Abstracts from Professional Poster Presentations at AMCP’s 22nd Annual Meeting & Showcase

The following poster presentations have been prepared for the Academy of Managed Care Pharmacy’s 22nd Annual Meeting & Showcase, April 7-10, 2010, in San Diego, California. Poster presentations are selected by the AMCP Program Planning and Development Committee from proposals that are submitted to AMCP. 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 the studies described below, please contact the corresponding authors, indicated by an asterisk (*), whose addresses are listed in full. The names of the individuals who are scheduled to present at the meeting are in shown in bold.

Adherence and Persistence with Duloxetine and Hospitalization in Patients with Major Depressive Disorder

Liu X, * Tepper P, Watson PR. Eli Lilly and Company, Lilly Corporate Center, DC 4123, Indianapolis, IN 46285; liu_xianchen@lilly.com, 317-433-4006

**BACKGROUND:** Adherence to medication therapy for a sufficient duration is important in the treatment of major depressive disorder (MDD), since poor adherence may be associated with relapse and increased costs. Duloxetine is a new selective serotonin and norepinephrine reuptake inhibitor that has been approved for acute and maintenance treatment of MDD.

**OBJECTIVE:** To examine the association between adherence and persistence with duloxetine and psychiatric and nonpsychiatric hospitalizations in the 1-year follow-up period after initiation.

**METHODS:** In a large U.S. commercial managed care claims database, 4,542 patients with at least 1 claim with a diagnosis of MDD (ICD-9-CM codes 296.2 and 296.3) were initiated on duloxetine during 2006. All of the patients had no active prescription of duloxetine for 6 months prior to initiation and had continuous enrollment for 12 months prior to and after duloxetine initiation. Adherence for the first 6 months after study medication initiation was defined as Medication Possession Ratio (MPR) ≥ 0.8, and persistence was defined as the length of therapy without medication initiation was defined as Medication Possession Ratio (MPR) ≥ 0.8, and persistence was defined as the length of therapy without initiation and had continuous enrollment for 12 months prior to and after duloxetine initiation. Adherence for the first 6 months after study medication initiation was defined as Medication Possession Ratio (MPR) ≥ 0.8, and persistence was defined as the length of therapy without exceeding a 30-day gap. Logistic regression analyses were performed to examine the associations between adherence and persistence with duloxetine and psychiatric and non-psychiatric hospitalizations in the 1-year follow-up period.

**RESULTS:** Overall, 53.9% of patients were adherent to duloxetine treatment; average length of treatment was 116.0 days (SD = 63.5) during the first 6 months after initiation. Compared with nonadherent patients, adherent patients had significantly lower rates of psychiatric (5.9% vs. 10.2%, P < 0.001) and nonpsychiatric (12.9% vs. 15.9%, P < 0.01) hospitalization. Both psychiatric (P < 0.01) and nonpsychiatric (P < 0.05) hospitalization rates declined significantly with length of treatment. After adjustment for demographics and comorbidities, adherence was associated with reduced psychiatric (OR = 0.66, P < 0.05) and nonpsychiatric (OR = 0.81, P < 0.05) hospitalization rates. Compared with patients with treatment persistence less than 31 days, patients with persistence > 30 days were 31% and 19% less likely to be psychiatrically and nonpsychiatrically hospitalized (P < 0.05), respectively.

**CONCLUSIONS:** Adherence and persistence with duloxetine during the first 6 months are associated with reduced hospitalizations in the 1-year follow-up period. Further research is needed to examine the long-term clinical and economic benefits of better adherence and persistence with duloxetine in the treatment of major depression.

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

Adherence to Chronic Medication Therapy Associated with 90-Day Supplies Compared with 30-Day Supplies

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**BACKGROUND:** A better understanding of adherence-influencing factors could improve patient care. Currently, there is little information on the association between medication adherence and 90-day supplies compared with 30-day supplies.

**OBJECTIVE:** To compare adherence within 3 chronic medication classes by days supply and evaluate potential adherence predictors.

**METHODS:** Members with a first claim for cholesterol lowering (Chol), hypertension (HTN), or diabetes (DM) medications in 2007Q1 were identified, and members were then followed for 540 days. Inclusion criteria were as follows: eligible for the entire follow-up, first and last claim with the same days supply, and 18 years of age or older. Each member’s adherence was measured at the therapy class level using the proportion of days covered (PDC), the primary outcome was the proportion of members with a PDC > 80%. Unadjusted chi-square and multivariate logistic regression were used to estimate the relationship between days supply and adherence, controlling for age, gender, current or new initiators (no therapy in the 180 days prior to index claim), total number of different therapy subclasses, and generic medication as the initial claim.

**RESULTS:** Overall, 46.3% of members were female; average age was 56.6 (SD 11.3); 62.2% of medications were generic; and 6.7% were new initiators. The PDC > 80% results are shown in the table. At the 540-day follow-up, PDC > 80% adherence rates across all 3 chronic medication classes was 71 to 99 points significantly higher within the 90-day supply group (P < 0.001). Multivariate logistic regression found significantly lower rates of nonadherence (P < 0.001) for 90-day supply groups, odd ratios (95% confidence intervals) of 0.61 (0.53-0.70) DM, 0.60 (0.57-0.64) Chol, and 0.60 (0.56-0.63) HTN.

**TABLE**

<table>
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<tr>
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<th>Cholesterol Lowering</th>
<th>Hypertension</th>
<th>Diabetes</th>
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<tr>
<td><strong>PDC ≥ 80%</strong></td>
<td>Absolute Difference</td>
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<td>30-day supply</td>
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<td>90-day supply</td>
<td>N = 7,219</td>
<td>75.0%</td>
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**PDC = proportion of days covered.**

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

Adherence Rates of Members Obtaining 90-Day Supplies Compared with 30-Day Supplies

Liu X, * Tepper P, Watson PR. Eli Lilly and Company, Lilly Corporate Center, DC 4123, Indianapolis, IN 46285; liu_xianchen@lilly.com, 317-433-4006

**BACKGROUND:** Poor adherence is associated with increased hospital use. Currently, there is little information on the association between medication adherence and 90-day supplies compared with 30-day supplies.

**OBJECTIVE:** To compare adherence within 3 chronic medication classes by days supply and evaluate potential adherence predictors.

**METHODS:** Patients with a first claim for cholesterol lowering (Chol), hypertension (HTN), or diabetes (DM) medications in 2007Q1 were identified, and members were then followed for 540 days. Inclusion criteria were as follows: eligible for the entire follow-up, first and last claim with the same days supply, and 18 years of age or older. Each member’s adherence was measured at the therapy class level using the proportion of days covered (PDC), the primary outcome was the proportion of members with a PDC > 80%. Unadjusted chi-square and multivariate logistic regression were used to estimate the relationship between days supply and adherence, controlling for age, gender, current or new initiators (no therapy in the 180 days prior to index claim), total number of different therapy subclasses, and generic medication as the initial claim.

**RESULTS:** Overall, 46.3% of members were female; average age was 56.6 (SD 11.3); 62.2% of medications were generic; and 6.7% were new initiators. The PDC > 80% results are shown in the table. At the 540-day follow-up, PDC > 80% adherence rates across all 3 chronic medication classes was 71 to 99 points significantly higher within the 90-day supply group (P < 0.001). Multivariate logistic regression found significantly lower rates of nonadherence (P < 0.001) for 90-day supply groups, odd ratios (95% confidence intervals) of 0.61 (0.53-0.70) DM, 0.60 (0.57-0.64) Chol, and 0.60 (0.56-0.63) HTN.

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**PDC = proportion of days covered.**

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

**ABSTRACTS**

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CONCLUSIONS: Based on multivariate logistic regression odds ratios, nonadherence was 40% less likely to occur among members utilizing 90-day supplies, and unadjusted results found 90-day supplies were associated with higher chronic medication adherence compared with 30-day supplies. These statistically significant findings suggest 90-day supplies improve adherence, which may result in improved patient care.

SPONSORSHIP: This research was funded by Prime Therapeutics LLC, Eagan, MN.

Adherence to Oral Antidiabetic Agents: Comparison of Fixed-Dose Combination Therapy to Monotherapy and Loose-Dose Combination Therapy

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BACKGROUND: Because multiple agents are often required to achieve adequate glycemic control in type 2 diabetes mellitus, it is important to identify therapies that benefit the patient clinically and economically. Several studies have shown that fixed-dose combination therapy (FDCT) products, compared with the analogous loose-dose combination therapy (LDCT), have resulted in better adherence and cost savings.

OBJECTIVE: To (a) describe adherence to monotherapy, LDCT, and FDCT of oral antidiabetic agents (OADs) containing pioglitazone and metformin; (b) assess changes in medication adherence of patients switching from monotherapy or LDCT to the corresponding FDCT while controlling for covariates; and (c) determine if there are differences in costs between LDCT and the analogous FDCT.

METHODS: The study sample comprised continuously enrolled Texas Medicaid recipients (18-65 years) who were prescribed pioglitazone+metformin FDCT in the post-index period and prescribed the analogous LDCT or monotherapy in the pre-index period. Prescription claims were extracted retrospectively from January 1, 2004, to August 31, 2007. Medication possession ratio (MPR) was calculated to determine medication adherence, and costs were assessed using the reimbursement amount to dispensing pharmacies.

RESULTS: Overall adherence to FDCT (n = 270) was 80.5 ± 19.7. Regarding patients who switched from LDCT (n = 60) to FDCT, adherence increased significantly (P = 0.008) by 8.9% (76.0 ± 16.8 to 82.8 ± 18.2), whereas those who switched from monotherapy (n = 210) to FDCT had a significant 9% (P < 0.001) decrease in adherence (87.7 ± 16.7 to 79.8 ± 20.1). Multivariate logistic regression analyses revealed that those who were not adherent were 56% less likely to be adherent with FDCT in the post-index period than those who were adherent (MPR ≥ 80) in the pre-index group. Medicaid reimbursement for FDCT was $0.26 less (9%) per tablet than the analogous LDCT.

CONCLUSIONS: While switching from monotherapy to FDCT resulted in decreased adherence, this study showed that switching from LDCT to FDCT of pioglitazone and metformin resulted in a 9% increase in adherence and a 9% decrease in costs.

SPONSORSHIP: This research was funded by Takeda Pharmaceuticals North America, Inc., Deerfield, IL.

Analysis of Costs Associated with Treatment of Multiple Myeloma

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BACKGROUND: Multiple myeloma (MM) is a complex progressive, debilitating malignancy, with ~20,000 new cases diagnosed in the U.S. annually. Improved outcomes have been achieved with the novel agents bortezomib (BOR, Velcade), lenalidomide (LEN; Revlimid) and thalidomide (THAL, Thalomid). However, few studies have reported real-life treatment costs from a payer’s perspective.

OBJECTIVE: To compare the health care costs for MM patients treated with BOR, LEN, THAL or other unspecified chemotherapies or radiation therapy (OTH).

METHODS: In a retrospective cohort study, patients aged ≥18 years, diagnosed with MM between January 1, 2005, and September 30, 2007, and treated with BOR, LEN, THAL, or OTH during this period were identified from claims data from a large national U.S. commercial health plan covering ~14,000,000 members. Patient costs and resource utilization data were analyzed at the treatment level. Treatment episodes (each treatment regimen) were identified from patient records. Inflation-adjusted health care costs were measured for 1 year from the beginning of each episode for all patients and for those who had not undergone stem cell transplant (SCT) to avoid total costs being skewed by SCT costs. Multivariate regression analyses were used to control for patient characteristics, comorbidities, and line of treatment.

RESULTS: 2,642 treatment episodes were identified for 1,990 patients. Medication costs associated with BOR were lower than with THAL, LEN, or OTH; differences between BOR and THAL or LEN remained significant after multivariate adjustment. Total health care costs were higher with novel agents than with OTH. After multivariate adjustment, total health care costs were significantly lower with BOR than THAL, LEN, or OTH. In non-SCT patients, total health care costs were significantly lower with BOR than THAL or LEN (see Table above).

CONCLUSIONS: The financial burden of MM treatment differs among novel agents: medication and total health care costs were lower for BOR.

SPONSORSHIP: This research was funded by Millennium Pharmaceuticals, Inc., Boston, MA.

Aromatase Inhibitors Utilization Management Opportunities: Assessment of Patient Diagnoses, Cost Savings, and Controlling Off-Label Use

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*P < 0.05 compared with bortezomib; medication costs = drug + administration of drug if applicable.

### TABLE

<table>
<thead>
<tr>
<th></th>
<th>Bortezomib (n = 244)</th>
<th>Thalidomide (n = 549)</th>
<th>Lenalidomide (n = 90)</th>
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*P < 0.05 compared with bortezomib; medication costs = drug + administration of drug if applicable.
BACKGROUND: Aromatase inhibitors block the conversion of androstenedione and testosterone into estrone and estradiol. Although third-generation aromatase inhibitors (anastrozole, letrozole, and exemestane) are indicated for postmenopausal women with hormonally sensitive breast cancer (HR+ or HR-unknown), the class is frequently used off-label for other conditions that respond to an increase in testosterone and/or diminish estrogen levels. In most of these cases, lack of efficacy or inconclusive results has been demonstrated in clinical trials along with deficits in long-term and/or safety data.

OBJECTIVE: To understand current treatment patterns for aromatase inhibitors, identify and implement opportunities for utilization management (UM) programs that promote FDA-approved indications within the drug class, and assess cost savings to the plan with the use of databases from an integrated health care management system.

METHODS: Retrospective claims review and cost-benefit analysis of the medical and pharmacy databases from January 2006 through December 2008 were performed on the aromatase inhibitor class. Using ICD-9-CM codes, members that had claims with any diagnosis outside of the indicated use of breast cancer were evaluated as well as anticipated migration analysis from targeted products to formulary preferred products.

RESULTS: Utilization of aromatase inhibitors by males increased from an average of 70 per month at the start of 2006 to an average of 221 per month at the start of 2009. During the time period from January 1, 2009, to August 15, 2009, prior to implementation of the edit, 524 members receiving aromatase inhibitors were males. Of these, 14 (less than 3%) had a medical claim with an ICD-9-CM code indicating breast cancer. The average weekly cost was $11,133 for an approximated annualized cost of $579,000. A prior authorization program allowing coverage only for breast cancer diagnoses was considered and implemented on August 15, 2009. After implementation of the edit, the cost of aromatase inhibitors for males fell to an average of $2,300 per week for the first month, contributing toward a $0.19 per member per month (PMPM) savings with an estimated annualized savings of $473,000.

CONCLUSIONS: Aromatase inhibitors have many opportunities for off-label use. A prior authorization UM program applied to a drug class for FDA-approved use can potentially reduce off-label utilization and promote cost savings for the plan.

SPONSORSHIP: There was no external funding for this research.

Baseline Differences in Patient Characteristics as a Predictor of Medication Switch Behavior in Response to a Pharmacy Benefit Change

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BACKGROUND: By recognizing meaningful differences in baseline member characteristics, pharmacy benefit managers may be better equipped to anticipate member behavior in response to a benefit change. On January 1, 2009, UnitedHealthcare (UHC) moved valsartan and valsartan with hydrochlorothiazide (VAL-HCT) from tier 2 to tier 3 resulting in an average increase in member copayment of $20 per month.

OBJECTIVE: To determine the association of baseline member characteristics with switch behavior following the up-tier of valsartan and VAL-HCT.

METHODS: Using UHC claims data, members aged 18-64 years filling a prescription for valsartan or VAL-HCT between November 24, 2008, and December 31, 2008, were identified. Members were followed for 6 months before the index claim and for the first 6 months after the benefit change. Member characteristics were captured from enrollment data, medical claims, and pharmacy claims. Medication switch was determined by a claim for any angiotensin-converting enzyme inhibitor, any angiotensin receptor blocker other than valsartan, or any direct renin inhibitor in the 6-month follow-up period. Adherence during the baseline period was also evaluated. A multinomial logistic regression was performed to determine which variables had a significant impact on switch behavior.

RESULTS: A total of 51,194 members met the inclusion criteria. The average age was 52 years with an equal distribution between males and females (49.9% vs. 50.1%). Overall, 70.0% of members continued with valsartan therapy, 22.6% switched medication; and 7.4% had no claims for any targeted drug in the follow-up period. Members 18-24, 35-44, and 45-54 years of age were 29.5% (P < 0.001), 7.1% (P = 0.041), and 5.3% (P = 0.025) more likely to switch therapy, respectively, versus those 55-64 years old. Males were 6.0% more likely than females to switch medications (P = 0.008). Members with renal disease, diabetes, hypertension, and heart failure/ischemic heart disease were 69.1% (P < 0.001), 19.2% (P < 0.001), 8.6% (P = 0.001), and 0.8% (P = 0.844) more likely to switch, respectively, versus those with no history of the pre-specified diagnoses. Those that were adherent (no gap >30 days) to therapy were 45.5%, 22.2%, and 31.0% (all P < 0.001) more likely to switch than those that were new to therapy, had a gap in therapy of 31-60 days, or had a gap in therapy of greater than 60 days in the baseline period, respectively.

CONCLUSIONS: Member age, gender, diagnosis, and prior adherence significantly impacted member switch behavior. These criteria may be used to more accurately predict the potential outcomes of similar strategies in the future.

SPONSORSHIP: There was no external funding for this research.

Budgetary Impact of Pemetrexed Maintenance Therapy for Advanced Nonsquamous Non-Small Cell Lung Cancer

Klein RW,* Lawson AH, Muchlenheim CE, Liepa AM, Wielage RC, Babineaux S, Koustenis A. Medical Decision Modeling Inc., 3600 Woodview Trace, Ste. 317, Indianapolis, IN 46268; rkw@mdm-inc.com, 317.704.3801

BACKGROUND: Pemetrexed is an antineoplastic agent approved in the United States for maintenance treatment of patients with advanced nonsquamous non-small cell lung cancer (NSCLC) whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy, as well as initial treatment in combination with cisplatin and as second-line monotherapy.

OBJECTIVE: To estimate the budgetary effect of adopting pemetrexed as maintenance treatment of nonsquamous NSCLC from a U.S. health plan’s perspective.

METHODS: A deterministic model was developed from the perspective of a 1 million-member health plan. A survey of 300 oncologists was used to estimate the market shares of maintenance therapies before and after introducing pemetrexed. Chemotherapy drug costs were obtained from Medicare reimbursement rates. Nondrug costs were derived from a claims database of lung cancer patients. The annual number of maintenance eligible nonsquamous NSCLC cases for the health plan is based on incident rates found in Surveillance, Epidemiology, and End Results (SEER) data. The estimated proportion of patients with stage IIIIB/IV beginning first-line chemotherapy, completing 4 first-line treatment cycles, while achieving stable disease or better and in generally good condition were derived from the survey. Model outputs included annual health plan cost, per member per month (PMPM) costs, and per treated member per month costs. One-way sensitivity analyses were conducted to assess the effect of changing input values.

www.amcp.org Vol. 16, No. 2 March 2010 JMCP Journal of Managed Care Pharmacy 143
RESULTS: Assuming a 50% increase in the number of patients receiving maintenance therapy from 26 to 39 in a 1 million-member health plan, the model estimates a total annual cost increase of $365,323. Savings from patients who would have continued first-line therapy at an annual cost of $48,253 results in an estimated net budget impact of $317,070, translating into a cost of $679.22 per treated member per month and PMPM of $0.026. The PMPM is sensitive only to the expected increase in maintenance use.

CONCLUSIONS: The adoption of pemeterxen as maintenance therapy is anticipated to increase the number of patients receiving maintenance treatment while reducing the number of patients continuing first-line therapy. This increase in maintenance therapy utilization is expected to increase the budget impact for a health plan by less than $0.03 PMPM.

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

- Cardiovascular Disease Event Attributable Cost Reduction After Treatment Initiation with Niacin Extended Release Plus any Statin Combination Therapy Versus Atorvastatin Monotherapy in a U.S. Managed Care Patient Population with Prior Cardiovascular Disease

Webb S, Bala S, Quinno R, Simko R,* Czurlyb M. Abbott Laboratories, 200 Abbott Park Rd., Dept. PHE, Bldg. AP30-3NW, Abbott Park, IL 60064; bob.simko@abbott.com, 847.937.6965

BACKGROUND: Treating multiple lipid abnormalities versus low-density lipoprotein cholesterol (LDL-C)-only may have the potential for improved clinical and economic outcomes. Studies researching the association between lipid treatment strategy (combination therapy targeting multiple lipids versus a statin-alone therapy) and cardiovascular disease (CVD) event-attributable total health care cost from a managed care organization’s perspective are limited.

OBJECTIVE: To compare annual CVD event-attributable total health care costs between patients initiating atorvastatin therapy (AT) and niacin extended-release [NER] + any statin (NERS) combination therapy among patients with prior CVD in a managed care setting.

METHODS: An observational cohort study of patients aged ≥18 initiating AT or NERS (addition of NER to an existing statin therapy) between January 1, 2001, and June 30, 2006, (index-date) was performed using the HealthCore Integrated Research Database. Patients with a minimum of 24 months of follow-up, CVD during 12 months prior to index-date, and with a complete lipid panel prior to index-date were included. Post-index-date annual CVD event-attributable total health care costs [sum of inpatient, emergency room, and outpatient visit costs] was compared through a generalized linear regression model, adjusting for treatment group, age, gender, baseline LDL-C, high-density lipoprotein cholesterol (HDL-C), triglycerides (TG), pre-index-date Deyo-Charlson comorbidity index score, CVD attributable costs, hypertension, and diabetes mellitus.

RESULTS: 482 patients were identified initiating AT (n = 379) or NERS (n = 103). NERS patients were more likely to be male (78.6% vs. 52.2%; P < 0.001), have a lower mean LDL-C level (130.2 ± 24.7 mg per dl vs. 148.4 ± 32.6 mg per dl; P < 0.001) and HDL-C level (37.3 ± 7.2 mg per dl vs. 43.1 ± 11.3 mg per dl; P < 0.001), and a higher mean TG level (248.2 ± 168.2 mg per dl vs. 209.8 ± 138.0 mg per dl; P = 0.035) versus AT patients at baseline. Patients initiating NERS had an adjusted 82% (95% CI = 59%-92%) lower annual CVD event-attributable total health care costs versus AT patients ($258 ± $94 vs. $1,462 ± $233; P < 0.001).

CONCLUSIONS: Treatment with NERS was associated with lower annual CVD event-attributable total health care costs compared with AT treated patients. Early initiation of NER therapy to existing statin therapy targeting multiple lipid parameter management appears to be cost beneficial to a managed care organization as compared with an LDL-C only focused treatment strategy.

SPONSORSHIP: Funded by Abbott Laboratories, Abbott Park, IL.

- Comparing Adherence Measures Against One-Year Outcomes for Patients with Epilepsy

Brixner DL,* Goodman MJ, Ye X, Forlenza JB, Durkin M. The University of Utah, 30 S. 2000 E. #258, Salt Lake City, UT 84112; diana.brixner@utah.edu, 801.581.3182

BACKGROUND: Epilepsy affects over 2.5 million people in the United States. Data on the relationship of various adherence measures to epilepsy outcomes from the managed care perspective are limited.

OBJECTIVE: To examine the association of medication nonadherence to selected negative outcomes in epilepsy, using 3 alternative measures of adherence.

METHODS: This retrospective analysis identified patients in the PharmMetrics database for the years 2004-2008 who were ≥18 years old, had an epilepsy diagnosis (ICD-9-CM code 345.xx), and received ≥60 days of antiepileptic drug therapy. Adherence status for the 365 days after an index prescription was defined using medication possession ratio (MPR) and proportion of days covered (PDC) at 70%, 80%, and 90% thresholds and for gaps of 15 and 30 days. For each definition of adherence, the odds ratios comparing nonadherent to adherent groups were assessed for statistical significance for number of hospital admissions, emergency room (ER) visits, traumatic brain injuries (TBI), falls/injuries, motor vehicle accidents (MVA), fractures and a “seizure” outcome defined as hospital admissions or ER visits with a primary diagnosis of epilepsy or convulsions. The number of significant and directionally consistent ORs were examined across adherence measure definitions and outcomes.

RESULTS: The inclusion criteria were met by 31,635 individuals. For all adherence measures, the nonadherent group had significantly higher (P < 0.05) odds of hospital admissions (OR range = 1.25–2.01) and ER visits (OR range = 1.23–2.15). For the outcomes of TBI (OR range = 1.13–1.55) and fractures (OR range = 1.19–2.46), the nonadherent groups’ odds were significantly higher (P < 0.05) for all PDC and gap measures plus MPR 90% for fracture. Across falls/injury (OR range = 0.82–2.58) and MVA (OR range = 0.73–2.58), only PDC 90% for falls reached significance, likely due to the small number of these 2 outcome events. Our proxy for seizure was inconsistently associated with adherence status and underscores the challenge of defining seizures from claims data.

CONCLUSIONS: All the adherence measures defined nonadherent groups that were associated with negative outcomes in epilepsy with few exceptions. Nonadherence defined by PDC was significantly associated with higher odds for more of the studied outcomes than MPR or gaps in therapy.

SPONSORSHIP: This research was funded by Ortho-McNeil Janssen Scientific Affairs, LLC, Titusville, NJ.

- Comparing Tamoxifen and Raloxifene in the Chemoprevention of Breast Cancer

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BACKGROUND: The Study of Tamoxifen and Raloxifene (STAR) trial
found that raloxifene was as effective as tamoxifen against breast cancer among high risk women. An economic evaluation of these drugs may provide decision makers opportunities to implement strategies to reduce cost and improve outcomes.

OBJECTIVE: To conduct a cost-minimization analysis of chemoprevention using tamoxifen and raloxifene in women with high risk for breast cancer from a payer’s perspective.

METHODS: A decision tree modeling with Markov health state-transitions was employed for this analysis in a hypothetical cohort of women aged 35 years and older. It was assumed that these women taking either tamoxifen or raloxifene for 5 years were followed until death or until they reach an age of 100. The incidence for the 8 health states (healthy, invasive and non-invasive breast cancer, endometrial cancer, osteoporotic fracture, cataract, deep venous thromboembolism, and death) was incorporated from the STAR study findings. Mortality rates were obtained from the Surveillance, Epidemiology, and End Results database, and the National Vital Statistics Report. The cost parameters were derived from Medicare Provider Analysis and Review files, CMS Consumer Initiatives public data files and published literature. Drug prices were averaged using the average wholesale price. A 5% discount rate was applied to all analyses. A one-way sensitivity analysis was conducted by varying all costs by ±20% except drug prices which were varied by ±50%.

RESULTS: For women commencing chemoprevention at the age of 35 years up to 49 years, the cost per life year saved by the use of tamoxifen was $14,878 and that for the use of raloxifene was $14,740. When initiating prophylaxis treatment at later stages, the cost per life year saved for tamoxifen was more than raloxifene in all age groups: 50-59 ($13,194 vs. $13,140), 60-69 ($11,862 vs. $11,824), and 70+ ($10,784 vs. $10,775), respectively. The results remained robust even with the sensitivity analysis.

CONCLUSIONS: Chemoprevention with raloxifene is less costly compared with tamoxifen in our study. Further research should be performed to incorporate effectiveness data from various other randomized clinical trials to validate these findings.

SPONSORSHIP: There was no external funding for this research.

Comparison of Cardiovascular Events and Associated Costs After Treatment Initiation with Simvastatin Plus Niacin Extended Release Combination Therapy Versus Atorvastatin Monotherapy in a U.S. Managed Care Patient Population with Prior Cardiovascular Disease


BACKGROUND: Prior research has shown that simultaneous achievement of multiple lipid goal values, based on published guidelines, is rarely realized in routine clinical practice. Limited research has been conducted estimating the clinical and economic benefits among patients initiating combination therapies versus monotherapy (statin).

OBJECTIVE: To compare annual cardiovascular (CV) event risk for patients initiating atorvastatin (mono)therapy (AT) versus niacin extended-release (NER) + simvastatin (NERS) combination therapy among patients with prior cardiovascular disease (CVD) in a managed care setting.

METHODS: An observational cohort study of patients aged ≥18 initiating AT or NERS therapy (addition of NER to existing simvastatin therapy) between January 1, 2001, and June 30, 2006 (index date), was performed using the HealthCore Integrated Research Database. Patients with a minimum of 24 months of follow-up and CVD during the 12 months prior to the index date were included. CV event risk was estimated using Kaplan-Meier analysis and Cox proportional hazards model (CPHM). CPHM covariates included treatment group, age, gender, Deyo-Charlson comorbidity index (DCI), prior diabetes, and hypertension. Post-index annual CV event-attributable total medical health care (TMH) costs (sum of inpatient, emergency room, and outpatient costs) were compared through a multivariate regression model. Model covariates included treatment group, age, gender, DCI, prior CVD related costs, hypertension, and diabetes mellitus.

RESULTS: 16,032 patients were identified initiating AT (n = 15,480) or NERS (n = 552). NERS patients were younger (58.5 ± 9.2 years vs. 59.7 ± 11.6 years; P = 0.002) and more likely to be male (85.1% vs. 61.8%; P < 0.001). NERS patients had lower DCI scores than AT patients (pre-index DCI score = 1.3 ± 1.4 vs. 1.4 ± 1.6; P = 0.003), though NERS patients were more likely to be hypertensive (88.6% vs. 72.7%; P < 0.001). Patients initiating NERS were 38% (hazard ratio [HR] = 0.62, 95% CI = 0.46-0.82; P < 0.001) less likely to experience a post-index CV event versus AT patients, while the adjusted rate was 33% (HR = 0.67, 95% CI = 0.50-0.90; P = 0.007). NERS patients had an adjusted 58% (95% CI = 46%-67%) lower annual CV event-attributable TMH costs versus AT patients ($545 ± 568 vs. $1,295 ± 530; P< 0.001).

CONCLUSIONS: Treatment with NERS was associated with lower CV event risk and associated health care costs compared with AT treated patients. Early initiation of NERS therapy emphasizing multiple lipid parameter management appears to be more beneficial as compared with an LDL-C only focused treatment strategy.

SPONSORSHIP: Funded by Abbott Laboratories, Abbott Park, IL.

Comparison of Employee Workers’ Compensation Costs and Absence Days Using a National Database

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BACKGROUND: Illnesses stemming from workplace conditions and injuries occurring on the job are covered under workers’ compensation (WC). Employees filing a WC claim can receive payment for WC claim-related medical expenses and a portion of salary while absent from work.

OBJECTIVE: To compare the incremental costs and absences due to WC among employees with bipolar disorder (BPD), other mental disorders (OMD), chronic constipation (CC), functional dyspepsia (FD), gastroesophageal reflux disease (GERD), gout, hepatitis-C (HCV), and insomnia.

METHODS: A 2001-2007 U.S. employee database was used to identify subjects with BPD, OMD, CC, FD, GERD, gout, HCV, and insomnia. All studies used 2-part regression models to control for differences between employees with the condition and control groups (employees without the condition). WC costs included salary replacement payments made to the employee and associated medical payments (adjusted to 2007 US$). Absences were based on days missed during the WC claim. In condition groups, index dates were the date of the employees’ first diagnosis (by condition). Controls (by study) used the average index date of subjects with the condition. Incremental costs and absences were defined as adjusted differences between the condition cohort and controls and considered significant at P<0.05.

RESULTS: Numbers of employees with WC eligibility varied from 339 to 17,714 in the condition cohorts and from 120,465 to 292,631 in WC control groups. All incremental WC cost differences between condition
and control cohorts were significant (P<0.05) except incremental costs associated with FD (P>0.05). Gout had the highest incremental annual costs ($813), while GERD had the most annual incremental absence days (0.80). FD had the lowest incremental WC costs (-$377) and the lowest incremental absence days (-0.36).

CONCLUSIONS: Most of the conditions studied were associated with significant incremental WC costs and absence days, even though they are not thought of as common workplace injuries or illnesses. Employees with GERD were among those with the highest incremental WC costs and days absent. Further research is required to determine if the incremental WC costs and days occur because these causes of absence are more susceptible to workplace injury or if they occur because employees with these conditions are more knowledgeable about using health benefits.

SPONSORSHIP: There was no external funding for this research.

Cost Benefit Analysis of Bimatoprost Compared with Other Prostaglandin Analogues in Patients with Primary Open Angle Glaucoma (POAG) in the United States: A Payer’s Perspective

**BACKGROUND:** Glaucoma is a slowly progressive disease that can lead to blindness. Multiple, prospective, randomized clinical trials have demonstrated that bimatoprost achieves greater intraocular pressure (IOP) lowering compared with other prostaglandin analogues (PGA). However, few studies have evaluated the associated cost savings of lower IOP and its impact on glaucomatous progression.

**OBJECTIVE:** To develop a cost benefit model from a payer’s perspective to compare glaucomatous progression and costs among POAG patients treated with bimatoprost, latanoprost, or travoprost in the United States.

**METHODS:** A health economic model was used to estimate glaucomatous progression for a cohort of POAG patients (baseline IOP 26 mm Hg) over 7 years. The absolute reduction in IOP from baseline secondary to treatment with a PGA was based on a systematic review of the literature; the base case model assumed a 1 mm Hg advantage of bimatoprost over latanoprost or travoprost. IOP was used to estimate the baseline mean deviation (MD) score in the worst eye and to determine the proportion of patients with MD score progression each year. Patients who progressed were assumed to progress at a mean rate of 0.6 decibels (dB) per year. Medical, pharmacy, and indirect costs associated with categories of MD scores from the published literature were applied to each treatment cohort to calculate the expected 7-year costs of treating patients with the different PGAs. Visual impairment costs were applied solely to severe disease patients. Costs were discounted at 3% per year.

**RESULTS:** The results of the base case in this analysis showed that for a managed care plan of 1,000,000 members with 19,000 glaucoma patients, treatment with bimatoprost would prevent progression in 130 patients, treatment with latanoprost or travoprost. The preservation of vision with bimatoprost resulted in cost savings of office visits, medication use, and surgeries, estimated at $796 per patient. There was an additional cost savings of $28 and $171 per treated patient in direct bimatoprost pharmacy costs compared with latanoprost and travoprost, respectively. The total cost savings with bimatoprost for a plan with 1,000,000 members, due to delayed/avoided progression, were estimated to be $103,480.

**CONCLUSIONS:** Results from this model demonstrate that greater reduction in IOP from treatment with bimatoprost is associated with lower rates of glaucomatous progression and increased cost savings compared with latanoprost or travoprost.

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

Daily Average Consumption and Daily Costs of Duloxetine, Venlafaxine XR, and Pregabalin Among U.S. Commercially Insured Patients

**BACKGROUND:** Health plans calculate daily average consumption (DACON) to help compare utilization and costs-per-day of therapy across pharmaceutical agents with similar therapeutic indications. Use of pharmacy data alone for calculating DACONs is common, but problematic when comparing medications with multiple indications.
OBJECTIVE: To (a) calculate a DACON for duloxetine for each of its U.S.-approved indications—major depressive disorder (MDD), generalized anxiety disorder (GAD), diabetic peripheral neuropathic pain (DPNP), and fibromyalgia (FM)—and to compare these results with venlafaxine XR and pregabalin DACONs across shared indications; and (b) examine costs-per-day ($DACON) across agents and indications.

METHODS: A descriptive retrospective analysis of commercially insured patients from large U.S. health plans receiving 1 or more prescriptions for duloxetine, venlafaxine XR, or pregabalin between 2006 and 2008 was conducted. MDD and GAD patient subgroups were constructed for duloxetine and venlafaxine XR. DPNP and FM subgroups were constructed for duloxetine and pregabalin. Subgroup assignments were based on ICD-9-CM diagnosis codes recorded during the 12 months prior to the first prescription for each agent during the study interval. DACON was calculated by dividing total units dispensed by total days of supply. DACONs were converted to pharmacy $DACON using June 2009 new wholesale prices.

RESULTS: A total of 47,089 duloxetine, 29,810 venlafaxine XR, and 22,987 pregabalin patients were included in the 2008 analysis. The overall DACON for duloxetine in 2008 was 1.37 capsules per day among patients with any of its indicated conditions, as well as 1.30 for DPNP, 1.33 for GAD, 1.33 for FM, and 1.43 for MDD. $DACON for duloxetine was $5.44 overall, $5.16 for DPNP, $5.28 for FM, $5.29 for GAD, and $5.68 for MDD. DACONs were 1.58 for venlafaxine XR (1.63 for MDD; 1.43 for GAD) and 2.36 for pregabalin (2.35 for DPNP; 2.36 for FM). $DACONs were $6.43 for venlafaxine XR ($6.64 for DPNP and $5.78 for GAD) and $5.06 for pregabalin ($5.03 for DPNP and $5.05 for FM). DACON and $DACON results for 2006 and 2007 were similar for each of the 3 studied agents.

CONCLUSIONS: Duloxetine and venlafaxine XR show fluctuation in DACON across indications. Duloxetine had similar average daily costs to pregabalin among patients with DPNP or FM and numerically lower values for duloxetine than venlafaxine XR among patients with MDD or GAD.

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

- Diabetes-Related Costs Associated with Hypoglycemia in Type 2 Diabetes Mellitus Patients Initiated on Oral Antidiabetic Drugs

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BACKGROUND: Hypoglycemia can be often associated with antidiabetic therapy and may require medical treatment. Estimates of hypoglycemia-related annual health care costs in type 2 diabetes mellitus (T2DM) vary among published studies.

OBJECTIVE: To estimate annual health care costs associated with hypoglycemia among T2DM patients initiated on oral antidiabetic drugs (OADs) in a large managed care cohort.

METHODS: T2DM patients initiated on OADs were selected from the Ingenix Impact database (1999-2008). Patients aged 18 years or older with at least 1 year of continuous eligibility following the index date (the first OAD prescription fill date) who were diagnosed with moderate to severe hypoglycemia events (ICD-9-CM 250.8x, 251.0x, 251.1x, 251.2x) were identified. Annual total, medical, pharmacy, and diabetes-related costs for patients with or without the diagnosis of hypoglycemia were compared during the 12-month post-index period. Diabetes-related medical costs included all non-pharmacy costs associated with T2D diagnosis. Generalized linear regressions with robust standard error accounting for skewed cost distribution were performed, adjusting for demographics, comorbidities, and OADs.

RESULTS: A total of 212,061 T2DM patients with at least 1 OAD treatment were identified (see Table on next page). Among them, 4,860 (2.29%) had a hypoglycemia diagnosis during the first year following the index date. Patients with hypoglycemia had significantly higher average annual total costs ($18,273 vs. $8,908, P<0.001) and diabetes-related total costs ($8,969 vs. $3,220, P<0.001) than those without hypoglycemia. After adjusting for confounding factors, hypoglycemia patients had significantly higher incremental annual total costs and diabetes-related total costs than patients without hypoglycemia ($5,031 and $3,751, respectively, both P<0.001). Similar trends were observed for annual medical costs and diabetes-related medical costs ($4,967 and $3,796, respectively, both P<0.001).
CONCLUSIONS: Hypoglycemia in type 2 diabetes patients initiated with OADs in a managed care setting is associated with significantly higher total, medical, and diabetes-related costs compared with those who did not experience hypoglycemia.

SPONSORSHIP: This research was funded by Takeda Pharmaceuticals North America, Inc., Deerfield, IL.

| TABLE Risk-Adjusted Annual Health Care and Diabetes-Related Costs of T2DM Patients |
|-----------------------------------------------|------------------------|--------------------------|--------------------------|
| Annual Health Care Costs (Estimated Mean S) | Hypoglycemia Patients (N = 4,860) | Patients Without Hypoglycemia (N = 207,201) | Difference | P Value |
| Total drug costs | [A] | [B] | [A] - [B] | [A] vs [B] |
| All drugs | 2,736 | 2,672 | 63 | 0.159 |
| Diabetes-related | 698 | 742 | -44 | <0.001 |
| Total medical costs | 11,302 | 6,335 | 4,967 | <0.001 |
| Any cause | 6,319 | 2,523 | 3,796 | |
| Diabetes-related | 7,017 | 3,265 | 3,752 | |

*aIncludes pharmacy expense for oral antidiabetic drugs, insulin, amylin analog, and incretin mimetic.

*bSignificant at 95% level.

T2DM = type 2 diabetes mellitus.

RESULTS: Both the duloxetine (N = 3,637) and pregabalin (N = 3,032) cohorts had mean age of 51 years. Many duloxetine and pregabalin patients had neuropathic pain other than DPNP (67.6% vs. 67.6%), low back pain (60.4% vs. 60.0%), cardiovascular disease (54.4% vs. 54.3%), and osteoarthritis (32.3% vs. 31.8%) and used opioids (81.3% vs. 81.2%). Controlling for demographics, pre-index clinical and economic characteristics, and prior medication history, duloxetine patients had significantly lower total ($21,826 vs. $27,064), inpatient ($4,807 vs. $6,492), outpatient ($10,571 vs. $13,385), and pharmacy costs ($6,448 vs. $7,186); higher MPR (0.69 vs. 0.51); and higher proportion of patients with MPR ≥ 0.8 (46.1% vs. 24.8%) than pregabalin patients (all P values < 0.05).

CONCLUSIONS: Fibromyalgia patients initiated on duloxetine had significantly lower direct health care costs but significantly higher medication compliance than those initiated on pregabalin.

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

■ Early Effects of Natalizumab on Patient-Reported Fatigue and Cognitive Function

**Stephenson JJ,* Rajagopalan K, Kumar S, Hou L, Agarwal S. HealthCore, Inc, 800 Delaware Ave, Wilmington, DE 19801; jstephenson@healthcore.com, 302.230.2142**

**BACKGROUND:** Fatigue and cognitive dysfunction are common symptoms of multiple sclerosis (MS) and are leading causes of disability in MS patients.

**OBJECTIVE:** To evaluate changes from baseline in patient-reported fatigue and cognitive function for MS patients after 3 natalizumab infusions.

**METHODS:** The study population consists of MS patients newly enrolled in the TOUCH (TYSABRI Outreach: Unified Commitment to Health) prescribing program who have agreed to participate in a 12-month longitudinal study assessing their experiences with natalizumab prior to treatment initiation and after 3rd, 6th, and 12th infusions. The current analysis reports change from baseline in patient reported fatigue and cognition after 3 infusions of natalizumab. Fatigue is measured by the 5-question Modified Fatigue Impact Scale-5 (MFIS-5, score range 0-20) with lower scores indicating lower impact of fatigue on physical, cognitive, and psychosocial functioning; cognitive function is measured by the 6-question Medical Outcomes Study Cognitive Functioning Scale (MOS-Cog Scale, score range 6-36) with higher scores indicating better reasoning skills, memory, concentration, ability to start several actions at one time, and ability to react to what is said or done. Paired t-tests compare differences in scores.

**RESULTS**: Results from this study are presented for 702 patients completing the baseline and 3rd infusion follow-up surveys (targeted sample size at 12 months > 725). The mean number of years since MS diagnosis was 10.16 (SD = 8.23). Most patients were female (77%), and the mean age was 46.09 (SD = 10.78). On average, MFIS-5 scores decreased significantly from baseline (baseline score 12.46 + 4.56; 3rd infusion score 10.29 + 4.78, P < 0.001), and MOS-Cog scores increased significantly from baseline (baseline score 24.48 + 7.84; 3rd infusion score 26.29 + 7.19, P < 0.001), suggesting improvement in both measures.

**CONCLUSIONS:** Results indicate that MS patients report improvements in fatigue and overall cognitive function even as early as after 3 infusions of natalizumab.

**SPONSORSHIP:** This research was funded by Biogen Idec and Elan Pharmaceuticals, Inc., Boston, MA.
Economic Value of Lidocaine Patch 5% Versus Gabapentin or Pregabalin in Medicaid Patients with Post-Herpetic Neuralgia


BACKGROUND: The economic value of treatment with lidocaine patch 5% (lidocaine) in post-herpetic neuralgia (PHN) has not been described.

OBJECTIVE: To compare direct health care resource utilization and costs of PHN patients initiating lidocaine or gabapentin/pregabalin.

METHODS: Patients with PHN diagnosis (ICD-9-CM codes 053.12, 053.13 or 053.19) or herpes zoster diagnosis (ICD-9-CM codes 053.0x, 053.10, 053.11, 053.2x, 053.7x-053.9x) and at least 30 days PHN-related treatment were identified from Medicaid claims data from Florida, Iowa, Missouri, and New Jersey from 1999 to 2007. Patients initiated monotherapy with lidocaine or gabapentin/pregabalin after PHN diagnosis, had continuous eligibility 6 months before (baseline) and 6 months after (study period) the medication index date, and were at least 18 years old. Lidocaine patients were matched to patients initiating gabapentin/pregabalin on age and propensity to initiate lidocaine based on baseline characteristics. Study period direct resource use and costs, calculated as reimbursements to providers for medical services and prescription drugs, were compared between the 2 matched groups using univariate analysis.

RESULTS: After matching on age and propensity to initiate lidocaine, baseline characteristics (such as age, comorbidities, prior resource use, and direct costs) were well balanced between the treatment groups. Matched patients were on average 61 years old; 73% were women; approximately 24% had a mental disorder diagnosis; and 55% had other painful conditions during the baseline period. Among matched lidocaine (n = 306) and gabapentin/pregabalin (n = 306) patients, there were no statistically significant differences in study period treatment with tricyclic antidepressants (16.0% in both groups), analgesic medications (86.6% vs. 86.9%), and other PHN-related treatments (6.9% vs. 6.2%), such as DREZ lesions, epidural steroids, and nerve blocks. No statistically significant differences were found in resource use, average total health care costs per patient ($8,740 vs. $8,630, \( P = 0.880 \)), and PHN-related costs ($1,046 vs. $1,067, \( P = 0.908 \)) between matched lidocaine and gabapentin/pregabalin patients.

CONCLUSIONS: Costs for PHN patients treated with lidocaine are no more than those for patients treated with gabapentin or pregabalin over the 6-month study period (see Table below).

SPONSORSHIP: This research was funded by Endo Pharmaceuticals, Inc., Chadds Ford, PA.

Effectiveness of Physician Alerts to Resolve Potential Gaps in Pharmacotherapy

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BACKGROUND: Evidence-based clinical practice guidelines for diabetes and chronic glucocorticoid steroid use include recommendations for adjunct medications to prevent hypertension, dyslipidemia, and osteoporosis.

OBJECTIVE: To determine the effectiveness of a fax-based provider messaging intervention on the implementation of guideline-based pharmacotherapy.

METHODS: A total of 337 employers and health plans, representing 5,508,559 individuals participated in a program that delivers fax alerts to providers when pharmacy claims indicate the absence of a recommended therapy. We evaluated intervention impact on 3 guidelines implemented January 1, 2009, including the recommendation to add (a) an osteoporosis-preventive agent for females on long-term glucocorticoid use, (b) an ACE inhibitor or ARB for adults with hypertension and diabetes, and (c) a lipid-lowering agent for individuals 30 years of age or older with diabetes. From January 1 to March 30, 2009, a total of 78,768 alerts were sent to providers: osteoporosis (n = 1,763), ACE/ARB (n = 22,915), and dyslipidemia (n = 54,090). Through September 30, 2009, therapy addition rates (“gap closure rate”) occurring within 90 days of the intervention were compared with a control group selected from employers and health plans who did not implement the program. Adjusted ORs were derived by logistic regression, including covariates for age, sex, prior medication use, and out-of-pocket participant cost share.

RESULTS: Gap closure rates were significantly higher for cases than controls: osteoporosis (23.5% vs. 15.1%); ACE/ARB (13.2% vs. 7.7%); and dyslipidemia (13.6% vs. 9.1%). The ORs for the addition of therapy by day 90 were significant (P < 0.001) for each intervention: osteoporosis (1.62); ACE/ARB (1.88); dyslipidemia (1.46). In each group, older age and higher risk score (Pharmacy Risk Group score) were significant predictors of filling the adjunct therapy. Participant out-of-pocket cost share was not significant.

CONCLUSIONS: Fax alerts to providers are an effective mechanism for communicating potential gaps in pharmacotherapy. In 3 months, these 3 fax alerts resulted in a total of 3,842 individuals implementing pharmacotherapy in accordance with evidence-based medicine. Future research should focus on the subsequent adherence and the medical value of additive therapy.

SPONSORSHIP: This research was funded by CVS Caremark, Woonsocket, RI.

### Table: All-Cause and PHN-Related Costs Over the 6-Month Study Period

<table>
<thead>
<tr>
<th></th>
<th>All-Cause</th>
<th>PHN-Related</th>
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<tr>
<td></td>
<td>Lidocaine (n = 306)</td>
<td>Gabapentin/pregabalin (n = 306)</td>
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<td>Total direct costs</td>
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<td>Medical costs</td>
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<td>Prescription drug costs</td>
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</tbody>
</table>

PHN = post-herpetic neuralgia.
Effects of Medicare Part D Coverage Gap on Diabetes Medication Adherence

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BACKGROUND: The impact of Medicare Part D coverage gap on medication adherence is not well understood.

OBJECTIVE: To evaluate the impact of Medicare Part D coverage gap on adherence to antidiabetic medications.

METHODS: This study is a retrospective cohort analysis based on pharmacy claims data. The evaluation period is from January 1, 2008, to December 31, 2008. The sample includes 13,142 Medicare Part D beneficiaries who entered the donut hole but never reached the catastrophic limit during the evaluation period. The study group consisted of beneficiaries with standard benefit plans, which do not provide coverage in the donut hole. Beneficiaries enrolled in plans offering supplemental coverage in the donut hole were used as the control group. Adherence was measured by the proportion of days covered (PDC). PDC before and after reaching the donut hole was calculated separately. Adherence was defined by having a PDC equal or greater than 0.8. A difference-in-difference (DID) regression analysis was used to evaluate the effect of coverage gap on adherence to antidiabetic medications.

RESULTS: There were 1,414 patients in the study group and 11,728 patients in the control group. The average age was 75.76 (SD = 7.03) for the study group and 74.85 (SD = 6.34) for the control group. Male patients accounted for 43.28% of the study group and 48.70% of the control group. After patients reached the donut hole, the average copayment for antidiabetic medications increased from $20.79 to $74.90 for the study group and from $19.12 to $41.89 for the control group. The adherence rate decreased from 82% to 74% for the study group and from 84% to 80% for the control group. The DID regression model shows that beneficiaries with no coverage in the donut hole were 20% less likely to be adherent (OR = 0.799, P = 0.023, 95% CI = 0.658-0.969).

CONCLUSIONS: A lack of supplemental coverage in the donut hole significantly reduced adherence to antidiabetic medications among Medicare Part D beneficiaries with diabetes.

SPONSORSHIP: This research was funded by Pfizer, Inc., New York, NY.

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BACKGROUND: Managed care organizations routinely use restrictions as a cost containment strategy. There is little information examining the effect of such strategies.

OBJECTIVE: To compare changes in medication use and costs over time between commercial health plans that implemented prior authorization (PA) policies restricting access to pregabalin for management of painful diabetic peripheral neuropathy (pDPN) or post-herpetic neuralgia (PHN) versus plans without pregabalin PA policies.

METHODS: Adults with a diagnosis of pDPN or PHN and at least 1 claim for pDPN/PHN-specific pain medication were selected. Pharmacologic therapy, health care utilization, and expenditures were analyzed using bivariate statistics and generalized linear models in a difference-in-difference approach comparing outcomes between cohorts year-over-year.

RESULTS: The 2 cohorts included 2,084 patients in PA plans and 1,320 patients in plans without PA. Patients with a PA experienced a 5.0 percentage points lower increase in patients using pregabalin year-over-year compared with non-PA plans (P < 0.01). Compared with non-PA plans, patients in PA plans using anticonvulsants other than pregabalin decreased 3.7 percentage points (P = 0.031), while those using nonopioid analogics decreased 5.2 percentage points (P = 0.013). There were no statistically significant differences for opioid use, antidepressants, other pDPN/PHN medication use, or pDPN/PHN-related total health care costs (see Table above).

CONCLUSIONS: Although the PA policy accomplished the objective of controlling access to pregabalin, the overall effect showed no statistically significant differences in pDPN/PHN-specific medication expenditures or in overall disease-related health care expenditures.

This research was funded by Pfizer, Inc., New York, NY.
diagnosis codes in all diagnosis fields (within the 6 months prior to their first ESA claim) were evaluated and hierarchically classified as chronic renal failure, cancer with anemia, anemia only, cancer without anemia, and, lastly, any other medical diagnosis during April 2007 to September 2007 and January 2008 to June 2008.

**RESULTS:** During all of 2006, medical benefit ESA total paid PMPM was $0.50, declining to $0.19 in the 2008Q4. Pharmacy benefit ESA total paid PMPM was $0.11 during 2006, declining to $0.09 in the 2008Q4. Members utilizing an ESA declined 16.1%, from 312 of 933,425 (33.4 per 100,000) to 252 of 898,341 (28.1 per 100,000), P=0.038. As shown in the table, use among members with a cancer diagnosis and lacking an anemia diagnosis decreased nonsignificantly, 30 of 312 (9.6%) to 20 of 252 (7.9%).

**CONCLUSIONS:** Although ESA utilization and expenditures declined significantly following safety issues identified in 2007, 7.9% or 1 in 13 ESA utilizers may still be at increased mortality risk. Insurers may wish to consider the role of an ESA utilization management program to decrease the potential safety risk.

**SPONSORSHIP:** This research was funded by Prime Therapeutics, LLC, Eagan, MN.

### Evaluation of a Chronic Heart Failure Medication Therapy Management Program

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**BACKGROUND:** Chronic heart failure (CHF) is a major public health problem in the United States. CHF is the most common diagnosis in the Medicare population, and more Medicare dollars are spent for the diagnosis and treatment of CHF than for any other diagnoses. The CHF Medication Therapy Management Program (CHF-MTMP) is a provider-based clinical intervention designed to enhance providers’ awareness of current recommendations from the American Heart Association and American College of Cardiology.

**OBJECTIVE:** To evaluate the effectiveness of the provider-based, mailing clinical intervention on the appropriate initiation of angiotensin converting enzyme inhibitor (ACEI), angiotension receptor blocker (ARB), and beta-blocker (BB) therapy within a Medicare Part D MTMP eligible patient population with the chronic condition of CHF.

**METHODS:** This was a retrospective cohort analysis using electronic medical and pharmacy claims databases. We identified over 6,000 Medicare patients with either a drug proxy or a diagnosis of CHF without pharmacy claims history for an ACEI, ARB, or BB in 2008. The CHF-MTMP intervention was a provider-based mailing that included an introductory letter, a provider-specific pharmacy utilization report, and an educational piece on the management of CHF. The primary outcome of interest was the percentage of cases that were resolved. Resolution was defined as pharmacy claims for an ACEI or ARB for ACEI/ARB eligible patients or BB for BB eligible patients within a 3-month post-intervention period.

**RESULTS:** Among the identified Medicare Part D patients, 12% of the ACEI/ARB eligible members and 9.8% of the BB eligible members had a resolution during the post-intervention period.

**CONCLUSIONS:** The results of this evaluation highlight the need for programs to improve quality of care for Medicare Part D patients with CHF.

**SPONSORSHIP:** There was no external funding for this research.

### Evaluation of the Impact of Triptan Quantity Limit on Health Care Utilization

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**BACKGROUND:** Quantity limit level (QLL) is one of the strategies that is employed by health plans to control overuse of medications. In May 2007, UnitedHealthcare implemented quantity limit of 4 units per member copayment for triptans. This analysis focuses on the impact of this strategy on medical health outcomes.

**OBJECTIVE:** To evaluate the impact of triptan quantity level limit on total health care utilization and costs.

**METHODS:** A retrospective review of UnitedHealthcare members with claims for triptans in April 2007 was conducted. Members were classified into 2 groups: members in health plans with QLL and in plans with no QLL. Members were followed for 1 year after index claim to determine health care utilization. A 6-month pre-period was used to determine the characteristics of members. Health care utilization included number of ambulatory visits, occurrence of emergency room (ER) visits, occurrence of inpatient (IP) visits, pharmacy costs (overall and triptan specific), and medical costs (overall and migraine specific). Multivariate regression models were used to determine the difference in outcomes between the 2 groups after controlling for member characteristics. Member characteristics included age, gender, health plan region, type of index triptan, charlson comorbid score, number of unique diagnoses, and whether member was new/existing to therapy.

**RESULTS:** A total of 31,781 members (QLL=17,012; non-QLL=14,769) were identified. Mean age was 44 years, and 14% were male in both groups. Eighteen percent of the members were new to triptan therapy in both groups. The most frequently used triptan was sumatriptan with 38% in the QLL group and 43% in the non-QLL group. After controlling for confounding factors, number of office visits and number of outpatient visits were not significantly different between the 2 groups. There was also no significant difference in occurrence of ER and IP visits in the follow-up period. Generalized linear models for costs did not reveal significant difference in migraine-related medical cost ($730.89 vs. $797.54, P=0.138) or overall medical cost ($8,843.57 vs. $8,834.57, P=0.842) between the QLL and non-QLL group. Migraine-related pharmacy cost ($794.05 vs. $1,465.28, P<0.001) and overall pharmacy cost ($3,214.16 vs. $3,950.61, P<0.001) were significantly lower in the QLL group.

**CONCLUSIONS:** Implementation of the QLL strategy resulted in a decrease in triptan pharmacy costs and did not result in increased medical costs in the QLL group. Health plans should continually evaluate the
impact of pharmacy benefit strategies on overall health outcomes.

**SPONSORSHIP:** There was no external funding for this research.

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**Fibromyalgia Burden: Medication and Other Medical Resource Use Among Fibromyalgia Patients in the United States**

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**BACKGROUND:** Fibromyalgia (FM) is a chronic disorder characterized by persistent, widespread pain, fatigue, and other symptoms. Diagnosed patients often experience suboptimal pain and symptom management, involving multiple visits to medical professionals and multiple trials of opioid and non-opioid medications.

**OBJECTIVE:** To examine medical resource use (MRU) associated with FM in routine clinical practice in the United States.

**METHODS:** This cross-sectional, observational study recruited 203 FM subjects from 20 community-based physician offices during routine visits in 2008. Subjects completed self-administered questionnaires about their pain, health-related quality-of-life, and out-of-pocket expenses related to FM. FM severity was based on Fibromyalgia Impact Questionnaire (FIQ) severity scores. Physician office staff recorded subject clinical characteristics, medications, and MRU based on a 3-month retrospective review of medical charts.

**RESULTS:** The mean age (SD) of subjects was 47.9 (10.9) years, and 94.6% were female. Subjects reported a mean (SD) FIQ total score of 63.2 (19.0), with the majority (65.5%) reporting severe FM and a mean (SD) average pain intensity score of 6.3 (2.1), with 53.9% reporting severe pain. Most subjects (91.6%) were receiving at least 1 prescription medication for FM, with the highest proportion of subjects prescribed anti-depressants (56.2%), analgesics other than anti-inflammatories (51.7%), and antiepileptics (37.9%). Approximately half (52.2%) were taking 3 or more prescription FM medications. Subjects reported a mean (SD) out-of-pocket cost for prescription FM medications over the past 4 weeks of $81.45 (102.31) totaling approximately $1,060 annually. Over the past 3 months, subjects had a mean (SD) of 6.1 (8.2) office visits, including 4.2 (4.5) physician visits with 27.0% of subjects having at least 1 FM-related diagnostic test. As FM severity worsened, the mean number of office visits (P = 0.06), prescription FM medications (P = 0.003), and subject-reported out-of-pocket costs for prescription medications (P = 0.02) increased. Additionally, total direct costs increased significantly with worsening FM severity (Mean [SD]: Mild: $4,855 [3509], Moderate: $5,662 [4,139], Severe: $9,318 [8,304], P = 0.002).

**CONCLUSIONS:** FM imposes a significant burden on society that increases as FM severity worsens. Despite high rates of MRU and prescription medication use related to FM, subjects reported severe levels of pain and FM, indicating a need for better management of FM and FM-related symptoms.

**SPONSORSHIP:** This research was funded by Pfizer Inc., New York, NY.

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**Health Care Resource Utilization and Costs Associated with Warfarin in Medicare Beneficiaries with Nonvalvular Atrial Fibrillation**

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**BACKGROUND:** Nonvalvular atrial fibrillation (NVAF) is associated with a 5-fold increase in stroke incidence, a serious and costly complication. Adjusted-dose warfarin reduces ischemic stroke risk in NVAF patients by 64% but is associated with costs due to monitoring and, if not managed properly, complications such as bleeding.

**OBJECTIVE:** To examine the impact of warfarin on related health care resource utilization and costs in Medicare patients with NVAF.

**METHODS:** Medical claims from Centers for Medicare and Medicaid Services 5% Sample Standard Analytic File were used to identify beneficiaries between 2004 and 2005 with at least 1 inpatient claim or 2 outpatient diagnosis claims for atrial fibrillation and no evidence of valvular heart disease or reversible causes. Pharmacy claims are not contained...
within this data, so a validated surrogate marker (at least 3 international normalized ratio [INR] claims within a 1-year period) was used to identify patients receiving warfarin. To assess the impact of warfarin, we estimated average resource utilization using nonparametric measures and average costs (reimbursed amounts in 2006 US$) by multivariable linear regression techniques.

**RESULTS:** Among over 2 million beneficiaries in the file, 119,764 patients with NVAF were included in the study. Of those included, 58.5% (n = 70,057) were treated with warfarin. The average annual total medical cost of this cohort was $19,888 per patient. Inpatient costs were the largest contributor to total cost, averaging $8,597 per year, followed by physician costs ($4,675), short-term nursing facility costs ($2,496), and outpatient visit costs ($1,769). Average incremental costs of events for patients with NVAF were $34,201 for ischemic stroke, $44,716 for hemorrhagic stroke, and $29,965 for major bleed. Patients receiving warfarin had an average of 12.9 INR claims per year. Warfarin users averaged significantly more office/outpatient visits yet had fewer hospitalizations than nonusers (21 vs. 13 and 0.8 vs. 1.0, respectively). Overall, oral anticoagulation with warfarin use was independently associated with an average reduction of $9,836 total medical costs per patient per year compared with those NVAF patients not receiving warfarin (P < 0.001).

**CONCLUSIONS:** In this sample of Medicare beneficiaries with NVAF, we found that warfarin use was associated with higher outpatient utilization; however, hospitalizations and overall medical costs were lower.

**SPONSORSHIP:** This research was funded by Boehringer Ingelheim Pharmaceuticals, Inc., Ridgebury, CT.

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### Health Care Utilization and Costs Associated with Nonadherence to a Chronic Opioid Regimen

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**BACKGROUND:** Appropriate opioid use is essential for chronic pain management. Opioid misuse, abuse, or use of nonprescribed or illegal drugs could indicate or contribute to inefficient health care resource use.

**OBJECTIVE:** To determine whether opioid utilization and related health care use or costs differ between patients who are adherent to an opioid regimen and those who are not.

**METHODS:** Patients with long-term prescription opioid use (>120 days’ supply over 6 months) were identified in a managed care claims database and then matched to a database of urine drug-monitoring test results. Based on monitoring results, adherent and likely nonadherent (drug absent, drug level high or low based on a proprietary algorithm; or presence of nonprescribed or illegal drugs) cohorts were formed. Between-cohort comparisons of health care utilization and costs were made based on the 6 months prior to testing (baseline) and 12 months of follow-up.

**RESULTS:** Adherent (n = 442) and nonadherent (n = 1658) cohorts did not differ with regard to age, sex, or region. During the baseline period, hydrocodone and oxycodone were the most commonly filled opioids in both cohorts. Fentanyl was more common among adherent patients than nonadherent patients (P = 0.014). Mean total follow-up health care costs were greater for nonadherent patients ($26,433 vs. $23,160; P = 0.036). During follow-up, nonadherent patients had more opioid dispensings (20.7 vs. 18.2; P = 0.001) and greater days supply (415 vs. 392; P = 0.004). They were more likely to have a hospital admission (24.3% vs. 19.3%; P = 0.032), an emergency visit (46.2% vs. 39.1%; P = 0.008), or an opioid-related emergency visit (2.2% vs. 0.7%; P = 0.039). The mean number of hospital admissions did not statistically differ between cohorts, but nonadherent patients had a greater number of overall (2,370 vs. 1,753 days per 1,000 patients) and pain-related (1,008 vs. 723 days per 1,000 patients) hospital days (P < 0.001).

**CONCLUSIONS:** Patients who were nonadherent to an opioid regimen had evidence of greater costs and health care utilization than adherent patients. Specifically, the nonadherent cohort had evidence of greater opioid use and more pain-related and overall hospital days. A greater proportion of nonadherent patients had emergency visits and hospital admissions. Further investigation of this population might reveal means to both improve adherence and reduce health care resource use.

**SPONSORSHIP:** This research was funded by Ameritox LTD, Baltimore, MD.

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### Impact of a Pharmacist-Led Diabetes Medication Management Program on Glycemic Control and Medication Adherence

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**BACKGROUND:** Proper medication management of diabetes can decrease health care costs and improve health outcomes. To achieve such benefits, an HMO plan in central Texas implemented a pharmacist-led diabetes medication management program. Patients enrolled in this program are also eligible for copay waivers on diabetic medications.

**OBJECTIVE:** To (a) determine if patients receiving medication management demonstrated improvement in diabetic control (i.e., change in A1c) and in medication adherence; and (b) compare the changes in A1c and medication adherence between the intervention and control groups before and after implementation.

**METHODS:** Patients were enrolled in the medication management program if they had baseline A1c levels greater than 7.5%, continuous enrollment throughout study period (‘rolling’ enrollment period from August 2006-July 2008), and a formal diagnosis of diabetes. The controls were matched 1:1 to the intervention group by age, gender, baseline A1c, and Charlson comorbidity index (CCI). A1c measurements were obtained from electronic medical records 1 year before and after implementation. Adherence was measured by Medication Possession Ratio (MPR) using prescription drug claims 1 year before and after implementation. Paired t-test compared the change in MPR and A1c pre- versus post-implementation in both groups.

**RESULTS:** 117 patients were enrolled in the medication management program for at least 1 year. Baseline mean A1c was 9.28 and 9.14 (P = 0.759) in the intervention and control groups, respectively; CCI was 1.84 and 1.79, respectively (P = 0.651). A1c decreased by 11.8% in the intervention group (P < 0.001) but did not change significantly in the control group (-1.1%, P = 0.685). The difference in A1c change between the groups was statistically significant (P < 0.010). For patients enrolled for 2 years of follow-up (n = 38), A1c decreased by 13.6%. In the intervention group, the MPR for oral hypoglycemics increased from 0.79 to 0.82 (P = 0.119) after program implementation. In the control group, the baseline MPR did not change post-period (0.77 vs. 0.78, respectively; P = 0.773). There was no significant difference in the change in MPR between matched control and intervention group pairs (P = 0.369).

**CONCLUSIONS:** The medication management program was shown to improve patients’ glycemic control; however, no statistically significant improvements in medication adherence were demonstrated, suggesting dose titration, education, and other pharmacists’ interventions may be improving outcomes. Future analyses will include larger sample size and evaluation of costs and utilization.
These changes translated into an incremental 14.5% reduction in plan sponsor share. The metrics will continue to be tracked and changes in adherence will be measured beginning 6 months post-implementation (see Figure above).

CONCLUSIONS: Two-tier plan designs increase member cost share without negatively impacting utilization.

SPONSORSHIP: There was no external funding for this research.

**Impact of Being a Medication User on Hospitalization and Spending for Medicare Beneficiaries with Chronic Obstructive Pulmonary Disease**

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) is an important cause of hospitalization and excess health care spending among the aged. Adherence with appropriate maintenance and rescue medications has been demonstrated to reduce hospitalization and health care spending. However, there is little research on the impact of use versus nonuse of these medications on health-related outcomes.

OBJECTIVE: To compare differences between users and nonusers of maintenance and rescue medications on hospitalization, re-hospitalization, and Medicare spending for a nationally representative sample of Medicare beneficiaries with COPD.

METHODS: We pooled annual data from 9 years of Medicare Current Beneficiary Surveys (MCBS) to create a large sample (n=9,161) diagnosed with COPD between 1997 and 2005. We identified users of maintenance medications (inhaled corticosteroids alone or in combination with long acting beta-agonists, anticholinergic agents, xanthines) and
rescue medications (short-acting beta-agonists, other agents) and then compared users to nonusers on 3 outcomes identified from Medicare claims: any hospitalization, any re-hospitalization within 30 days, and total annual Part A and B Medicare expenditures. We used logistic regression for the binary outcomes and a gamma distribution with log link to estimate Medicare spending. Analyses controlled for demographic characteristics, comorbidities, disease severity, and health behaviors.

**RESULTS:** Annually, only 53.2% of the sample filled prescriptions for recommended COPD medications, with 39.9% using maintenance drugs, and an additional 13.3% using only rescue drugs. The conditional odds of hospitalization and re-hospitalization for maintenance users compared with nonusers were 0.70 (P = 0.000) and 0.74 (P = 0.000), respectively. For rescue-only users the conditional odds for hospitalization and re-hospitalization were positive but non-significant. Annual Medicare spending in 2006 dollars averaged $20,157 for the sample but was $3,916 (P = 0.000) lower among maintenance users in the multivariate model. Rescue medications had a positive but insignificant impact on costs.

**CONCLUSIONS:** Analyses focused on adherence with medications used to treat COPD miss an important subset of the aged COPD population—patients who fill neither maintenance nor rescue medications. We demonstrate that being a nonuser of maintenance drugs significantly raises the risk of hospitalization and re-hospitalization and increases Medicare costs by nearly 20%.

**SPONSORSHIP:** This research was funded by GlaxoSmithKline, Research Triangle Park, NC.

### Impact of Ranolazine on Revascularization and Health Care Costs Among Angina Patients

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**BACKGROUND:** Prior studies have shown that patients with angina symptoms incur substantial health care costs due to frequent medical visits, hospitalizations, and revascularization procedures.

**OBJECTIVE:** To assess the impact of ranolazine, a novel antianginal treatment, on revascularization procedures and health care costs.

**METHODS:** A retrospective case-control analysis was conducted using medical and treatment information of angina patients retrieved from a national health insurance database. Patients with angina ICD-9-CM diagnosis codes and antianginal prescriptions between July 2005 and February 2008 were identified. Patients who added or switched to ranolazine, nitrates, beta-blockers (BB), or calcium channel blockers (CCB) were assumed to have angina symptoms and were assigned to the corresponding treatment group: ranolazine, nitrates, or BB/CCB. For each group, frequency of hospitalizations, revascularization procedures (PCI or CABG), and health care costs were evaluated for a period of 6 months post-antianginal medication change. Risk of revascularization and health care costs for each group were adjusted for differences in demographic, comorbidity, and prior revascularization, using logistic regression and generalized linear modeling.

**RESULTS:** Ranolazine (n = 881), nitrates (n = 1,788), and BB/CCB (n = 1,876) patients had similar demographic characteristics, comorbidities, and prior revascularization rates (25.0%, 26.5%, 25.2%, respectively). Six-month post-antianginal medication change, ranolazine patients had significantly lower rates of PCI than the nitrate and BB/CCB groups (8.3% vs. 14.1%, 11.9%, P < 0.01), CABG (2.0% vs. 6.5%, 4.0%, P < 0.01), and hospitalizations (27.4% vs. 33.2%, 33.8%, P < 0.01). Odds of revascularization in the ranolazine group were 58% lower than the nitrate group (OR = 0.42 [0.33-0.55]) and 40% lower than the BB/CCB group (OR = 0.60 [95% CI = 0.46-0.77]). Adjusted health care costs were 21% to 23% less in the ranolazine group ($13,961) compared with the nitrate ($18,166, P < 0.01) and BB/CCB ($17,612, P < 0.01) groups.

**CONCLUSIONS:** Use of ranolazine in patients with angina was associated with lower rates of hospitalizations, PCI, CABG, and lower health care costs in the first 6 months following initiation of the drug.

**SPONSORSHIP:** This research was funded by Gilead Sciences, Inc., Foster City, CA.
Improving Persistency for Maintenance Medication Therapy Through an Interactive Voice Response Program

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BACKGROUND: Interactive Voice Response (IVR) messaging delivers cost-effective adherence interventions to plan participants. However, little is known about the impact of IVR refill reminders delivered before or after the expected refill date (based on the exhaustion of dispensed days supply).

OBJECTIVE: To determine the impact of an IVR program on medication adherence.

METHODS: From October 2008 to February 2009, a total of 94,467 commercially insured mail pharmacy users received IVR adherence messages. Their first fill persistency rates (FFPRs) were compared with those of 11,615 controls. Outbound IVR messages included combinations of early and tardy reminders to initiators of selected maintenance drugs: statins, ACE inhibitors, and metformin. Bivariate and multivariate logistic regression analyses were used to estimate the impact of IVR on FFPR.

RESULTS: Average FFPRs for IVR targeted participants were 77.8% (statins), 78.3% (ACE inhibitors), and 72.4% (metformin); rates that were 2.4% (P < 0.001), 1.8% (P < 0.01), and 1.7% (P = 0.16) higher than controls. Among participants receiving the early refill reminders, average FFPR was 3.5% higher than controls (78.8% vs. 75.3%; P = 0.008). In contrast, the FFPR for participants receiving refill reminders after their drug supply exhausted was 1.4% higher than controls (72.8% vs. 71.4%; P = 0.044). Early refill and tardy reminders increased the adjusted odds of refilling an index therapy by 1.12 (95% CI = 1.06-1.17; P < 0.001) and 1.08 (95% CI = 1.01-1.16; P = 0.0375), respectively. FFPR was strongly associated with whether a participant was reached by IVR. The FFPRs among the participants who were attempted but not reached by IVR did not differ from controls, while those who answered the telephonic IVR call had increased odds of refilling of up to 70.6% (95% CI = 1.49-1.96; P < 0.001). Among reached participants, the odds of a tardy reminder resulting in refill were greater for participants who had an early reminder to refill but did not (OR = 1.46, 95% CI = 1.10-1.90; P < 0.001), compared with participants who received only the tardy message (OR = 1.22, 95% CI = 1.01-1.48; P < 0.001), suggesting repeated IVR calls increased the likelihood of refill among intransigent participants.

CONCLUSIONS: IVR messaging improved persistent maintenance therapy at mail. Early refill reminders intended to prevent discontinuation had greater impact than tardy reminders delivered after discontinuation. However, there was an increased impact of tardy IVR calls if preceded by early refill reminders. Finally, IVR effectiveness depends in large part on its ability to reach and engage targeted participants.

SPONSORSHIP: This research was funded by CVS Caremark, Woosocket, RI.

Incidence Rate of Venous Thromboembolism and Hemorrhage in Patients Undergoing Total Hip or Knee Arthroplasty: A Managed Care Perspective

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BACKGROUND: Venous thromboembolism (VTE) is a common and preventable cause of death. Patients undergoing total hip arthroplasty (THA) and total knee arthroplasty (TKA) are at increased risk of developing VTE. The benefit of VTE prevention using anticoagulation therapy may be offset by an increased risk of bleeding.

OBJECTIVE: To assess the incidence rate of VTE and bleeding after THA or TKA.

METHODS: An analysis of health care insurance claims from the Ingenix Impact National Managed Care Database was conducted. Between January 2004 and September 2008, all subjects aged ≥18 years with at least 1 procedure code for THA or TKA and ≥ 180 days of presurgery observation were selected. Only the first procedure was included for each subject. VTE and bleeding events occurring within 3 months following the surgery were included. VTE was defined as at least 1 diagnosis code for deep vein thrombosis (DVT) or pulmonary embolism (PE). Bleeding events were also identified through diagnosis codes and classified as major and nonmajor events. The incidence rates of VTE and bleeding events were calculated as number of patients with an event divided by patient-years of observation, censored at the time of the first event.

RESULTS: A total of 43,670 THA and 76,059 TKA patients were identified. Overall, mean population age (SD) was 60.2 (9.8) years; 56% were female. A total of 7,974 patients developed VTE, and 4,849 patients developed a bleeding event. Among all VTE events, 7,054 were DVT, and 1,599 were PE. Gastrointestinal bleeding was the most frequent major bleeding event (1.06%) and hematuria the most frequent nonmajor bleeding event (1.53%). Mean hospital length of stay was 4.6 days for patients developing VTE, 4.5 days for patients developing any bleeding events, and 3.5 days for patients with no VTE or bleeding. The incidence rates of VTE and any bleeding were, respectively, 29.7 and 17.6 events per 100 patient-years. When considering only major bleeding events, the incidence rate decreased to 7.9 events per 100 patient-years (see Table above).

CONCLUSIONS: In this population of patients undergoing THA and TKA, VTEs were more frequent than bleeding events. Accurate assessment of the risk of VTE and bleeding is important for clinicians when determining the risk and benefit of initiating anticoagulation therapy in patients after THA and TKA.

SPONSORSHIP: This research was funded by Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, NJ.

Incremental Impact of Offering Two Copay Waivers in a Generic Copay Incentive Program

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BACKGROUND: Generic copay waiver (GCW) programs that incentivize brand medication users to choose generic medications, thereby reducing overall pharmacy costs, have gained popularity among pharmacy plan sponsors.

OBJECTIVE: To evaluate and compare the impacts of 1 or 2 mail GCWs.

METHODS: A large-size employer client offered its plan participants...
2 copay waivers targeting brand medication users of 52 therapeutic classes. Targeted brand users who changed their mail service prescription to the recommended generic medication within a 6-month period received 2 mail copay waivers on the generic prescription (180-day supply). However, targeted brand users who made the change to generic prescriptions, but missed the 6-month period only received 1 mail copay waiver (90-day supply). The study focused on generic adopters who continued therapy after the last generic copay waiver had been used. Sustained generic dispensing ratio (GDR) was defined as examination of the last prescription within a specified observation period (18 months after the GCW program inception plus 4 trailing months) and measuring the percentage of plan participants who continued to purchase the generic after converting from a brand medication.

RESULTS: Overall sustained GDR of 2-waiver recipients was 88.2%, which was 16.5 percentage points higher than the 71.7% sustained GDR of 1-waiver recipients. Among the 4 top therapeutic classes measured by the number of generic adopters, sustained GDR of 2-waiver recipients was 12 to 31 percentage points higher than those of 1-waiver recipients (see Table above).

CONCLUSIONS: Among the 4 top therapeutic classes, generic adopters who received 2 mail copay waivers were more likely to stay on generic medications than those who received 1 mail copay waiver.

SPONSORSHIP: There was no external funding for this research.

### Influenza Antiviral Drug Utilization During Traditional Flu Seasons and the Present H1N1 Pandemic: Quantity Limit Opportunity Assessment

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BACKGROUND: Novel influenza A (H1N1) was confirmed in the United States in mid-April 2009; a global pandemic was declared June 11; and intense localized outbreaks continued into the summer. The CDC recommended antiviral treatment of H1N1 in select populations only in September 2009.

OBJECTIVE: To (a) examine interstate utilization trends of influenza antiviral drugs (IAD), comparing use during the recent H1N1 pandemic to typical flu seasons, and (b) determine frequency of high-quantity oseltamivir claims.

METHODS: Claims for IADs (oseltamivir, zanamivir, rimantadine) since September 2006 for 9 million members enrolled in commercial health plans across 10 states were summarized.

RESULTS: The 2008 influenza season per-capita IAD utilization was twice as high (peaking at 0.52 claims per 1,000 members per day) compared with the 2007 and 2009 seasons. A spike to 0.35 claims per 1,000 members per day occurred in late-April 2009; claims then
decreased through the summer, though still were at a much higher level than typical interseasons. Beginning in August 2009, claims began increasing rapidly again and by September were at a level approaching the 2008 peak. In most months, 90% of IAD claims were oseltamivir; 75 mg capsules represented 65-75% of claims in flu seasons, with nearly all of the remainder as suspension. Within each flu season, 98-99% of claims for oseltamivir 75 mg were for a quantity of 0-10 capsules. One exception was April 2009, where 97.5% of claims were for 0-10 capsules, and 1.9% were for 20-50 capsules. From April-September 2009, 99% of oseltamivir-utilizing members had 1 claim, and 98.2% had a total quantity dispensed of 10 or fewer. A south central state had peak use in typical influenza seasons at least 3 times that of a north central state, and this trend was even more pronounced with the emergence of H1N1 (see Figure on previous page).

CONCLUSIONS: There is variability in IAD use between typical seasons and geographic regions. Data from the early 2009 season suggest the combination of typical seasonal influenza and novel H1N1 will spur heavy utilization of IADs. The impact of an IAD quantity limit program may be limited given the current infrequent prevalence of large quantity oseltamivir claims.

SPONSORSHIP: This research was funded by Prime Therapeutics, LLC, Eagan, MN.

# Letrozole (Femara) Medical and Pharmacy Integrated Analysis: Utilization Management Opportunity

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**BACKGROUND:** Letrozole (Femara) is a nonsteroidal oral aromatase inhibitor indicated for post-menopausal women with hormone receptor-positive breast cancer. Letrozole has also been studied for the treatment of infertility; however, there is insufficient evidence to provide definite guidance in ovulation induction and the potential teratogenic effects have not been prospectively studied or evaluated.

**OBJECTIVE:** To evaluate the use of letrozole for non-FDA approved indications and assess the potential for a utilization management opportunity.

**METHODS:** Members from 2 BlueCross BlueShield commercial plans (approximately 1.4 million members) with a letrozole claim between July 2008 and June 2009 were identified, and letrozole expenditures were calculated. Further analyses required members to be continuously enrolled July 2007 through June 2009. Members were grouped by age as of July 1, 2008, into 2 categories: aged 0-50 and > 50 years. Pharmacy claims were queried for concomitant tamoxifen (GPI starts with 214,026) from July 2008 through June 2009. Medical claims diagnoses in any field or line from July 2007 through June 2009 were queried and hierarchically ordered: breast cancer (ICD-9-CM codes 174.xx, 175.xx, 198.81, 233.0x); infertility (ICD-9-CM codes 628.xx, 256.xx); other medical claims, and no medical claims.

**RESULTS:** 7,000 30-day equivalent letrozole claims July 2008 through June 2009 were identified with a total plan paid of $2,122,849 and $303 average total paid per claim. Among the 837,957 continuously enrolled members from July 2007 through June 2009, 10 per 10,000 had a claim for letrozole. As shown in the table, 29.3% of members appear to be using letrozole to treat infertility. Among members over 50 years old, 95.3% had a medical claim for breast cancer. A total of 285 (35.4%) members did not have an FDA-approved diagnosis (per medical claims) for letrozole (see Table).

**CONCLUSIONS:** Approximately 3 in 10 letrozole utilizers appear to be treating infertility, which may be placing the fetus at increased risk. If a utilization management prior authorization program would have denied letrozole claims for the 285 utilizers without a breast cancer diagnosis or prior tamoxifen use, safety may be improved, and there may have been $0.013 per member per month (PMPM) in total paid pharmacy savings.

SPONSORSHIP: This research was funded by Prime Therapeutics, LLC, a PBM for BlueCross BlueShield of Florida, Eagan, MN.

## Measuring Cost Savings Associated with the Removal of 10 mg, 20 mg, and 40 mg Strengths of Atorvastatin from a Medicaid Plan Formulary

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**BACKGROUND:** Atorvastatin is available only under its proprietary name, while moderate potency statins (simvastatin, lovastatin, and pravastatin) are currently available in generic form from several manufacturers at significantly lower cost. Converting members to generic products has the potential to reduce drug spend for the entire statin class. Formulary exclusion of atorvastatin (10 mg, 20 mg, and 40 mg), while encouraging the use of generic products, may be an effective strategy for managed care plans to contain the cost of statin therapy. High potency statins will be required by some patients in order for therapeutic goals to be reached and maintained. On April 1, 2009, a Medicaid plan implemented the removal of atorvastatin 10 mg, 20 mg, and 40 mg from formulary. Patients receiving atorvastatin 80 mg were allowed to remain on this strength.

**OBJECTIVE:** To assess the cost-effectiveness of removing low and moderate strength atorvastatin from formulary and promoting the use of generic statins.

**METHODS:** A retrospective analysis was conducted between January 2009 and June 2009 (3 months pre- and 3 months post-removal of atorvastatin 10 mg, 20 mg, and 40 mg) to evaluate monthly pharmacy claims history (cost and utilization) during that time. Claims data were utilized to determine the impact of the removal before and after the implementation.

**RESULTS:** A comparison of the pre-implementation costs to the post-implementation costs demonstrated the savings the program could generate. Reduction of atorvastatin 10 mg, 20 mg, and 40 mg utilization in the post-implementation period resulted in a cost reduction of $201,171. Utilization of preferred statins increased during this time frame, resulting in a net cost reduction of $176,791 for the class.

**CONCLUSIONS:** A therapeutic interchange from atorvastatin 10 mg, 20 mg, and 40 mg to a formulary statin resulted in significant cost savings for the Medicaid population that was evaluated for the time frame.

SPONSORSHIP: There was no external funding for this research.
Measuring Physician e-Prescribing Rates: Overcoming Challenges with Existing Data

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BACKGROUND: The Massachusetts General Physicians Organization (MGPO) Quality Incentive (Q) Program sets goals and uses performance measures to recognize and modestly reward physician’s efforts to improve the quality and efficiency of care. One measure is the rate of e-prescribing (e-Rx), which improves the safety and efficiency of prescribing because the electronic medical records (EMRs) offer decision support. Measuring and improving e-Rx rates helps the institution meet pay-for-performance targets with select insurers.

OBJECTIVE: To measure physician e-prescribing rates using existing data sources to analyze, report, and expand e-Rx and EMR adoption.

METHODS: We calculated e-Rx rates for each department and for individual physicians who are not fully integrated in a department. The denominator for each measured group was 40 randomly sampled new pharmacy claims from the most recent 3-month period available. The numerator of the measure was the number of sampled claims that could match an event in the EMR. The claims were manually matched by trained staff with defined criteria of prescribing events in the EMR. Incorporating visit data allowed reviewers to resample claims where pharmacy misattribution of the ordering physician appeared likely. The resulting e-Rx rates were assessed against an 80% e-prescribing goal.

RESULTS: Department and individual level e-Rx rates were calculated and used to determine modest incentive payments to individual physicians. Twenty-five of 30 departments met the 80% e-Rx target. Out of 42 individually measured physicians, 25 met the e-Rx target. Nonperforming departments and prescribers were targeted for improvement efforts.

CONCLUSIONS: Current EMR and insurance data do not contain a common field that unambiguously links pharmacy claims and EMR events, which limits current measures. Physician acceptance of the e-Rx measure necessitated high sensitivity to true e-Rx events but tolerated lower specificity. High sensitivity ensured that unmatched events represented true opportunities to improve workflows, technical systems, or prescriber training. Several interventions were developed to target deficient areas. The measurement and incentive program will continue in 2009 with a higher target rate (85%) and will transition to an individual measure in 2010, facilitated by a transition from manual to automated matching.

SPONSORSHIP: This research was funded by Massachusetts General Physicians Organization, Boston, MA.

Measuring the Impact of Outreach Phone Calls on Statin Compliance

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BACKGROUND: Nonadherence to prescription medications is a documented public health problem. Medication nonadherence costs an estimated $100 billion annually in the United States and accounts for 10% of hospital admissions. Medication persistence among patients with chronic conditions is considerably low, dropping most dramatically after the first 6 months of therapy. Approximately half of patients receiving statins will discontinue their medication within 6 months of starting the therapy.

OBJECTIVE: To (a) improve medication adherence and cholesterol screening; and (b) determine if outreach phone calls can influence compliance to statin medications.

METHODS: The plan utilized outbound phone calls to encourage compliance with statins and regular cholesterol testing. The study included a randomized population and various statistical methods to test for differences between study and control groups both in the baseline and analysis periods. The population included members with pharmacy coverage and a diagnosis of diabetes or cardiac disease consistent with HEDIS specifications and a recent LDL cholesterol level over 100. Members with claims evidence of certain side effects of statin use were excluded. The identified members were randomly assigned into study and control groups. The outcome metrics included statin compliance and percentage of members without a statin prescription. Compliance is defined as the ratio of the total days supply with statin and the total days in the follow-up period.

RESULTS: There were a total of 72,678 members in the study group and 24,247 members in the control group. 23,488 members were reached by phone calls. There were no significant differences between study and control groups in mean compliance rate and proportion of members without statin (P > 0.05). However, the subset analysis of members who were reached showed significant differences relative to the control groups (P < 0.001) after adjusting for differences in age, gender, and risk. Members who were reached had a significantly higher statin compliance (0.70 vs. 0.63, P < 0.001) with fewer members without a statin (17.0% vs. 22.18%, P < 0.001).

CONCLUSIONS: Overall, no increase in the use of statin therapy was observed for the group that received the outreach; however, members who heard the call showed significantly greater compliance to statins with fewer members without a statin during the follow-up period.

SPONSORSHIP: There was no external funding for this research.

Measuring Time to Goal in Newly Diagnosed Patients with Type 2 Diabetes Identified Using Electronic Health Record Data

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BACKGROUND: Current treatment guidelines for type 2 diabetes (T2D) recommend that patients achieve a hemoglobin A1c (A1c) measurement of < 7%. Little is known about the time it takes a newly diagnosed patient to reach this goal and whether time-to-goal (TTG) varies for different first-line therapies.

OBJECTIVE: To characterize first-line therapies (any oral antidiabetic drug or insulin) prescribed for newly diagnosed T2D patients and assess TTG differences for combination (2 or more drugs) versus monotherapy.

METHODS: We performed a retrospective (2004-2008) analysis of electronic health record (EHR) data from Geisinger Health System, an integrated health care delivery system. Eligible patients with T2D were identified by lab data (A1c > 7%) and ICD-9-CM codes (250.x); the T2D diagnosis (“index”) date was defined as the earliest date any eligibility criterion appeared in the EHR. Patients were required to have 12 months of history in the EHR prior to diagnosis and 4 or more A1c measurements. First-line therapy was defined as medication(s) prescribed closest to the index date. TTG was defined as time between the index date and the first A1c < 7%. Cox proportional hazard regression was used to assess TTG.

RESULTS: We identified 3,882 newly diagnosed T2D patients, of whom
2,410 (62%) had A1c < 7% at the index date and were excluded. Of the remaining 1,472 patients, 50% were female; 97% were Caucasian; and mean age was 59 years. The majority of patients (57%) initiated monotherapy versus 8% on combination therapy; 35% did not initiate drug therapy. Overall, 77% reached goal during the study period; TTG differed significantly by first-line therapy. After applying Cox regression to control for age, baseline A1c, and year of diagnosis, effects of therapy type remained significant; monotherapy versus combination therapy: Hazard ratio (HR) = 1.37 (95% CI = 1.08-1.73; P = 0.009); monotherapy versus none: HR = 1.39 (95% CI = 1.22-1.59; P < 0.05); and none versus combination therapy: HR = 0.98 (95% CI = 0.77-1.26; P = 0.90) (see Table above).

CONCLUSIONS: These data suggest that T2D patients who initiate monotherapy upon diagnosis of T2D have a shorter TTG than patients initiating combination or no therapy, a finding that differs from other studies. These incident diabetics may differ from other studied populations. Further analysis is needed to characterize the TTG first-line therapy relationship in this population.

SPONSORSHIP: This research was funded by Takeda Pharmaceuticals North America, Inc., Deerfield, IL.

— Medical Service Cost Associated with Pioglitazone and Sulfonylurea Treatment Among Type 2 Diabetic Patients Enrolled in an Integrated Health Care System

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BACKGROUND: Sulfonylureas (SU) and pioglitazone (PIO) are 2 commonly used oral antidiabetic medications for treatment of type 2 diabetes mellitus (T2DM). However, there are limited published data regarding economic outcomes associated with PIO and SU therapy in a real-world setting.

OBJECTIVE: To assess overall and diabetes-related medical service costs associated with PIO and SU treatment among T2DM patients.

METHODS: A retrospective cohort study based on electronic medical records (January 1, 2004-January 31, 2009) from the Geisinger Clinic was used to compare medical service costs between T2DM patients who were initiated on PIO or SU therapy. The date of the initial prescription for PIO or SU was denoted as the index date. Patients were required to be aged 18 years or older and prescribed an oral antidiabetic treatment in the 1 year prior to index. Patients with type 1 or gestational diabetes and prior insulin use were excluded, as were those who had prescriptions for the index drug in the 90 days prior. Propensity score 1:1 matching and a second stage of generalized linear regression were employed to assess overall and diabetes-related medical service costs (pharmacy costs were not available in the database) in the 2 years following the index date, adjusting for patient demographics, baseline comorbidities, medication use, and health care resource utilization.

RESULTS: A total of 2,758 patients, 1,379 each in the PIO and SU cohorts, were analyzed. For both cohorts, mean age was 62 years; 46% were male; and 96% were Caucasian. The 2 cohorts were similar in terms of current smoking status and diabetes-related comorbidities. The unadjusted total and diabetes-related medical costs were $1,258 and $705 higher for SU versus PIO patients. Inpatient services were 61% of overall and 84% of diabetes-related medical service costs. After adjusting for covariates, the overall and diabetes-related medical service costs remained higher for patients receiving SU versus PIO ($8,360 vs. $7,400 for overall, and $5,577 vs. $5,238 for diabetes-related costs, P < 0.05 for both comparisons).

CONCLUSIONS: Over a 2-year follow-up, patients with T2DM initiated on PIO therapy incurred lower overall and diabetes-related medical service costs than patients initiated on SU. Further studies describing clinical and humanistic aspects of PIO versus SU are warranted.

SPONSORSHIP: This research was funded by Takeda Pharmaceuticals North America, Inc., Deerfield, IL.

— Medication Reconciliation Implementation at a Medicaid Managed Care Plan

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BACKGROUND: In March 2009, a medication reconciliation program was implemented at a Medicaid managed care plan in Orange County, California. The goal of the program is to provide prompt assistance to recently discharged Medicaid members to evaluate the medication regimen, facilitate access to hospital discharge medications, and to review all of the medications with the member to increase understanding and compliance.

OBJECTIVE: To evaluate the impact of a medication reconciliation program at a Medicaid managed care plan on rehospitalization rates.

METHODS: All members hospitalized from June 1, 2009, to August 31, 2009, who received pharmacist medication reconciliation were selected for the analysis. To evaluate the impact on rehospitalization rates, a control group of members was selected from the same time period a year prior, June 1, 2008, to August 31, 2008. The control group was identified using similar parameters as the intervention group: similar male/female ratio; similar age range; at least 1 hospitalization between June 1, 2008, to August 31, 2008; and similar length of stay. Once the control group was identified, rehospitalization rates within 30 days of the first admission that were identified during the time period of June 1 to August 31 were compared between the 2 groups.

RESULTS: Fifty-nine members were hospitalized between June 1, 2009, and August 31, 2009, and received medication reconciliation services from a plan pharmacist. In this intervention group, 28 members were female (47%), and 31 were male (53%). The average age was 39 years. The average hospital stay was 5 days. Eleven of the 59 patients were...
rehospitalized within 30 days (18.6%). Fifty-nine members were identified as controls and were hospitalized at least 1 time between June 1, 2008, and August 31, 2008. In the control group, 30 members were female (51%), and 29 were male (49%). The average age was 45 years. The average hospital stay was 4 days. Sixteen of the 59 members were rehospitalized within 30 days (27.1%).

**CONCLUSIONS:** Medication reconciliation performed by pharmacists resulted in improving outcomes and decreasing rehospitalization rates through member education and facilitating access to discharge medications.

**SPONSORSHIP:** There was no external funding for this research.

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**Misleading Claims by Pharmaceutical Manufacturers: A Trend Analysis of the Warning Letters Issued by the U.S. Food and Drug Administration from 2003-2008**

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**BACKGROUND:** Previous studies reported an increase in the empirical judgment of the FDA pertaining to marketing and promotional activities of pharmaceutical manufacturers in the last decade. This led to a Health and Human Services policy implementation in 2002, which required the Office of Chief Counsel to review warning letters before they were issued by the FDA.

**OBJECTIVE:** To (a) conduct a content analysis of warning letters issued by the FDA from 2003-2008 to pharmaceutical manufacturers after the policy implementation; and (b) evaluate frequently violated claims, therapeutic categories, and the target audience to determine if there was any trend associated with these letters after the policy implementation.

**METHODS:** Warning letters issued by the Division of Drug, Marketing, Advertising and Communications (DDMAC) of the FDA to manufacturers for misleading drug promotional claims to physicians and consumers were downloaded and printed from the FDA website. A data abstraction form was developed that included the name of the drug, manufacturer, therapeutic category, type of claim violated, and targeted audience for the claim. Misleading claims were broadly classified as clinical (unsubstantiated efficacy, safety and tolerability, superiority, broadening of indication, and/or omission of risk information), humanistic (unsubstantiated quality of life and/or health-related quality of life claims), and others. Any promotional claim other than clinical and humanistic claims was placed in the others category. SAS 9.1 was used for analysis.

**RESULTS:** In the 6-year study period, 65 warning letters were issued by FDA, which contained violations for a total of 183 claims and around 3 claims per letter. There were 144 clinical, 3 humanistic, and 36 other claims. Omission of risk information was the most frequently violated claim (30.6%) followed by unsubstantiated efficacy claims (23.6%). The majority of these letters were issued to manufacturers of cardiovascular (14.6%), antimicrobial (14.6%), and central nervous system agents (14.6%). Superiority claims were the second most frequently violated claim (14.6%) followed by claims directed at physicians (12.3%) and contained violation for claims directed to consumers (12.3%). An average of 11 warning letters per year was observed, which was higher than a previously yearly average of 2 during 1997-2002.

**CONCLUSIONS:** The rise in warning letters following the policy implementation signifies the increased FDA surveillance in recent years of pharmaceutical manufacturer's promotional activities. Managed care decision makers in the formulary inclusion process should be aware of these violations to develop appropriate strategies of patient care.

**SPONSORSHIP:** There was no external funding for this research.

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**Novel Methodology to Measure Adherence to Complex Medication Regimens in HIV/AIDS Patients**

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**BACKGROUND:** Patients with HIV/AIDS often have complex and evolving drug treatment regimens where high levels of adherence are required to achieve clinical benefits. These multi-drug regimens pose a challenge for evaluating a patient’s medication adherence based on pharmacy claims data. Traditional measures of medication possession ratio (MPR) can fail to provide an accurate measure of adherence for complex regimens with frequent therapy switching.

**OBJECTIVE:** To design a multidrug adherence measure that enables more accurate targeting of patients for pharmacist interventions.

**METHODS:** A new methodology for measuring adherence with multidrug therapy regimens was tested for a sample of HIV patients identified in a national pharmacy claims database. Patients were 18 years of age or older, had continuous eligibility for prescription benefits for a minimum 6-month period, and had filled prescriptions for 2 or more HIV drugs or a combination HIV drug. Medication use was tracked over a 6-month period. MPR was initially calculated at the drug level for each patient and then adjusted for drug discontinuations and switches. Discontinuation of therapy was identified by a gap of 45 days or more in days supply of a given drug. A therapy switch was identified by a new drug claim within 15 days before or after the discontinuation date of the previous drug. After adjusting for drug switches, the drug-level MPR measures were aggregated at the patient level to define a new metric, the medication adherence rate (MAR). The results of the new measure were compared with the traditional measure of MPR.

**RESULTS:** The widest disparities between the 2 metrics were observed for patients identified as having lower adherence by traditional MPR measurement. The traditional MPR tended to underestimate adherence for patients making drug switches because it did not fully account for the additional days supply of the newly added drug.

**CONCLUSIONS:** The new methodology better represents adherence for complex and dynamic HIV medication regimens, thereby providing a more accurate basis for identifying low-adherence patients for pharmacist interventions.

**SPONSORSHIP:** This research was funded by Medco Health Solutions, Inc., Franklin Lakes, NJ, and Pfizer Inc., New York, NY.

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**Oral Oncology Prescription Abandonment Association with High Out-of-Pocket Member Expense**

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**BACKGROUND:** Increased out-of-pocket (OOP) member expense may result in members abandoning therapy. Oral oncology regimens can fail to provide an accurate measure of adherence for complex regimens with frequent therapy switching.

**OBJECTIVE:** To determine if a relationship exists between increasing member OOP expense and the prescription abandonment rate for oral oncology agents.

**METHODS:** Members attempting to newly initiate an oral oncology agent (defined as no paid claim in the previous 90 days) were identified from approximately 8 million commercial members during July 2006 to June 2009. Oral oncology agents included Tarceva, Gleevec, Sutent,
Nexavar, Tykerb, Syclret, and Tasigna. Members were continuously enrolled +/-90 days from their first adjudicated (paid or reversed claim). Abandonment was defined as a reversed oral oncology claim and no paid claims in the ensuing 90 days. The member OOP expense from their first adjudicated oral oncology claim was captured. The proportion of members abandoning in each OOP expense group ($0-$100, $101-$200, $201-$500, or >$500) was calculated. Oral oncology abandonment rate association with member OOP expense was tested using a logistic regression model ($0-$100 OOP as the reference group) adjusting for age, gender, and oral oncology drug.

RESULTS: Overall, 1,909 members (average age 55 years, 51.7% male) had an adjudicated oral oncology claim and 163 (8.5%) abandoned therapy. Tarceva and Gleevec were the most commonly utilized agents with 722 (37.8%) and 427 (22.4%) members, respectively. Average member cost share was $293.09 (SD = $825.75). The majority of members' OOP expense was $0-$100 (81.8%). The abandonment rate was 4.9% (77 of 1,562) in the $0-$100 group, 6.5% (2 of 31) in the $101-$200 group, 16.1% (9 of 56) in the $201-$500 group, and 28.8% (75 of 260) in >$500 group. Multivariate logistic regression OR for abandonment in each OOP group were $0-$100 OR = 1.48, 95% CI = 0.34-6.35; $201-$500 OR = 3.66, 95% CI = 1.70-7.88; >$500 OR = 5.98, 95% CI = 2.77-12.44. Age and gender were not associated with abandonment.

CONCLUSIONS: One in 6 members with an OOP expense of greater than $200 abandoned therapy and were at least 3 times more likely to abandon than members with an OOP of $100 or less. Health insurers should consider member cost share potential impact on abandonment rates when designing pharmacy benefits.

SPONSORSHIP: This research was funded by Prime Therapeutics LLC, Eagan, MN.

2. Patterns of Care for Patients with Chronic Myelogenous Leukemia in a Commercially Insured Population in the United States

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BACKGROUND: Treatment with clopidogrel reduces secondary cardiovascular events following hospitalization for acute coronary syndrome (ACS). The use of clopidogrel is required for patients undergoing Percutaneous Coronary Intervention or medically managed patients undergoing medical management.

OBJECTIVE: To evaluate ACS patient characteristics and clopidogrel use in the first 30 and 60 days, and the impact of patients who receive clopidogrel pharmacy fills within these timeframes.

METHODS: To evaluate ACS patient characteristics and clopidogrel use in the first 30 and 60 days, and the impact of patients who receive clopidogrel pharmacy fills within these timeframes.

RESULTS: Of the 2,293 patients identified, 1,626 (71%) had a clopidogrel prescription filled within 30 days, and 1,479 (65%) had a clopidogrel prescription filled within 60 days. The majority of patients (62%) were able to fill their clopidogrel prescription within 7 days. Patients who received a second line drug (n = 9), all had lab test within 90 days prior to the index date. The median time from diagnosis to first treatment was 3.7 months. 48 patients (80%) consistently had Q3 lab test performed during drug therapy. However, 12 patients (20%) had no labs prior to first dose, the median time from diagnosis to first drug was 3.7 months. 48 patients (80%) consistently had Q3 month or more frequent labs performed during drug therapy. However, 12 patients had at least one 3-month period with no lab tests. 85% had Q-PCR, 13% had RT-PCR, 2% had FISH; and no patients had karyotyping before mutation analysis. PCR testing was carried out prior to treatment in 58% of patients. Although we were unable to account for every specialty lab, in general it appears that CML-specific molecular tests use met or exceeded NCCN guidelines. PCR testing was carried out prior to drug change; however, the use of mutation analysis was not identified. Educational efforts to promote the use of karyotyping/FISH analysis should be considered.

SPONSORSHIP: This research was funded by Bristol-Myers Squibb, Plainsboro, NJ.
Pharmacist-Led Oncology-Based Authorization and Reimbursement Center

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BACKGROUND: University of Southern California (USC) Norris Cancer Hospital is a 60-bed USC-owned and operated research and teaching hospital with an outpatient chemotherapy infusion center. Hospital administrations review of Norris financial reporting revealed evidence of poor reimbursement of chemotherapy agents administered through the outpatient infusion center adding to larger write-off amounts for unpaid and disputed claims.

OBJECTIVE: To determine whether a managed care trained pharmacist could improve overall chemotherapy reimbursement from third-party payers for USC Norris Cancer Hospital.

METHODS: Hospital administration hired a managed care pharmacist with health plan and PBM background to investigate the issues surrounding the poor financial reimbursement of chemotherapy-based reimbursement. The pharmacist was given the task with the responsibility of reporting the findings back to the administration and developing a process improvement plan based on the findings to improve reimbursement of chemotherapy drugs.

RESULTS: Eighteen months post-implementation of a clinical-based authorization process, the pharmacist-led center demonstrated significant improvements in hospital revenue through a reduction in the number of unpaid and disputed claims and was instrumental in securing approximately $1 million through a combination of chemotherapy drug or payment through effective use of the manufacturer-sponsored drug replacement programs.

CONCLUSIONS: The managed care pharmacist-led authorization center was instrumental in improving the hospital’s overall reimbursement on chemotherapy through the advent of a clinical authorization process that reduce disputed claims and reduced pharmacy costs through procurement of chemotherapy drug product through various manufacturer-sponsored patient assistant programs.

SPONSORSHIP: There was no external funding for this research.

Prevalence of Diabetes and Lipid-Lowering Medications by Antipsychotic Drug in a Commercial Population

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BACKGROUND: Cardiovascular mortality rates for patients with schizophrenia are twice that of the general population. This is due to multiple factors, including medication therapy. Some antipsychotics may detrimentally impact certain metabolic parameters, such as lipid control and insulin resistance.

OBJECTIVE: To evaluate the prevalence of lipid-lowering and diabetes medication use in patients receiving antipsychotics according to prescription claims.

METHODS: A retrospective analysis of commercial pharmacy claims was conducted by a pharmacy benefit manager on antipsychotic claims submitted between August 2008 and August 2009. The data was then analyzed to identify those antipsychotic claims with concomitant claims for diabetes and lipid-lowering medications. Members must have had at least 3 claims for 1 antipsychotic to be included.

RESULTS: 5,924 unique patients, average age 49.1 ± 18.2 years and 55% female, had 77,473 total prescriptions claims for antipsychotics, diabetes, or lipid-lowering medications—a median of 8 claims per patient. 89% of patients received atypical antipsychotics: quetiapine (47%), risperidone (22.9%), aripiprazole (19%), olanzapine (10.8%), and ziprasidone (6.8%). 6% received haloperidol. 10.8% of patients received more than 1 antipsychotic agent; 1% received 3 or more agents. Concomitant lipid-lowering and diabetes medications were present in 21% and 10.7% of patients, respectively. Logistic regression analyses, controlling for age, gender, class of antipsychotic (atypical vs. typical), specific antipsychotic agent, duration of antipsychotic use, and antipsychotic polypharmacy, demonstrated that haloperidol (OR = 1.17, CI = 1.1-1.2), aripiprazole (OR = 1.07, CI = 1.05-1.08), risperidone (OR = 1.06, CI = 1.05-1.08), olanzapine (OR = 1.06, CI = 1.03-1.08), quetiapine (OR = 1.06, CI = 1.05-1.07),
and ziprasidone (1.04, CI = 1.02-1.06) were significantly more likely (all P < 0.001) to be associated with the use of lipid-lowering medications. Controlling for the same parameters, haloperidol (OR = 1.14, CI = 1.1-1.2), aripiprazole (OR = 1.07, CI = 1.05-1.09), risperidone (OR = 1.05, CI = 1.04-1.07), olanzapine (OR = 1.05, CI = 1.02-1.08), ziprasidone (OR = 1.05, CI = 1.03-1.07), and quetiapine (OR = 1.05, CI = 1.04-1.06) were significantly more likely (all P = 0.003) to be associated with the use of diabetic medications.

CONCLUSIONS: Consistent monitoring of metabolic parameters in patients receiving antipsychotic medication is an important step in controlling cardiovascular risk. Implementation of a more coordinated approach to patient care may help improve the health status of this population.

SPONSORSHIP: There was no external funding for this research.

Proton Pump Inhibitor Prescribing and Utilization Patterns in an Era of Generic and Over-the-Counter Availability

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BACKGROUND: With the increasing availability of generic and over-the-counter proton pump inhibitors (PPIs), there is a need to reassess PPI utilization patterns in patients receiving prescription PPIs through their pharmacy benefit.

OBJECTIVE: To examine current PPI utilization patterns.

METHODS: Using pharmacy and medical claims data from Medicare Part D and commercial members, we identified patients started on a PPI between January and May 2008. With a hierarchical approach, we stratified patients into 1 of 7 PPI indication cohorts: (1) gastrointestinal (GI) hypersecretory condition, (2) GI ulcer plus gastroesophageal reflux disease (GERD), (3) GI ulcer, (4) GERD, (5) nonsteroidal anti-inflammatory drug (NSAID) prescription, (6) nonindicated (off-label) GI condition, or (7) no indication. For each cohort, we examined the average number of tablets/capsules per day, average daily dose, average duration, and average pharmacy ingredient cost over a 180-day follow-up period.

RESULTS: Among 26,440 patients identified, breakdown by PPI indication was as follows: GI hypersecretory condition 0%, GI ulcer plus GERD 2%, GI ulcer 3%, GERD 25%, NSAID prescription 15%, nonindicated (off-label) GI condition, or (7) no indication. For each cohort, we examined the average number of tablets/capsules per day, average daily dose, average duration, and average pharmacy ingredient cost over a 180-day follow-up period.

CONCLUSIONS: Although PPI utilization appeared appropriate for most indications, over 85% of patients received only 1 tablet/capsule per day without a documented PPI indication contributed 41% of PPI costs, and significantly more likely (all P = 0.003) to be associated with the use of diabetic medications. PPI medica-

Sponsorship: There was no external funding for this research.

Retrospective Comparison of Medication Adherence Between Once Weekly Generic and Branded Bisphosphonates

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BACKGROUND: Bisphosphonates are commonly used to prevent and treat osteoporosis and decrease fracture risk by inhibiting bone resorption. The first generic bisphosphonate, alendronate, became available in February 2008. Alendronate is an AB-rated generic of Fosamax; therefore, it is inferred that the side-effect and efficacy profile of the generic will be comparable to brand Fosamax and Actonel (risedronate). Many health plans are promoting generic conversion programs; however, questions have arisen regarding the side effect profile of alendronate.

OBJECTIVE: To compare adherence and switch rates between weekly generic alendronate and weekly brand bisphosphonates Fosamax and Actonel.

METHODS: A retrospective database analysis of pharmacy claims was conducted for patients on once-weekly bisphosphonate therapy. Two cohorts identified as new starts to either brand or generic bisphosphonates were compared. New start was defined as patients having no claims for a bisphosphonate 120 days prior to the first fill in the study period (index date). New starts of Fosamax and Actonel (brand group) were identified between November 1, 2006, and January 31, 2007, while alendronate (generic group) new starts were identified between February 6, 2008, and April 30, 2008. Both groups were followed for 12 months after the index date. Patients had to be continuously enrolled from the beginning of the study period until 12 months after the index date for both groups. Switch rate and medication adherence was compared between the 2 groups using the 2-sample T-test. Medication adherence was measured using the Medication Possession Ratio (MPR) and required patients to have at least 2 claims for the comparator agents.

RESULTS: 371 and 120 patients met the inclusion criteria for analysis in the brand and generic groups, respectively. The brand group had 347 (93.5%) females, while the generic group had 110 (91.7%) females. The mean age was 65 years and 70.5 years for the brand and generic groups, respectively. There was no statistically significant difference between the mean MPVs of the brand and generic groups (0.773 vs. 0.768, P = 0.862). 17 (4.85%) patients switched from either Fosamax or Actonel to another branded bisphosphonate, while 2 (1.67%) patients switched from alendronate to a branded agent.

CONCLUSIONS: Both the weekly brand and generic groups demonstrated good patient acceptance based on comparable adherence and the low number of switches to alternate products. These findings favor therapeutic interchange programs designed to switch patients from weekly brand products to weekly alendronate.

SPONSORSHIP: There was no external funding for this research.

Trends in Cost-Effectiveness of High Budget Impact Drugs

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BACKGROUND: As health care payers in developed nations come under increased budgetary pressures, it is evident that the medical products that are not superior in efficacy or are not cost-effective would not be covered by payers. The recently made coverage decisions by UK’s NICE, Scotland’s SMC, and the allocation of $1.1 billion for comparative effectiveness research by the United States provide a strong indication of trends in pricing and reimbursement that would be observed in the future.
OBJECTIVE: To (a) analyze the cost-effectiveness studies for the top 20 highest-selling drugs, which collectively generated ~ $150 billion-$160 billion in worldwide sales in 2008; and (b) understand the trends in cost-effectiveness of top 20 highest selling drugs.

METHODS: For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas, and availability of generic alternatives. We analyzed the model methodologies and incremental cost-effectiveness ratios of these drugs.

RESULTS: Our analysis shows that there is a large variability in cost-effectiveness ratios for the same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable cost-effectiveness ratios than specialty drugs. For example, incremental cost-effectiveness ratios (ICER) for clapidogrel range from $13,000 to $32,000/QALY, whereas for bevacizumab, it ranged from $125,000 to $390,000 per quality-adjusted life year (QALY), based on indications. Our analysis of “availability of generic alternatives” and the “impact of new clinical evidence” shows that previously deemed cost-effectiveness drugs, could be re-assessed as being not cost-effective when generics or new branded drugs with comparable efficacy become available (e.g., CATIE clinical trial data for quetiapine). This will play a major role in the future, as more payers, including the U.S. public payer Centers for Medicare and Medicaid Servives, are exploring ways to design a continuum in coverage decision-making process, implying that updated cost-effectiveness ratios could change previously established coverage policies. Furthermore, we found some drugs used a longer time horizon to demonstrate cost-effectiveness, while others used a shorter duration.

CONCLUSIONS: Our complete analysis shows the range, variability, and methods used for calculation of ICER values for these high budget impact drugs and provide lessons for executives and health care policy makers.

SPONSORSHIP: This research was funded by PAREXEL International, Waltham, MA.

Trends in HIV-1 Resistance Mutations and Antiretroviral Prescription Data from 2003-2008

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BACKGROUND: The availability of multiple fixed-dose drug combinations has the potential to reduce the development of HIV-1 resistance mutations. Moreover, use of fixed-dose drug combinations has shown a lower rate of M184V development in comparison to 3TC in clinical trials.

OBJECTIVE: To analyze the overall time trends in HIV-1 resistance mutation prevalence within a large U.S. database and compare this to antiretroviral drug usage over the same period.

METHODS: All samples submitted for routine resistance analysis (phenotype or genotype) to Monogram Biosciences from 2003-2008 were analyzed for HIV-1 resistance mutations. For the same period, total retail and mail-order U.S. drug prescription data were acquired (Wolters Kluwer Health Prescription Database). Changes in mutation prevalence and antiretroviral usage by year were analyzed in tandem.

RESULTS: Among all samples analyzed (n = 79,993), the 8 most prevalent RT and protease resistance (PI-R) mutations were M184V, K103N, M41L, T215Y, L90M, D67N, K70R, and L210W, respectively. From 2003-2008, there was an apparent ~60% reduction in the prevalence of resistance mutations. For M184V, prevalence declined from 43% to 22%. K65R also declined from 4.3% to 2.3%. When samples were selected with NNRTI resistance but <3 TAMs and no PI-R (presumed early NNRTI regimen failures, n = 15,695), prevalence of K103N was stable at ~70%, but M184V still decreased over time (48% to 29%), as did K65R (5.4% to 2.5%) and other nucleoside-associated mutations. NNRTI-R mutations G190A/S and Y181C also decreased, whereas L100I and P225H increased. Over the same time period, EFV use increased by 50%; use of FTC relative to 3TC increased from 1% to 60%; AZT use declined by 50%; abacavir was stable; and tenofovir DF use increased ~3-fold. Moreover, there has been a striking increase in the use of fixed-dose drug combinations over this period.

CONCLUSIONS: Overall, the prevalence of antiretroviral resistance mutations decreased from 2003-2008, while the use of fixed-dose combinations has increased. Tenofovir DF and FTC use has also increased markedly, while the prevalence of their corresponding resistance mutations, K65R and M184V, has decreased. Albeit multifactorial in causality, increased use of FTC relative to 3TC, decreased use of AZT, shorter periods of virologic failure, and increased use of fixed-dose combinations/ regimens are likely contributing factors.

SPONSORSHIP: This research was funded by Gilead Sciences, Inc., Foster City, CA.

Two-Year Longitudinal Study of Biologic Switching and Discontinuation Among Rheumatoid Arthritis Patients in a Health Plan

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BACKGROUND: Biologic agents are efficacious in the treatment of rheumatoid arthritis (RA). Varying mechanisms of action, including inhibition of tumor necrosis factor, B-cells, and T-cells, offer clinicians and patients different biologic treatment options. However, some patients do not have an adequate clinical response, lose response over time, or experience adverse events and require a switch to another biologic or discontinuation of biologic therapy. Health plans may be interested in understanding the potential for biologic switching within their RA population.

OBJECTIVE: To estimate the proportion of RA patients switching or discontinuing biologics, and describe patterns of switching and discontinuation across biologic agents.

METHODS: A retrospective study utilizing medical and pharmacy claims from a large health plan database was conducted for adult RA patients receiving abatacept, adalimumab, etanercept, or infliximab. The first biologic between January 1, 2005, and June 30, 2006, was identified (index date), and patients were followed for 24 months after starting the index biologic. Discontinuation was defined as a gap of ≥ 60 days beyond the last days supply of drug. Switching was defined as use of a different biologic after the index biologic, with no discontinuation. The specialty of the provider who prescribed the first switch was determined.

RESULTS: A total of 1,794 patients using biologics were analyzed. Over two-thirds (77%) were female, and the mean age was 50 ± 12 years. Overall, a total of 1,168 (65%) patients switched or discontinued the index biologic; 222 (12.4%) of all biologic patients switched at least once; and 946 (52.7%) of all biologic patients discontinued. Biologic users took, on average, 269 ± 186 days to experience the first switch and 197 ± 181 days to discontinue the index biologic. The majority of first switches (81.5%) were prescribed by rheumatologists.

CONCLUSIONS: These results indicate that while just over one-third of RA biologic users in a health plan (35%) stay on their initial biologic,
half discontinue, and about 12% switch at least once in 2 years following their first treatment with a biologic. Further studies are needed to investigate the reasons for biologic switching and discontinuation and their impact on economic and clinical outcomes.

**SPONSORSHIP:** This research was funded by Centocor Ortho Biotech Services, LLC, Horsham, PA.

### U.S. and UK Budget Impact Estimates and Cost-Effectiveness Analyses (CEA) of Lopinavir/Ritonavir (LPV/r) and Atazanavir Plus Ritonavir (ATV+RTV) Regimens for Antiretroviral Naive HIV-1 Infected Patients Based on CASTLE 48-Week Study Results

**BACKGROUND:** The CASTLE trial, comparing the protease inhibitors LPV/r and ATV+RTV each combined with tenofovir/emtricitabine, showed no significant clinical differences in the percent of patients with viral load (VL) < 50 copies/mL or in CD4+ T-cell count increase at 48 weeks. However, total cholesterol (TC) levels were elevated in 18% and 7% of patients receiving LPV/r and ATV+RTV, respectively, at 48 weeks. Measures of VL, CD4+ T-cells, and TC predict specific clinical outcomes, which affect the future cost of managing HIV. This is an important issue in the U.S. and UK health care systems.

**OBJECTIVE:** To conduct U.S.- and UK-derived CEA and budget impact analyses comparing LPV/r with ATV+RTV for antiretroviral-naive patients, contrasting national results.

**METHODS:** We used newly developed cost data in a previously published Markov model of HIV disease, which incorporated coronary heart disease (CHD) events based on TC levels at 48 weeks using the Framingham equation. We compared the short- and long-term budget impact of the 2 regimens. A baseline CHD risk of 4.6% was assumed for the analysis population. Baseline TC and CD4+ T-cell distribution was similar to the CASTLE population. U.S. costs were based on utilization records for HIV-1 infected South Carolina Medicaid patients from 2004 to 2006. UK costs were based on CD4+ T-cell group-specific utilization rates recorded for 5,766 British patients from 2004 to 2006. All costs were indexed to 2009. A health services (all payor) perspective was calculated using paired t-test for normally distributed continuous measures and Wilcoxon signed-rank test for non-normally distributed data.

**RESULTS:** A total of 9,988 fibromyalgia cases and 9,988 matched controls were included in the analysis. The mean [SD] annual utilization of pain-related medications was 2.1 times higher among the cases (8.5 [13.6]) compared with the controls (3.9 [8.3]) during the 12-month pre-diagnosis period and 2.4 times higher among cases (10.6 [15.4]) than controls (4.4 [9.0]) in the 12-month post-diagnosis period (P<0.001). The most commonly used medications were opioids and NSAIDs. During the 12-month pre-diagnosis period, the mean [SD] outpatient services utilization per year among the cases was 22.5 [23.9] versus 14.8 [20.5] among controls and 31.1 [26.6] versus 16.3 [24.5], respectively, during the 12-month post-diagnosis period (P<0.001). Office visits, tests, and procedures represented the majority of utilization within outpatient services. The mean per patient per month costs for outpatient services during the 12-month pre-diagnosis period were 27.3% higher among the cases ($261) compared with the controls ($190), and 42.2% higher among the cases ($377) compared with the controls ($217) during the 12-month post-diagnosis period (P<0.001).

**CONCLUSIONS:** Fibromyalgia subjects had significantly higher health care utilization and costs than controls. Office visits, tests, procedures, and use of pain-related medications accounted for the largest absolute differences between the 2 groups.

**SPONSORSHIP:** This research was funded by Pfizer Inc., New York, NY.

### Use and Costs of Health Care Resources in Fibromyalgia: A Case Control Comparison

**BACKGROUND:** Significantly higher total health care costs have been reported among patients with fibromyalgia. However, a more detailed understanding of the determinants of utilization and costs among these patients is lacking.

**METHODS:** We used a retrospective cohort design to analyze 24 months of Humana members’ medical and pharmacy claims data comparing health care utilization and costs among members with fibromyalgia and a propensity score matched control group. Health care services were categorized into outpatient, emergency room (ER), inpatient, and pharmacy (pain-related and nonpain-related). We identified as fibromyalgia cases members 18 years and older, with at least 2 medical claims for ICD-9-DM codes 729.0 and/or 729.1 between June 2002 and March 2007. The first medical claim for fibromyalgia was the index date. Statistical significance of differences among cases and controls was calculated using paired t-test for normally distributed continuous measures and Wilcoxon signed-rank test for non-normally distributed data.

**RESULTS:** A total of 9,988 fibromyalgia cases and 9,988 matched controls were included in the analysis. The mean [SD] annual utilization of pain-related medications was 2.1 times higher among the cases (8.5 [13.6]) compared with the controls (3.9 [8.3]) during the 12-month pre-diagnosis period and 2.4 times higher among cases (10.6 [15.4]) than controls (4.4 [9.0]) in the 12-month post-diagnosis period (P<0.001). The most commonly used medications were opioids and NSAIDs. During the 12-month pre-diagnosis period, the mean [SD] outpatient services utilization per year among the cases was 22.5 [23.9] versus 14.8 [20.5] among controls and 31.1 [26.6] versus 16.3 [24.5], respectively, during the 12-month post-diagnosis period (P<0.001). Office visits, tests, and procedures represented the majority of utilization within outpatient services. The mean per patient per month costs for outpatient services during the 12-month pre-diagnosis period were 27.3% higher among the cases ($261) compared with the controls ($190), and 42.2% higher among the cases ($377) compared with the controls ($217) during the 12-month post-diagnosis period (P<0.001).

**CONCLUSIONS:** Fibromyalgia subjects had significantly higher health care utilization and costs than controls. Office visits, tests, procedures, and use of pain-related medications accounted for the largest absolute differences between the 2 groups.

**SPONSORSHIP:** This research was funded by Pfizer Inc., New York, NY.

### Utilization of Psoriasis Assessment Instruments in Dermatology Offices: Results from a Chart Review

**BACKGROUND:** Managed care plans providing formulary access for the use of biologic agents in plaque psoriasis may need information to assist with the development of biologic utilization guidelines. An understanding of instruments, including severity and health-related quality-of-life measures, used by dermatologists to assess psoriasis will inform payers.
OBJECTIVE: To identify utilization of psoriasis severity measures and validated health-related quality of life instruments in clinical practice.

METHODS: A retrospective medical record review was conducted at 5 community dermatology offices in different geographic regions of the United States. Patients were required to be ≥ 18 years of age, diagnosed with plaque psoriasis, currently treated with a biologic agent for ≥ 3 months, and have therapy immediately preceding first biologic agent available in the medical record. Patients were excluded if they were receiving a biologic for a condition other than plaque psoriasis or currently enrolled in a randomized biologic agent clinical trial.

RESULTS: A total of 279 patients, representing 3,496 dermatology office visits, were included in the analyses. The mean [SD] age was 48.9 [13.1] years, 33.7% were female, and the mean [SD] duration of time with a psoriasis diagnosis was 16.9 [11.4] years. The majority of patients (45.2%) had a PPO as the payer type. Documentation of assessment instruments was recorded for only 7.5% of total visits. The body surface area (BSA; 4.9%; n = 170 visits) and Dermatology Life Quality Index (DLQI; 1.7%; n = 58 visits) were most often used. Upon initiation of a biologic, use of assessment instruments was documented for 35% (n = 97/279) of all patients. BSA, DLQI, Psoriasis Area and Severity Index (PASI), and Physician Global Assessment (PGA) were recorded for 28%, 32.2%, 2.9%, and 0.7% of all patients, respectively.

CONCLUSIONS: Minimal documentation of psoriasis assessment instruments was found in clinical practice. Documentation was more likely at the start of the biologic but in the minority of patients. The predominant severity measure was BSA. Measurement of health-related quality of life, when documented, was done with the DLQI. Payers should consider the real-world frequency of documentation of assessment instruments when developing psoriasis utilization guidelines.

SPONSORSHIP: This research was funded by Centocor Ortho Biotech Services, LLC, Horsham, PA.

■■ Validated Data Analysis Tool Examines Comorbidities, Concomitant Medication Use, and Other Utilization Patterns for Patients with Rheumatoid Arthritis

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BACKGROUND: With the launch of new rheumatoid arthritis (RA) medications with unique mechanisms of action and a variety of administration methods, there is a need to assess and understand treatment patterns for conventional disease modifying antirheumatic drugs (DMARD), biologic treatments (antitumor necrosis factor (TNF) therapies, and non anti-TNF treatment such as interleukin-6 receptor inhibitor, CD20 antigen, and T-cell co-stimulation modulators.

OBJECTIVE: To develop a data analysis tool with a user-friendly interface using pharmacy and medical claims, along with member eligibility information that performs analyses of the treatment utilization patterns for patients receiving RA medications.

METHODS: A Rheumatoid Arthritis Outcomes Analyzer was developed based on published treatment guidelines and evidence-based literature to accommodate importation of claims and eligibility files and perform the treatment utilization analyses. An analysis of patients at least 18 years of age who had received at least 1 traditional (nonbiologic) or biologic DMARD medication between January 2005 and December 2007 was conducted. All patients included had at least 2 RA diagnoses (ICD-9-CM 714.0X) more than 2 months apart. A validation of the model is being conducted with WellPoint to validate the tool and compare results.

RESULTS: A total of 140,383 patients, 10,869 female (75.6%) and 3,514 male (24.4%), were identified with a mean age of 55 years. The mean Charlson Comorbidity Index for the population was 2.06 [SD = 1.68]. Prescription-level analyses revealed a total of 263,294 prescriptions for DMARDs with 183,639 (69.7%) traditional, 77,291 (29.4%) anti-TNF Biologics, and 2,364 (0.9%) non anti-TNF Biologics. Concomitant corticosteroid use was identified in 8,728 (60.7%) of the patients while NSAIDS and a narcotic analgesics were used by 8,717 (60.6%) and 8,113 (56.4%), respectively. Behavioral health medications were the most commonly used other concomitant medications (43.1% [6,197] of patients). The majority of patients (67.4%) received traditional DMARDs only, while 14.7% used only anti-TNF therapies, and 17.3% were treated with an anti-TNF and traditional DMARD.

CONCLUSIONS: Analytic tools such as the Rheumatoid Arthritis Outcomes Analyzer will allow MCOs to better understand utilization and treatment patterns, which in turn will provide valuable insights to inform decision making for the management of patients receiving RA therapies.

SPONSORSHIP: There was no external funding for this research.

■■ Value of Evidence-Based Medicine: Cost Savings with Therapeutic Advances in Pediatric HIV Care

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BACKGROUND: Pediatric HIV is one area of medicine where there has been rapid implementation of results from clinical trials into treatment guidelines, such as that from the AIDS Clinical Trial Group (ACTG) Protocol 076. This evidence-based finding guided treatment with generic zidovudine and reduced perinatal HIV transmission rates from 25.5% to 8.3%, moving us from an era of many pediatric HIV cases to an era of few cases, with cost savings in pediatrics HIV care.

OBJECTIVE: To determine the national longitudinal cost-savings to children when moving from a pre-prophylactic to a post-prophylactic era.

METHODS: We reviewed 354 pediatric medical charts to collect health care utilization on 112 children at a major HIV/AIDS specialty clinic from 1986-2007, each with at least 7 years of data. Costs were assigned for HIV-related drugs (Redbook) and all HIV-related hospital and medical care (CPT/ICD9/HCUP codes). Longitudinal costs by HIV status were compared for children born in the pre-prophylaxis era (1979-1993) with those in the post-prophylaxis era (1994-2007), and log costs were compared with t-tests. National cost-savings were estimated using our average costs and national incidence rates in the 2 eras.

RESULTS: In the pre-prophylaxis era, the average 7-year cost to treat HIV(+) children was $75,262 (95% CI =$42,491-$102,633) and for HIV(-) children was $1,427 (95% CI =$962-$1,892). In the prophylaxis era, treatment cost was $81,150 (95% CI = $60,401-$101,899) for HIV(+) children and $2,993 (95% CI = $1,937-$4,050) for HIV(-) children. The cost difference between HIV(+) (P = 0.064) and HIV(-) (P = 0.288) children across eras was not statistically significant but when comparing HIV(+) to HIV(-) children within an era, the difference was significant (P < 0.001 for both eras). Using those cost averages and national annual incidence and transmission risk statistics, we project a $41.7 million annual national 7-year direct cost savings from using prophylaxis regimens.

CONCLUSIONS: This study represents the first longitudinal comparison of the costs of treating pediatric HIV infection in the pre- and post-prophylaxis eras and represents a model of pediatric chronic disease treatment success across time. When evidence-based medicine is used
to address a chronic disease, such as HIV, successful treatment outcomes result, and as we show here, there can be significant cost savings.

SPONSORSHIP: This research was funded by NIH/NCCRR UCSF-CTSI Grant No. UL1RR024131, Bethesda, MD.

- Value of Financial Analyst Projections for Drug Pipeline Forecasting in Managed Care

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BACKGROUND: Financial analysts typically assess the size of the targeted patient population and the estimated cost of therapy per patient per year to project potential sales broadly based on the following 3 key considerations: (a) probability of FDA approval and related labeling restrictions; (b) potential for high prescriber demand based on the product’s profile and the ability to address unmet clinical needs; and (c) sustainability of high utilization based on payer coverage, market developments in the related therapeutic class, and emergence of safety issues.

OBJECTIVE: To apply financial analyst projections to the list of drugs in the near-term pipeline (within 2 years of approval) in order to identify potential blockbusters and to assess their potential impact on drug utilization.

METHODS: Near-term pipeline data extracted from DrugPipeline Forecast.com were merged with financial projections from publicly available sources in order to compile a list of drugs with an estimated sales potential of at least $600 million per year. Twenty-nine agents were identified and presented to managed care professionals (N = 47). Clinical profile highlights for 15 agents were discussed, and participants were polled on the anticipated impact of the top 4 drugs with the greatest sales potential.

RESULTS: Most participants were pharmacists representing key managed care sectors: managed care organizations (49%), pharmacy benefit managers (25%), department of defense (11%), and specialty or hospital pharmacy (8%). The MSIS-29 scale consists of 20 items evaluating the physical impact from a patient’s perspective. Statistical regression models were used to evaluate changes in physical and psychological impact scores from baseline through the 6th natalizumab infusion after controlling for age, years since MS diagnosis, number of natalizumab infusions received, baseline (BL) disability and functional status, number of MS drugs used prior to natalizumab, and comorbidity burden.

RESULTS: Data from 440 patients indicated that the mean age was 46.6 +/- 10.5 years, 76.3% were female, and they had been diagnosed with MS 10.6 years ago. After controlling for covariates, a statistically significant improvement in physical impact scores (BL 46.87 +/- 16.26, 3rd 39.60 +/- 16.26; 6th 39.27 +/- 16.26; P < 0.001) was observed; similarly psychological impact scores showed statistically significant improvements (BL 4.56 +/- 5.54, 3rd 3.37 +/- 5.54, 6th 3.32 +/- 5.54, P < 0.001) suggesting an improvement over time in physical and psychological well-being after initiating natalizumab.

CONCLUSIONS: This study indicates that patients receiving natalizumab experienced a sustained improvement in their physical functioning and psychological well-being over time in the usual care setting. These results are indicative that natalizumab may have lowered the negative impact of MS on the everyday functioning of patients and are consistent with previously published data showing improvement in physical disability in some patients.

SPONSORSHIP: This research was funded by Biogen Idec, Wellesley, MA.

- What Do Multiple Sclerosis Patients Experience? Effect of Natalizumab on Disease-Specific Quality of Life over Time

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BACKGROUND: Multiple sclerosis (MS) has significant social, psychological, and physical effects that can adversely impact patients’ quality of life (QoL). In pivotal clinical trials, natalizumab demonstrated not only a reduction in relapse rate and disability progression but also improved QoL. The Multiple Sclerosis Impact Scale-29 (MSIS-29) is a reliable and valid disease-specific QoL scale that assesses the impact of MS on QoL from a patient’s perspective.

OBJECTIVE: To assess changes in the physical and psychological impact of MS on patients receiving natalizumab over time.

METHODS: In the United States, MS patients starting natalizumab volunteered to participate in a longitudinal observational study to document their experiences with natalizumab. MS patients completed the MSIS-29 before natalizumab initiation and after the 3rd, 6th, and 12th infusions. The MSIS-29 scale consists of 20 items evaluating the physical impact and 9 items evaluating the psychological impact of MS. Scores range from 0 to 100 where lower scores indicate better QoL.

RESULTS: Data from 440 patients indicated that the mean age was 46.6 +/- 10.5 years, 76.3% were female, and they had been diagnosed with MS 10.6 years ago. After controlling for covariates, a statistically significant improvement in physical impact scores (BL 46.87 +/- 16.26, 3rd 39.60 +/- 16.26, 6th 39.27 +/- 16.26; P < 0.001) was observed; similarly psychological impact scores showed statistically significant improvements (BL 4.56 +/- 5.54, 3rd 3.37 +/- 5.54, 6th 3.32 +/- 5.54, P < 0.001) suggesting an improvement over time in physical and psychological well-being after initiating natalizumab.

CONCLUSIONS: This study indicates that patients receiving natalizumab experienced a sustained improvement in their physical functioning and psychological well-being over time in the usual care setting. These results are indicative that natalizumab may have lowered the negative impact of MS on the everyday functioning of patients and are consistent with previously published data showing improvement in physical disability in some patients.

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