during the same time period. The hospitalization rate for bronchitis was 11% (217). The average cost for bronchitis was $579 for episodes treated in an outpatient setting and $11,915 for inpatient treatment, with an overall average cost of $2,642 per episode.

**CONCLUSION:** This study showed that there is a considerable economic burden of infections in PID patients. Direct costs attributable to pneumonia and bronchitis are substantial, driven by high inpatient expenditure. Despite IVIG treatment, factors such as patients’ health history, non-compliance with IVIG treatment, sub-optimal dosing, or site of care could lead to patients developing infections. Further research is warranted to examine how these factors can affect the rate of infections among PID patients.

**SPONSORSHIP:** Baxter Health Care.

**U20** Direct Costs of Pneumonia and Bronchitis Among Patients with Primary Immunodeficiency Receiving Intravenous Immunoglobulin Treatment

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**BACKGROUND:** Intravenous immunoglobulin (IVIG) therapy reduces infection rates among patients with primary immunodeficiency (PID) and improves patients’ quality of life. Despite being treated, some patients may still experience infections because of factors such as compliance, dosing, or site of care.

**OBJECTIVE:** To compare the incidence and costs of oversupply in members using pharmacies in a pharmacy benefit management (PBM)-based program (ChoiceSpecialty) with members using retail pharmacies for human immunodeficiency virus (HIV), multiple sclerosis (MS), and autoimmune-related (AR) drugs.

**METHODS:** Retrospective analysis using pharmacy fill information from a national PBM claims database to assess adherence, oversupply and drug costs during 2013 for members with target specialty drugs filled exclusively at either ChoiceSpecialty pharmacies (CS) or retail pharmacies (retail). Additional selection criteria included: commercial enrollees, age ≥18 years, ≥2 claims for adherence measurement, ≥3 claims for oversupply measurement. Members were classified as adherent if proportion of days covered (PDC) ≥80% for MS or AR drugs or ≥90% for HIV drugs. Oversupply was estimated using cumulative medication gap (CMG) with CMG<-110% considered to be potential wastage. Cost savings were modeled based on the difference in days of oversupply in excess of CMG≥-110%, the mean drug cost (plan paid plus copay), and disease prevalence data.
RESULTS: The size of CS and retail cohorts were, respectively: n = 3,321, n = 6,467 for AR; n = 6,680, n = 18,670 for MS; n = 472, n = 15,126 for HIV. The proportion of adherent members was significantly greater for CS compared to retail cohorts for all classes (AR: 64.6% vs. 60.3%, P < 0.001; MS: 73.0% vs. 69.1%, P < 0.001; HIV: 71.9% vs. 67.2%, P < 0.009). The proportion of members with oversupply was significantly less in CS compared to retail cohorts for AR and MS (2.2% vs. 5.1%, P < 0.001 and 1.8% vs. 3.4%, P < 0.001, respectively). The CS and retail cohorts for HIV did not differ significantly in oversupply incidence (5.1% vs. 4.6%, P = 0.65), however the average days of oversupply per overutilizing member was less in the CS cohort compared to the retail cohort (15.1 vs. 34.8 days). The potential PMPY cost savings was calculated to be $0.15 for HIV, $0.08 for MS, and $0.20 for AR.

CONCLUSION: This study demonstrated less oversupply and greater adherence in a PBM-based specialty pharmacy program compared to retail pharmacy use for AR, MS and HIV drugs. The modeled cost savings of oversupply avoided was $0.43 PMPY. This cost savings would likely mitigate increased drug costs due to adherence improvements.

SPONSORSHIP: None.

U23 Impact of Clinical Pharmacist Interventions on High-Risk Patients Enrolled in a Multidisciplinary Case Management Program

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BACKGROUND: The case management model is based on a collaborative process that facilitates coordination of care and communication among providers to improve patient outcomes. Case managers advocate for quality, cost-effective options and services to meet a patient’s health care needs.

OBJECTIVE: This report describes the impact of clinical pharmacist interventions on high risk patients enrolled in a multidisciplinary case management program at a regional health plan.

METHODS: From July 1, 2013 to June 30, 2014, high risk patients enrolled in case management were referred to a clinical pharmacist for consultation and assessment of medication related problems. Patients could be referred by any member the multidisciplinary team which included a nurse, a social worker and a dietician. Once referred, the clinical pharmacist reviewed the patient’s medication profile and medical history. The pharmacist then conducted telephonic outreach to patients and providers to provide education, discuss cost savings opportunities and resolve medication related issues. All of the pharmacists’ activities were documented in the health plans clinical documentation system.

RESULTS: In total, 243 patients, median age 63 (range 4-93), were referred to the clinical pharmacist. The pharmacist provided consultation for 104 patients with financial barriers to obtaining medication, 57 patients with a request for medication education, 70 patients with a safety concern, 17 patients with access to medication issues and 4 patients for adherence concerns. The pharmacist made 56 recommendations to change drug therapy with 50 recommendations accepted (89%). Financial interventions resulted in $40,031 projected yearly savings for patients and $220,910 in projected yearly savings for the health plan.

CONCLUSION: Patients enrolled in case management programs are often at high risk for poor outcomes and increased hospitalizations due to challenges with medication management. The clinical pharmacist provided valuable services to patients and providers including educational support and identification of opportunities to optimize medication regimens which resulted in significant savings for patients and the health plan. Development of additional methods to identify appropriate patients for pharmacist intervention is on-going in order to further expand the program.

SPONSORSHIP: HealthNow, Buffalo, NY.

U25 Treatment Patterns Among Patients Switching from Immediate-Release Gabapentin to Either Gastroretentive Gabapentin or Pregabalin

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BACKGROUND: Gastroretentive Gabapentin (G-GR, approved for treatment of PHN) and pregabalin (P) are currently prescribed to patients with pain indications. Both therapies must be titrated to an effective dosage.

OBJECTIVE: Compare treatment patterns among patients switching from gabapentin immediate release (G-IR) to G-GR or P, to better understand dosage patterns, adherence, switching, and costs.

METHODS: Using Humana claims data from April 2011 to September 2013, patients with a pre-index Rx of G-IR, an index Rx for G-GR or P, and 6-month enrollment pre- and post-index, were included. Every G-GR patient was matched with two P patients by pain-related diagnosis, comorbidity score, age, and race.

RESULTS: 316 G-GR patients met all entry criteria and were matched with 632 P patients for a total of 948. The most common pain-related diagnoses were back-pain-related (57%) and neuropathy/neuritis (10%). During the pre-index period, the percentage of days on G-IR was higher for G-GR cohort than the P cohort (51% vs. 41% of the time); maximum median G-IR dosage for both groups was 900 mg/day; 79% of the P cohort and 86% of the G-GR cohort had ≥1 opioid Rx (P < 0.01). The median morphine equivalent dosage was 150 mg for the P cohort and 315 mg for the G-GR cohort (P < 0.0001). During follow-up, the median daily dosages were 1,800 mg for G-GR and 150 mg for P. More patients in the G-GR cohort reached a therapeutic dosage—66% (1,800 mg/day) vs. 30% (300 mg/day) for the P cohort (P < 0.0001). The mean ± SD days on therapy were similar (P, 95 ± 56 days; G-GR, 89 ± 56 days). It took fewer days to reach maximum ± SD dosage (P, 30 ± 48 days vs. G-GR, 5 ± 21 days). Addition of ≥1 therapy was similar for the cohorts (P, 43%; G-GR, 41%) with opioids the most common add-on (P, 33%; G-GR, 28%). Discontinuation of the index therapy for ≥30 days was common for both cohorts (P, 70%; G-GR, 71%), as was discontinuing and not resuming within 6 months (P, 99%; G-GR, 63%). Opioid use dropped minimally for both cohorts to 77% for P and 85% for G-GR. There was no statistically significant change in opioid dosage between cohorts. Mean total 6-month healthcare costs per member were $11,144 for the G-GR and $11,023 for the P cohort, and were not significantly different after statistical adjustment.

CONCLUSION: On the index date, patients taking G-GR may have had more severe pain than those treated with P. More patients taking G-GR reached the recommended therapeutic dosage, and reached that dosage more quickly than patients taking P. Differences in total healthcare costs were negligible between the two agents.

SPONSORSHIP: Research funded by Depomed Inc., Newark, CA.

U26 Evaluation of Compounded Prescription Medications in a Commercial Health Plan

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BACKGROUND: Compounded prescription are widely used in wide range of treatment options. Many specialists from Dermatology to Neurology have used compounded products. Most recently, pain management prescribers have used this practice to treat pain. Blue Cross Blue Shield of Vermont has historically covered compounded medication, initially unrestricted, then with some Utilization Management, and most recently with a dollar threshold over which required Prior Authorization Review.

OBJECTIVE: Review active ingredients, costs, and prescribing patterns.

METHODS: A retrospective review was performed for compounded medication submitted by all network pharmacies from January 1, 2007 to May 31, 2014. To accurately assess, types of medications being compounded and costs. Over the review period, impact of a strict Prior Authorization policy, and then modification of the Prior Authorization policy to allow Prescriptions with a net cost below a $300 threshold were evaluated.

RESULTS: The evaluation was conducted on 10,963 prescriptions over 89 months. In 2007 with no restrictions, the plan processed 2,779 compound prescriptions with ingredient costs totaling $674,417. In 2008, following the implementation of a strict Prior Authorization for all compound drugs: 1,299 prescriptions processed totaling $227,316. In 2009, 2010, and 2011 numbers dropped to 771 RXs total $172,193, 751 RXs totaling $176,867, and 864 totaling $169,859 respectively. In 2012, data review found that if we removed the PA for any compound under $300, we would cut out 89% of the PAs but still protect 67% of the dollars spent on compounds. In August 2012, a dollar threshold on compound drugs only reviewing compounds above $300 was implemented. In 2012, compounded drugs rose to 1,301 RXs totaling $192,354. In 2013, there were 2,205 RXs totaling $393,406 and for the first five months of 2014 993 RX totaling $427,755. The top three in 2014, $192,354. In 2013, there were 2,205 RXs totaling $393,406 and for the first five months of 2014 993 RX totaling $427,755. The top three in 2014, Gabapentin $436,810, Fluticasone Pripionate $228,010, and Ethoxy Diglycol $136,004.

CONCLUSION: Prior Authorizing compounded medications saw a dramatic decrease in both utilization and spend. Relaxing the PA rules even slight to allow for a threshold of a modest $300 and below saw a large spike in costs. The average compound med rose from $147 to now a $291 just under the threshold for Prior Authorization.

SPONSORSHIP: None.

U28 Economic Outcomes of Chronic Pain Patients Treated with Tapentadol ER or Oxycodone CR

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BACKGROUND: The decade-long growth in U.S. opioid prescribing has increased the need for health plans to understand the economic impact of chronic pain patients on managed care pharmacy and medical budgets.

OBJECTIVE: To compare healthcare utilization and costs between matched cohorts of chronic pain patients treated with tapentadol ER or oxycodone CR.

METHODS: Pharmacy and medical claims data from the Optum Research Database were analyzed for commercial and Medicare Advantage adult patients with ≥ 1 prescription fill for either branded oxycodone CR (OXY CR) or tapentadol ER (TAP ER) between September 1, 2011 and September 30, 2012; the date of the first observed OXY CR or TAP ER claim was the index date. Patients had 6 months of continuous health plan enrollment before and after the index date, no history of the index product in pre-index, and ≥ 90 days supply of any opioid in the pre- and/or post-index to focus on patients with chronic pain. Patients in the TAP ER and OXY CR cohorts were propensity score matched in a 1:2 ratio (TAP ER: OXY CR) with unconditional logistic regression controlling for demographics, insurance type, prior medication use, pain conditions and comorbidities. Match quality was assessed with comparisons of matched cohort attributes and visual inspection of propensity histograms. Differences in post-index utilization and costs between the non-independent matched cohorts were tested by Rao-Scott Chi-square statistics for categorical variables and generalized linear models with robust variance estimators for continuous measures. No adjustment was made for multiplicity.

RESULTS: The matched cohorts of 1,120 TAP ER and 2,240 OXY CR patients appeared well matched by both statistical and visual evaluation. In the 6 months post-index, a significantly greater proportion of the OXY CR cohort than the TAP ER cohort had ≥ 1 inpatient stay (20.5% vs. 14.6%, P < 0.001) and ≥ 1 emergency department visit (37.5% vs. 33.4%, P = 0.021). The TAP ER cohort had higher mean [standard deviation] pharmacy costs ($4,467 [5,147] vs. $3,694 [4,410] for OXY CR; P < 0.001). The OXY CR cohort had higher mean inpatient costs ($6,309 [22,572] vs. $3,625 [14,015]; P < 0.001) and total health care costs ($19,330 [33,323] vs. $16,510 [24,604]; P < 0.001).

CONCLUSION: In a matched cohort analysis of patients with chronic pain, TAP ER patients were less likely to be hospitalized or visit the emergency department and had significantly lower total health care costs than did their matched OXY CR counterparts.

U29 Retrospective Analysis on the Impact of an Integrated MTM Program on Return on Investment (ROI) to the Pharmacy

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BACKGROUND: Community pharmacies provide medication therapy management (MTM) services to patients, however, not all pharmacies offer this service. Those pharmacies that focus on medication-related problems such as indication, safety, efficacy and compliance provide targeted medication reviews (TMR). Those that offer a holistic approach to MTM provide comprehensive medication reviews (CMR). The traditional model that many pharmacies use to offer MTM is to have specially trained pharmacists provide the reviews. Recently, an integrated approach has been adopted in which all pharmacists incorporate MTM into the pharmacy workflow. By integrating MTM services, pharmacists can potentially reach more patients through MTM and ultimately decrease costs to the pharmacy through MTM reimbursement programs.

OBJECTIVE: To evaluate the effect of an integrated MTM model versus the traditional model on return on investment (ROI) at a regional pharmacy chain in North Carolina.

METHODS: A retrospective analysis of MTM claims billed in 2010 and 2012 by pharmacists in 76 pharmacies across North Carolina was conducted. All paid claims for CMRs and TMRs were included. In claims in which the patient could not be contacted were excluded. Pharmacy revenue was calculated by totaling the reimbursement paid per claim. Pharmacy investment was calculated by determining the total investment of pharmacist time on average for MTM services. The total time
invested by pharmacists in 2010 and 2012 was multiplied by the average hourly pharmacist salary for that year.

**RESULTS:** In 2010, 8,757 claims were conducted by 122 pharmacists to 4,089 patients. In 2012, 13,730 claims were conducted by 119 pharmacists consulting 4,896 patients. In 2010, $164,623.91 was invested in pharmacist salary and $173,498.00 was received in reimbursement, resulting in an ROI of + $8,874.09 (+5.4%). Pharmacist salary expenditure in 2012 totaled $279,019.55 and the revenue via reimbursement reached $302,963, resulting in a ROI of + $23,943.45 or (+8.6%).

**CONCLUSION:** The integrated model of MTM implemented in 2012 showed an increase in pharmacist provided MTM interventions and an increase in patients seen, ultimately resulting in a higher ROI. While a higher ROI was evident in 2012, both models resulted in positive earnings showing reimbursement programs can be cost effective with different execution strategies. Integrating MTM into the pharmacy workflow while expanding reimbursement programs are both key factors for the sustainability of MTM services in community pharmacies.

**SPONSORSHIP:** This study was conducted without funding.

**U30 Using the FDA’s Adverse Event Database to Perform Comparative Safety Research**

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**BACKGROUND:** Comparative effectiveness research (CER) helps healthcare organizations make better evidence-based coverage and formulary decisions. Drug adverse event (AE) information included in CER is often comprised of clinical trial results. Unfortunately, reported safety outcomes from clinical trials are not always relevant to healthcare decision makers. Additionally, AE trial results from relatively homogeneous patient groups frequently do not correlate with real-world AEs in heterogeneous populations. In summary, drug safety data are often deficient. Therefore, MCOs are looking for additional sources of current, real-world, and actionable safety data that can be used to mitigate the substantial costs associated with AEs.

**OBJECTIVE:** To describe a new comparative safety research tool that can improve patient safety and identify potential cost savings.

**METHODS:** Approximately 5 million AE case reports from 1997-2014 were imported from FDA’s Adverse Event Reporting System (FAERS). Misspellings were corrected and duplicate cases were removed. Data were filtered with fuzzy string and phonetic matching algorithms, text mapped with RxNorm, and manually curated. Existing comorbidities, reporting disproportionality measures, and FAERS fields such as “Outcome,” “Adverse Event Seriousness,” and “Report Type,” were assigned numerical values and totaled to produce a 1-100 scale, with 100 being the worst safety profile.

**RESULTS:** 1,122 drugs were included. The median score was 54. 36 drugs had scores ≥ 70 while 213 drugs were ≥ 60. The 50 highest scoring drugs included various classes and there were multiple examples of CNS-acting agents, muscle relaxants, anesthetics, vasodilators, and contrast agents. As an example of a within-class comparison, nine Disease Modifying Therapies for relapsing remitting MS showed a range of 33-55 for the total score while individual components had percentage ranges (of the maximum) from 20-44 for “Outcome,” 19-47 for “Adverse Event Seriousness,” and 13-34 for disproportionality.

**CONCLUSION:** The promise of increased use of CER is very encouraging but the integration of real-world AE data into current methods is often lacking. The addition of post-marketing safety evidence from FAERS can provide a timely, real-world, and actionable reference point for healthcare decision makers tasked with estimating a drug’s impact on downstream costs and patient safety.

**SPONSORSHIP:** This research was funded internally by AdverseEvents, Inc.

**U34 Evaluation of a Cost-Reduction Pharmacy Benefit Program on Pregabalin Utilization and Costs in a Commercially Insured Health Plan Population.**

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**BACKGROUND:** Health plans have implemented various strategies to reduce pharmacy expenditures. Evaluations of these programs report mixed results in cost savings.

**OBJECTIVE:** To evaluate a novel pharmacy program started in 2011 that required commercial health plan members using retail pregabalin to switch to mail-order services and/or gabapentin, or pay full retail pharmacy price for pregabalin.

**METHODS:** This retrospective study of administrative claims included data from a sample of geographically diverse U.S. health plan members. Members were at least 19 years of age, had ≥1 pharmacy claim for pregabalin and ≥1 inpatient or ≥2 outpatient claims with diagnosis codes for diabetic peripheral neuropathy, fibromyalgia, postherpetic neuralgia or partial onset seizure. Members’ index dates were the first retail pregabalin pharmacy claim after the start of the pharmacy program (program cohort) or during the identification period (non-program cohort). Members were continuously enrolled for 12 months before and after their index date. Members in the program and non-program cohorts were propensity score matched 1:1 on selected pre-index demographic and clinical factors.

**RESULTS:** A total of 4,528 members (1,218 program cohort, 3,310 non-program cohort) met the inclusion criteria. After propensity score matching, 2,436 members remained with average age 51 years and 77% female. The most common inclusion diagnosis was fibromyalgia. Members in both cohorts had an average of 5 pre-index pregabalin claims (P = 0.912). The average count of pregabalin claims decreased from 5 pre-index to 4 post-index (P < 0.001) among program cohort members and increased in the non-program cohort to 6 claims (P < 0.001). Pharmacy costs increased approximately $800 for both study cohorts (program cohort: $7,033 pre-index to $7,853 post-index, P < 0.001; non-program cohort: $7,064 to $7,854, P < 0.001). Mail-order pregabalin use increased from 3% pre-index to 48% post-index (P < 0.001) in the program cohort versus 3% to 9% in the non-program cohort (P < 0.001). Program members were more likely than non-program members to change to gabapentin (31% vs. 16%, P < 0.001). The change in total health care costs (including pharmacy) from pre-index to post-index was not significantly different between cohorts (P = 0.474).

**CONCLUSION:** After program implementation, a significant decrease in pregabalin utilization was observed in the program cohort; however, total health care and pharmacy costs did not differ between program and non-program cohorts.

**SPONSORSHIP:** Pfizer Inc.

**U36EM The Cost-Effectiveness of Non-Comprehensive Medication Review Compared with Comprehensive Medication Review on Making Successful Medication Changes**

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BACKGROUND: Experts estimate that 1.5 million preventable medication-related adverse events occur each year, some of which lead to serious injury and death. The Center for Medicare and Medicaid services has indicated that all Medication Therapy Management programs are required to offer comprehensive medication reviews (CMRs) to all beneficiaries at least annually. During a CMR, an extensive amount of information is provided to patients. In contrast, non-comprehensive medication reviews (non-CMRs), are more targeted and focused on resolving potential medication-related problems (MPRs) through short patient consultations, patient letters, and direct provider interventions.

OBJECTIVE: To conduct a cost-effectiveness analysis comparing non-CMRs with CMRs to successfully make medication regimen changes and reduce adverse drug events.

METHODS: A decision analytic model was created based on published studies to compare the cost-effectiveness of non-CMRS and CMRs from the perspective of a healthcare system. A successful outcome was defined as a case that did not have an adverse drug event due to MRP. The model was subjected to both a thorough one-way sensitivity analysis and a second-order probabilistic sensitivity analysis with 10,000 iterations from the variable distributions.

RESULTS: Non-CMR was less costly and more effective than CMR. The point estimate direct medical cost was $349 for non-CMR and $405 for CMR. The estimated probability of avoiding an ADE was 0.87 for non-CMR and 0.85 for CMR. The 10,000 iteration-Monte Carlo simulation indicated that non-CMR dominated CMR for preventing harmful ADEs by being both more effective and less costly; however, there was overlap in the 95% CIs for both cost and ADEs prevented. Non-CMR was estimated to save $3,846.94 per an ADE prevented. The cost-effectiveness acceptability curve demonstrated that in 100% of cases non-CMR was most likely to be the most cost-effective intervention regardless of willingness to pay. The one-way sensitivity analysis indicated the results were sensitive to the proportion of medication changes accepted by prescribers in the non-CMR group.

CONCLUSION: This analysis suggests that non-CMR was more effective and less costly than CMR, however, there was overlap in 95% CIs for cost and ADEs prevented. The cost-effectiveness acceptability curve demonstrated that in 100% of cases non-CMR was most likely to be the most cost-effective intervention.

SPONSORSHIP: This research was conducted by University of Arizona, College of Pharmacy, Tucson, AZ, without external funding.

U37 Prescription Delivery at Discharge to Improve Patient Access to Medication: Results from Implementation Through Year One at an Academic Medical Center

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BACKGROUND: Medication non-adherence is a multifaceted problem that leads to unnecessary costs, hospital readmissions and poor outcomes. Adherence to medication is estimated to be 50%, which accounts for 10% of hospital admissions. Patients attribute low adherence and difficulty accessing medications as reasons for readmission. Upon discharge from the hospital, anywhere from 24-28% of patients do not fill their prescriptions. Pharmacists should explore methods to help reduce primary non-adherence.

OBJECTIVE: To increase patient access to medication, reduce non-adherence, and help decrease hospital readmissions by implementing a bedside prescription delivery service.

METHODS: A prescription delivery service (iMeds) was developed at The University of Toledo Medical Center (UTMC), a 211 bed academic medical center. Patients are offered the service on admission, with responses noted in charts. A pharmacy team member reviews the daily census and identifies patients nearing discharge. The team arranges for prescriptions to be sent to the outpatient pharmacy. A pharmacist reviews prescriptions and patient charts for medication-related problems and makes interventions. A nurse sends discharge updates and patients pay upon delivery. Patient counseling is provided by a pharmacist or trained student.

RESULTS: In May 2013, the outpatient pharmacy began a pilot program on one unit of the hospital. This program expanded to include all units and outpatient surgery centers in March 2014. The program displayed growth between May 2013 and June 2014, as the number of patients who were offered the program each month who filled prescriptions (capture rate) increased from 16.67% to 54.29%. (M = 42%; SD = +/- 23) The gross monthly margin also increased from $260 to $11,483 during that same time frame. (M = 3308; SD = 3884) Lastly, patient access to medication improved. The program evolved from serving five patients to 209 patients (M = 93) and prescription count increased from 21 prescriptions to 644 prescriptions per month (M = 295).

CONCLUSION: The iMeds program demonstrates positive trends in number of patients served, prescriptions filled, capture rate, and gross margin. The program has evolved from using pharmacy residents and students to a full time pharmacist and two technicians, who were justified by profit. A bedside prescription delivery service should be considered by hospitals as a self-sustaining, managed care solution to help improve patient access to medication and adherence. Further evaluation is needed to determine the effect of bedside prescription delivery on readmissions, patient satisfaction, and health outcomes.

SPONSORSHIP: This program was conducted at The University of Toledo Medical Center without external funding.
and grading policies, course format, and the schedule of topics and speakers for each lecture.

**RESULTS:** After taking the elective, students gained a better understanding of the roles of a managed care pharmacist. There was an increased awareness of non-traditional pharmacy career opportunities and how applying managed care skills can improve outcomes. Students felt they had a more comprehensive view of the relationship between key participants within healthcare management. The elective also addressed current issues in healthcare and discussed the future direction of pharmacy.

**CONCLUSION:** Steps will be taken to broaden access to the course by increasing the enrollment cap and opening the class to UCSF students in the Schools of Medicine, Nursing, Dentistry, and Physical Therapy. In the future, course content may be hosted online to allow students outside of UCSF to access course materials and lectures and receive a certificate upon completion.

**SPONSORSHIP:** None.

**U40 Controlling High Risk Medication Use in a Dual Eligible Medicare Part D Plan: A Three-Tiered Approach to Impacting the HRM Part D STAR Measure**

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**Pharmacy, Gateway Health Plan**

**BACKGROUND:** Gateway Health Medicare Assured is a Part D sponsor with a large special needs population and a high percentage of members with behavioral health issues. All Medicare Part D Sponsors are rated on performance and quality measures referred to as STAR measures. The use of high risk medications in the elderly (HRM) is a patient safety measure calculated by the percentage of Medicare beneficiaries 65 years or older who received two or more fills of at least one drug with a high risk of serious side effects in the elderly. The American Geriatrics Society recently released the Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. These medications have been linked to drug-related problems, adverse drug events, and overall poor patient outcomes in older adults, however, some of these medications continue to be prescribed for older adults, and are sometimes used as first-line treatment.

**OBJECTIVE:** To impact our HRM part D STAR rating by implementing formulary changes and targeting outreach to both members and providers at different levels.

**METHODS:** (1) Formulary management: (a) Removing unsafe medications from formulary where there are safer alternatives; (b) Implementing prior authorization criteria for members over the age of 65 for other high risk medications. (2) Individualized member approach: (a) Assessing the MTM population weekly when a new HRM has been filled; (b) Outreaching to members if a HRM was approved, providing education and notifying prescriber of a recommendation given for change. (3) Provider education/outreach: (a) Providing benchmarking analysis to prescribers comparing their prescribing patterns to peers; (b) Targeting education on medications that are more frequently prescribed. i.e., tricyclic antidepressants

**RESULTS:** Preliminary results show a decrease in high risk medication usage in the elderly after implementing formulary restrictions. Results showed a decrease in HRM rates from 12% to 7% when comparing January-May of 2013 to January-May of 2014. The full impact of these results will continue to be measured through the end of 2014. Similarly, analysis is ongoing to measure the impact of the member and provider outreach.

**CONCLUSION:** Combining formulary management as well as member and provider outreach may show a positive impact on Medicare Part D Sponsor’s high risk medication STAR rating.

**SPONSORSHIP:** Gateway Health.

**U42 An Independent Pharmacy-Based Transition of Care Program for a Managed Medicaid Population**

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**BACKGROUND:** Patients discharged from the hospital are at risk for adverse events due to poor care coordination. A growing body of evidence suggests that transition of care programs involving pharmacists can prevent unplanned readmissions. Many currently published studies focus on academic/integrated healthcare settings with established provider networks.

**OBJECTIVE:** This study explores the feasibility of developing a community pharmacy-based transition of care program in collaboration with a managed Medicaid plan, with the goal of preventing unplanned readmissions.

**METHODS:** A transition of care program was implemented between a managed Medicaid plan and an independent pharmacy in an underserved community in California. The plan referred recently admitted high-risk adults. Members were excluded for elective procedures, pregnancy complications, or suicide attempts, or for discharge to a skilled nursing facility, rehabilitation center, or hospice. Prior to and for 30 days post-discharge, the health plan coordinated discharge planning, appointments, and case management. The pharmacists provided medication reconciliation and review, post-discharge consultation with 30 day follow-up, and communication with primary care providers.

**RESULTS:** In the first 14 months, 685 patients were referred to the program, of whom 78 were excluded, 29 declined services, and 148 could not be reached, leaving a total of 430 patients. Of the 430 patients, 31% were male and the mean age was 49 years. On average, each patient received 2.5 post-discharge phone calls, each lasting a mean of 21 minutes (range 6-105). The mean face-to-face visit lasted 59 minutes (range 15-130). Using prescription claims, hospital records, and patient self-report, the pharmacists performed medication reconciliation and review for all 430 patients, as well as 144 patient education sessions, 113 communications with providers, and identification of 22 cases requiring medication changes to prevent adverse events.

**CONCLUSION:** Barriers to care included incomplete medical records, delays in communication with providers, difficulty contacting patients, health literacy, resistance to care, lack of transportation, and poor caregiver support. Factors associated with success included patient motivation, rapport with local providers, use of the in-house dispensing pharmacy, and face-to-face encounters. The impact of the program on readmission rates will be evaluated in future publications.

**SPONSORSHIP:** Synergy Pharmacy Solutions.

**U43 Assessment of the Level of Satisfaction and Unmet Needs of Drug Formulary Decision Makers**

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**BACKGROUND:** A formulary system is a serial process of establishing the policies that would offer the most medically and economically
desirable therapeutics for the patients. Formulary management within a limited budget is critical especially for specialty drugs, which are used for serious medical conditions, are very expensive, with six times higher annual cost increase than non-specialty drugs. Consequently, formulary decision should be based upon strong clinical and economic evidence. Despite previous attempts, it is inconclusive whether data needs of formulary decision makers for specialty drug formulary management are satisfied.

OBJECTIVE: This study aimed to assess (a) strength of current available data sources, and (b) the level of satisfaction and unmet needs of specialty drug formulary decision makers regarding clinical, economic, and unpublished evidence.

METHODS: We targeted pharmacy and medical directors at health plans, or PBMs in a national, large regional, and local level. Uncompensated individuals involved in specialty formulary decisions from these organizations were contacted for survey participation. An online survey instrument (Qualtrics), taking no more than 20 minutes was open for 21 days. Before distributing the questionnaire, a pre-test was conducted with 3 respondents to assure content validity of survey items. Responses were coded for descriptive and statistical analysis.

RESULTS: The online survey was disseminated to 69 health plans and 5 PBMs. As a total, 24 questionnaires were completed during June 14-July 5 in 2014, resulting in a response rate of 32%. When asked to evaluate the strength of evidence using 5 Likert scales, published RCT studies (+4.04±0.86), and internal financial analysis of own data were deemed as strongest sources (+4.14) among clinical and economic data respectively. Unpublished data didn’t show any statistical significance among data sources. Both clinical and economic data offered highest satisfaction in terms of accessibility to data, but clinical data was better satisfied (6.19±1.7, and 4.64±3.28) respectively. RCTs with active comparators (2.96±0.04) and cost-effectiveness analysis data (2.52±0.53) were in highest needs for better formulary decision making when using 3 Likert scales. The information from manufacturers was evaluated as most valuable for unique specialty drugs with a novel mechanism of action.

CONCLUSION: Strength and satisfaction levels of formulary decision makers were perceived differently by data sources, supporting that targeted approaches may best satisfy unmet needs.

SPONSORSHIP: None.

Z00-Z99 Factors Influencing Health Status and Contact with Health Services (i.e., Adherence, Oral Contraceptives)

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Oregon State University

BACKGROUND: Timely access to clinical trial data is critical for evaluating newly approved drugs. Since 2008, summary trial results are required to be posted to the ClinicalTrials.gov registry within thirty days of FDA approval. The impact on this reporting requirement on data availability for newly approved drugs is unclear.

OBJECTIVE: To quantify the timeliness of clinical trial data reporting for newly approved drugs in ClinicalTrials.gov, on the FDA website, and in published form.

METHODS: All phase three studies for new molecular entities (NMEs) between 2009 and 2013 were identified using the FDA website. Orphan drugs and diagnostic products were excluded. Trials were matched to their ClinicalTrials.gov entry using enrollment and trial design features provided in the FDA approval review. Availability and dates of ClinicalTrials.gov results posting were compared to the FDA approval date to evaluate compliance with the reporting requirement. Publication status was assessed using similar methods.

RESULTS: Between 2009 and 2013, 77 NME were approved by the FDA. Approvals ranged from 13 to 20 per year. The most common category of approval was infectious disease (19%). The median time from approval to posting on the FDA website was 40 days (min=0, max=437). Of the 227 phase three trials supporting these approvals, 171 (79%) contained results posted to ClinicalTrials.gov. The median time until results were posted was 27 days. Ninety-eight trials (43%) either failed to post or did not post results within thirty days. Of trials with posted results, but failing to meet the reporting requirement, the median time until posting was 95 days. Compliance with reporting requirement was lowest for NME approved in 2010 (26%) and highest in 2012 (81%). Of therapeutic categories with more than ten trials, respiratory trials had the highest rate of reporting compliance (74%) and infectious disease had the lowest (33%). Matching publications were identified for 180 trials (79%) with 99 (44%) published prior to approval. Of trials published after approval, the median time until publication was 168 days. There were 54 trials (24%) that were not published or reported on clinicaltrials.gov within 30 days.

CONCLUSION: Although clinical trial reporting has improved over time, a quarter of trials supporting newly approved drugs are not reported in a timely manner.

SPONSORSHIP: None.

Z4 Supporting Retail Clinicians in Brief Cessation Intervention

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BACKGROUND: Retail clinicians need up-to-date, tailored information on supporting their patients to quit tobacco.

OBJECTIVE: Beginning in 2013, the Foundation for Health Smart Consumers and partners at the Convenient Care Association initiated the Inspire Smoking Cessation Training Program. Inspire’s objective is to increase smoking cessation interventions in retail-based clinics by providing nurse practitioners and other attending clinicians with training and counseling resources. Ultimately, Inspire aims to promote/support tobacco cessation among those utilizing retail-based health care services.

METHODS: This presentation will share mid-program Inspire findings and discuss tailored brief intervention training. Inspire’s evaluation focuses on reach, changes among trainees (in the areas of knowledge, confidence, buy-in and behavior) and trainee feedback.

RESULTS: Trainings at the 2013 and 2014 Retail Clinicians Education Congress conferences and online trainings garnered 295 trainees across 31 states in the U.S. The majority of trainees are full time Nurse Practitioners. 98% of trainees describe the training as useful and 95% intend to refer patients post-training. Prior to the training, 58% of trainees report being familiar with at least five tobacco cessation support options or pharmacotherapies; following the trainings 98% of trainees report being more comfortable discussing cessation aids because the of the review and/or new information provided as part
of Inspire. In comparing paired pre/post data, Inspire trainees report significant increases in confidence regarding their ability to refer their clients to obtain services to quit using tobacco and in confidence helping clients quit using tobacco ($P<0.01$, $95\%$ CI). In addition, Inspire trainees report high feasibility for them to consistently use brief intervention in the future (Mean = 8.6, Mode = 10 on 1-10 scale). Preliminary 3-month follow-up data indicate increases in consistency of Ask, Advise, Refer use, with reduced drop off between Ask and Refer. Additional follow up data is needed to draw conclusions about sustained change in confidence and post-training behaviors.

**CONCLUSION:** Retail-based clinic care is becoming more widely available and a benefit covered by many health plans. Retail clinicians have direct service opportunities to increase brief cessation interventions and referral for a variety of tobacco user supports. Tailored trainings for retail clinicians have the potential to increase referral behavior among clinicians.

**SPONSORSHIP:** Grant provided by the Pfizer Independent Grants for Learning & Change and the support of the Smoking Cessation Centennial, CO 80112; nhancy@welldynerx.com; 888.479.2000 ext. 8323

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**Z6 Implementation of Pharmacist-Directed Hypertension Program for Participants in a County Government Plan**

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**WellDyneRx**

**BACKGROUND:** On-site clinics staffed with a clinical pharmacist in the workplace are a proven approach, reducing health care costs and enhancing overall health outcomes. Chronic conditions such as diabetes mellitus and cardiovascular (CV) disorders contribute to increased medical utilization, decreased productivity and increased costs. The number of working-age adults with a chronic health condition has increased by 25%, affecting close to 58 million people. In addition, nearly 90% of adults with uncontrolled hypertension in the U.S. have health insurance; resulting in an opportunity to implement programs that improve patient adherence. With the increasing prevalence of chronic diseases, many employers are concerned about their impact on health care costs.

**OBJECTIVE:** To evaluate the impact of an on-site pharmacist-directed hypertension program on clinical outcomes for patients with hypertension.

**METHODS:** Patients were assessed on the status of their hypertension and were required to have lab work taken at the county's government wellness center or provide copies from their doctor. Appointments with the clinical pharmacist were scheduled based on the degree of disease control. Each appointment involved the collection of patient weight and blood pressure along with a discussion that included dietary strategies, lifestyle changes, risk management strategies and medication management. Program participants received a copay reduction for their antihypertensive medications.

**RESULTS:** The percentage of adherent (medication possession ratio ≥80%) patients increased; leading to an average reduction of 7 mmHg in systolic blood pressure and 2 mmHg in diastolic blood pressure. Mean arterial pressure decreased 4 mmHg and the pulse pressure was 5 mmHg lower than baseline at 12 months. Of the 231 patients analyzed, 124 individuals showed an improvement in their blood pressure (combined systolic and diastolic reduction > 10 mmHg). Subsequently, 81 patients had stable blood pressure (a change < 10 mmHg), while 26 patients showed a slight increase. In addition, the percentage of patients meeting age-adjusted Joint National Committee 8 (JNC 8) goals increased from 66% to 83%. When compared to non-enrolled patients, program participants had a lower percentage of CV-related hospital admissions (6.7% vs. 18.2%) and average length of stay for CV-related admissions was reduced by more than 2 days.

**CONCLUSION:** The pharmacist-provided hypertension program demonstrated improved blood pressure control in patients who were not meeting their treatment goals and revealed a reduction in CV-related medical spend from the previous year.

**SPONSORSHIP:** None.

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**Z7 Impact of a 6-Month Step Edit in Medicare Part D Population with Osteoporosis**

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**Merck and Co., Inc.**

**BACKGROUND:** A high proportion of women diagnosed with osteoporosis (OP) are untreated either because they are unable to take or unwilling to continue bisphosphonates (BIS) for various reasons. They will likely remain untreated leading to worse outcomes, higher healthcare utilization and costs. Step-edits are put in place to encourage prescribing of the cheapest alternatives available. Common step edits assess use of OP medication in the prior 6 months for patients to qualify for alternative treatment. Depending on the patient’s reason for discontinuation, they may be unwilling to re-initiate treatment with an agent from the same drug class i.e., BIS. A review of the prior 6 months only will potentially miss patients that were treated beyond the window of the 6 month step edit requirement resulting in non-treatment of such patients.

**OBJECTIVE:** To estimate the proportion of patients who would not pass a 6 month step edit among osteoporosis patients enrolled in Medicare part D Humana plan.

**METHODS:** This retrospective study identified women ≥65 years enrolled in Medicare Part D, and diagnosed with osteoporosis as of July 1, 2012. OP medications included all bisphosphonates and non-bisphosphonates. In order to estimate proportion of patients who would not pass 6 month step edit, we defined “step edit untreated” as patients without evidence of OP treatment during the last 6 months of 2012. Among “step edit untreated” patients, patients were “previously treated” if they were continuously enrolled and had evidence of OP treatment during the 3-year look back period prior to June 30, 2012 and OP diagnosed prior to the look back period.

**RESULTS:** Of 152,116 women who met inclusion criteria, a majority (76%) had no evidence of OP treatment during the last 6 months of 2012 and would not pass a step edit. Among the “step edit untreated” patients, $n=38,167$ who were continuously enrolled in the 3 year look back period, $n=14,061$ (37%) were “previously treated.”

**CONCLUSION:** Although, step edit is an effective method for appropriate drug utilization; nearly 1 in 4 elderly osteoporotic women would either need to restart previously discontinued treatment, or have their physician complete documentation in order to qualify for an alternative therapy. Plans that intend to implement step edits should allow for a sufficient look back period (several years, ideally) to identify patients who have tried/failed prior treatment, allowing access to new medications without treatment repetition or laborious administrative process. Future research should investigate the impact and burden of non-treatment among OP patients.

**SPONSORSHIP:** This study was sponsored by Merck and Co., Inc.
**Z9** Clinical and Economic Impact of a Pharmacist-Led Diabetes Collaborative Drug Therapy Management Program in a Medicaid ACO Setting

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**BACKGROUND:** This study describes changes in clinical and economic outcomes associated with a pharmacist-led Collaborative Drug Therapy Management (CDTM) program in Medicaid patients with poorly controlled type 2 diabetes mellitus (T2DM).

**OBJECTIVE:** The aim was to assess the program’s potential for improving outcomes in patients who could potentially enroll in a new Medicaid Accountable Care Organization (ACO) starting January 1, 2013.

**METHODS:** A retrospective cohort study was conducted in patients treated at a university health system’s primary care providers using electronic Medical Record (EMR), medical claims, and pharmacy claims data from January 1, 2008 to December 31, 2012. The study included adults with T2DM, HbA1c ≥ 7.0%, Medicaid coverage any time during the observation period, and ≥1 HbA1c reading 90+ days after the first CDTM visit or after 6 months of EMR activity for comparison patients (index date). A subset with Medicaid claims data through the ACO health plan were identified for cost analyses. Outcomes included change in HbA1c from baseline to 6-months follow up and change in normalized costs 6 months pre- to 6-months post-index date. T-test and chi-square or Fisher’s exact tests were used to test differences between groups.

**RESULTS:** The study included 79 CDTM and 131 comparison patients. Mean (SD) age was 53.2 (12.9) and 53.9 (13.0) years respectively (P=0.70); 30.4% and 37.4% were male (P=0.30). At baseline and relative to comparison patients, a greater proportion of CDTM patients had been prescribed Metformin (55.7% vs. 40.5%; P=0.03) or insulin (76.0% vs. 16.8%; P<0.001). The CDTM group had a higher mean baseline HbA1c [10.3% (1.7) vs. 8.6% (1.8) P<0.001] and a larger decrease in HbA1c [-2.04% (2.0) vs. -0.90% (2.1) (P<0.001)] which reduced but did not eliminate the difference at follow-up between CDTM and comparison patients [8.3% (1.7) vs. 7.7% (1.6), P=0.02]. In the subset of patients with Medicaid claims data (CDTM n=46, comparison n=67), total all-cause costs during the follow-up period did not differ from the baseline period for either group (P<0.05). The mean (median) change in costs between periods also did not differ ($822 ($68) for CDTM vs. $1881 (2) for comparison, P=0.64).

**CONCLUSION:** A CDTM program shows promise for substantially improving glycemic control in Medicaid ACO patients with poorly controlled T2DM. Costs were not significantly different with the CDTM program versus comparison patients, but the small study size and short time frame made it difficult to identify a cost impact.

**SPONSORSHIP:** None.

**Z10** Improvement in Medication Adherence and Reduction in Total Medical Expenditure in Patients who Received a Pharmacist-Provided In-Home Medication Assessment

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**BACKGROUND:** Non-adherence to prescribed medications can significantly impact clinical outcomes, leading to a decrease in quality of life, increase in hospitalizations and total medical expenditure (TME). Pharmacist interventions have been shown to increase adherence to medications and improve clinical outcomes for many chronic disease states.

**OBJECTIVE:** This intervention sought to improve member adherence to statins (STN), renin-angiotensin system antagonists (RAS), and oral diabetic medications (OAD) in a population who were currently non-adherent, or at highest risk of becoming non-adherent using the Drug Adherence Index predictive model.

**METHODS:** In July-December 2013 greater than 3,000 Medicare Advantage plan members in Alabama were visited at home by a licensed pharmacist. Medication management software was used to document adherence barriers, interventions specific to each encounter, and communications with the prescribing physician. Members received regular telephonic follow-up reinforcing education provided during the home visit. Pharmacy and medical claim data was tracked pre- and post-visit. The data was analyzed for changes in adherence (Proportion of Days Covered–PDC), and total medical expenditure.

**RESULTS:** Non-adherent members seen by a pharmacist compared to those targeted but not visited, showed a +11%, -6%, and +13% change in the percent of members adherent (>80% PDC) on RAS, OAD, and STN medications, respectively. A greater percentage of adherent members at highest risk of becoming non-adherent, were maintained as adherent when compared to members targeted but not visited (+11% RAS, +11% OAD, +17% STN). Visited members had a +23%, -25%, and -18% change in pharmacy claims, medical claims and TME, respectively, compared to those targeted but not visited.

**CONCLUSION:** Pharmacists providing in-home comprehensive medication reviews with regular telephonic follow up can improve medication-related problems and barriers to medication adherence. Resolution of medication issues and interventions targeting the root cause of the identified issues improve medication adherence and drive down total medical expense.

**SPONSORSHIP:** Dovetail Health and Optum Health.

**Z12** Analysis of Medication Adherence Among Patients Using Worksite Clinic and Pharmacy Services Compared with Those Using Offsite Facilities

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Cerner Corporation

**BACKGROUND:** Cerner Corporation established the Healthe Clinic in 2006 to provide a range of worksite healthcare benefits. All Cerner associates and their dependents are eligible for the clinic’s services, which include an onsite pharmacy available to provide patients with a convenient economical option for filling prescriptions, along with patient counseling and education. Additionally, Cerner offers a condition management program for all members and dependents with a diagnosis of diabetes, hypertension and/or obesity. These programs provide personal support, educational materials and other tools provided by a multi-disciplinary team.

**OBJECTIVE:** To determine if worksite clinic and pharmacy services have an effect on medication adherence for patients being treated for depression, diabetes, hypertension or hyperlipidemia. To evaluate the effect of condition management program enrollment on medication adherence.

**RESULTS:** The study included 79 CDTM and 131 comparison patients. Mean (SD) age was 53.2 (12.9) and 53.9 (13.0) years respectively (P=0.70); 30.4% and 37.4% were male (P=0.30). At baseline and relative to comparison patients, a greater proportion of CDTM patients had been prescribed Metformin (55.7% vs. 40.5%; P=0.03) or insulin (76.0% vs. 16.8%; P<0.001). The CDTM group had a higher mean baseline HbA1c [10.3% (1.7) vs. 8.6% (1.8) P<0.001] and a larger decrease in HbA1c [-2.04% (2.0) vs. -0.90% (2.1) (P<0.001)] which reduced but did not eliminate the difference at follow-up between CDTM and comparison patients [8.3% (1.7) vs. 7.7% (1.6), P=0.02]. In the subset of patients with Medicaid claims data (CDTM n=46, comparison n=67), total all-cause costs during the follow-up period did not differ from the baseline period for either group (P<0.05). The mean (median) change in costs between periods also did not differ ($822 ($68) for CDTM vs. $1881 (2) for comparison, P=0.64).

**CONCLUSION:** A CDTM program shows promise for substantially improving glycemic control in Medicaid ACO patients with poorly controlled T2DM. Costs were not significantly different with the CDTM program versus comparison patients, but the small study size and short time frame made it difficult to identify a cost impact.

**SPONSORSHIP:** None.
METHODS: A retrospective analysis of claims data was used to assess medication adherence among employees and dependents that received medication from the worksite pharmacy and/or used the worksite clinic as compared with those that used offsite facilities. Patients who received medications associated with treatment of asthma, depression, diabetes, hypertension or hyperlipidemia were included and followed for 365 days. Medication adherence was assessed using MPR and PDC. In addition, a subanalysis was performed for patients in a condition management program.

RESULTS: 365 fixed MPR is significantly higher for all conditions among onsite pharmacy users; moreover, 720 fixed MPR is significant or approaches significant for all conditions. PDC is significantly higher for all conditions for onsite pharmacy users. Average time to discontinuation (30- and 60-day gaps) are higher for all conditions among onsite pharmacy users. Percent of patients remaining on therapy without a 30-day gap are significantly higher for all conditions among onsite pharmacy users at 180 days. At 1-year, there are trends that approach significance. Adherence remains significantly higher among onsite pharmacy users who are taking multiple classes of medications. Condition management participation trended to being associated with higher medication adherence.

CONCLUSION: The worksite pharmacy improved medication adherence among employees and their dependents. In addition, medication adherence was significantly higher among condition management program participants. The results of this study also have implications regarding the importance of pharmacist involvement in condition management programs.

SPONSORSHIP: Cerner Corporation.