

Abstracts from Professional Poster Presentations at AMCP's 2012 Educational Conference

The following poster presentations have been prepared for the Academy of Managed Care Pharmacy's 2012 Educational Conference, October 3-5, 2012, in Cincinnati, Ohio. Poster presentations are selected by the Program Planning and Development Committee from proposals that are submitted to the 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 shown in bold.

■ A Suboxone-Opioid Program: Members Identified for Intervention and Success

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BACKGROUND: According to the journal *Drug and Alcohol Dependence*, the risk of death for those dependent on opioids is 5.71 times higher than healthy individuals in the population of the same age, gender, and race. A Suboxone-opioid monitoring program launched June 2010. This patient safety program notifies Suboxone prescribers via letter about overlapping Suboxone and opioid and/or tramadol pharmacy claims. A Suboxone prior authorization is required. The prior authorization criteria confirms an opioid dependence diagnosis, enrollment in a drug addiction treatment program, and verifies that the Suboxone prescriber has an "X" DEA number. Once the Suboxone prior authorization is completed, members receive an approval letter informing them not to fill opioids/tramadol ongoing.

OBJECTIVE: To reduce prescription drug misuse and abuse while helping ensure safe and appropriate Suboxone use.

METHODS: A retrospective programming application runs weekdays to identify fully insured commercial members who have Suboxone pharmacy claims and concurrent opioid and/or tramadol pharmacy claims. Once an overlap is identified, a letter is generated and mailed to the Suboxone prescriber. Within 2 weeks following the mailing, a pharmacist makes an outbound phone call to the Suboxone prescriber. The pharmacist makes sure the Suboxone prescriber received the letter and, if needed, answers questions and/or provides additional information. The Suboxone prescriber is encouraged to discuss the opioid/tramadol fill with the member. As of May 1, 2012, if ongoing opioid/tramadol use is identified as misuse, future coverage for opioid/tramadol pharmacy claims is denied.

RESULTS: Letters were mailed to 2,224 Suboxone prescribers, of which 1,320 were male and 904 were female. The member age bracket with the highest number of letters mailed was aged 30-34 years. Florida was the state where the highest member percentage (16.9%) resided followed by California (14.7%), Texas (10.6%), Pennsylvania (9.5%), and New Jersey (9.1%). The Suboxone-opioid program identified members belonging to 1,503 unique plan sponsors. Success was defined by members stopping opioid/tramadol use within the post-analysis period, which was 4 months. The start period was the date the letter was mailed plus 15 days to allow time for the Suboxone prescriber to receive the letter. The end date was the last day of the fourth month after the letter was mailed or the next letter mailed, whichever came first.

CONCLUSIONS: There were 1,243 members who successfully stopped opioid/tramadol use in the post-analysis period. The successful member population was 57% male and 43% female. Overall, after Suboxone-opioid program letters were mailed and phone calls were completed, 53% males and 60% females within the post-analysis period obtained success stopping opioid/tramadol use. While there were more letter and phone outreaches completed on males than females, the success rate was higher for females. The overall success rate of the Suboxone-opioid program for males and females from June 2010 to April 2012 was 56%. Identifying gender, age, residence, and plan sponsor will assist with targeting behavioral health and educational programming to help the opioid-dependent member population.

SPONSORSHIP: This research was conducted by Aetna Inc., Hartford, CT, without external funding.

■ Acute Coronary Syndrome (ACS): Mortality and Morbidity Following a Diagnosis of ACS

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BACKGROUND: Acute coronary syndrome (ACS) encompasses acute myocardial infarction (AMI; either ST elevation or non-ST elevation MI) or unstable angina. Recently, the adequacy of current treatment strategies has come into question, given the excess burden of illness associated with ACS treated in accordance with accepted clinical practice guidelines.

OBJECTIVE: To document the rate at which patients develop additional cardiovascular comorbidities over a 3-year period following their index ACS events.

METHODS: The 5% Medicare database was used to identify patients with a hospitalization claim containing a code for AMI (410, 410.X, 410.X0, or 410.X1) or unstable angina (411 or 411.X) during 2005-2006. Patients with no documented evidence of prior ACS, atrial fibrillation (AF), or heart failure (HF), indicated by at least 1 Part A inpatient claim or 2 Part A outpatient or Part B claims, in the year prior to ACS and who survived the hospitalization were included. Kaplan-Meier methods were used to estimate the probability of patients experiencing the composite endpoint of AF, HF, or death. A Cox proportional hazards model was developed to examine factors associated with subsequent AF, HF, or death.

RESULTS: Of 19,427 Medicare patients with a new diagnosis of ACS, 6,800 (35%) developed AF, HF, or both within 3 years. Of these patients, 14% developed AF alone, 66% developed HF alone, and 20% developed both AF and HF. Based on Kaplan-Meier methods, 29% of patients with newly diagnosed ACS and no prior AF or HF would be expected to develop AF, HF, or die within 1 year; by 3 years after the diagnosis of ACS, 45% would be expected to develop AF, HF, or die. From the Cox model, the following risk factors contributing significantly ($P < 0.0001$) to the development of any of these 3 outcomes were identified: chronic kidney disease (HR=1.57, 95% CI=1.48-1.66), liver disease (HR=1.44, 95% CI=1.22-1.70), chronic obstructive pulmonary disease (HR=1.42, 95% CI=1.36-1.49), venous thromboembolism (HR=1.38, 95% CI=1.22-1.57), and diabetes (HR=1.26, 95% CI=1.20-1.32).

CONCLUSIONS: ACS is a red flag for the development of additional cardiovascular disease and mortality, especially in patients with chronic diseases such as diabetes and chronic kidney disease.

SPONSORSHIP: This research was conducted by Janssen Scientific Affairs, LLC, Raritan, NJ, without external funding.

■ **Adherence Measurement for Long-Acting Injectable Antipsychotics: An Empirical Analysis of Days Supply and Quantity Fields on Prescription Claims**

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BACKGROUND: Administrative claims data are increasingly being relied upon for quality measures, including measures of adherence to treatment. Calculation of adherence using administrative claims data is dependent on the accuracy of the days supply field on prescription claims. Little has been published on the validity of days supply for long-acting injectable antipsychotics (LAI) and the implications for adherence measurement.

OBJECTIVE: To investigate the effect of using raw unadjusted days supply data versus validated days supply data in adherence calculation for LAIs.

METHODS: The analysis used LAI prescription claims from August 1, 2009, through July 31, 2011, from a large national administrative claims database. Claims for products dispensed in multidose vials were excluded because the number of doses per container cannot be determined from these administrative claims. Days supply from claims for single-dose LAIs were validated from multiple perspectives, including an examination of the ratio of reported days supply to quantity dispensed and a comparison of reported days supply to a days supply value calculated from quantity dispensed and package insert (PI) recommendations. In cases where the observed quantity dispensed field value for liquid vial products represented product volume in mL, it was replaced by a quantity in number of product units. The percent of claims excluded as unverifiable was calculated at the product and strength within product levels. Adherence, as measured by proportion of days covered (PDC) over 1 year from the date of a patient's first observed LAI prescription, was compared between raw unadjusted claims and validated claims. PDCs were calculated for individual products and for strengths within product.

RESULTS: There were 894,846 LAI antipsychotic claims in the database. Claims for multidose vials of fluphenazine (n=142,084) and haloperidol decanoate (n=95,399) were excluded. The final analytic sample included 657,363 single-dose LAI claims for the following products: haloperidol decanoate (1 mL), paliperidone palmitate, risperidone microspheres, and olanzapine pamoate. Replacing mL quantity dispensed values with the appropriate unit quantity allowed re-inclusion of >80% of the claims with observed liquid volume quantities that were initially excluded. A strict requirement of days supply in accordance to PI would eliminate from 16% to 85% of claims, varying by product. The elimination of unverified claims reduced the sample available for adherence calculation from 25%-85% at the product level. At the product level, differences between the PDC calculated for all available raw claims and for the sample of validated claims ranged from <1% to 16%.

CONCLUSIONS: The number of claims excluded and the magnitude of effect on calculated adherence varied by product and within product, by strength. The observed use of volume in mL rather than product units in the quantity dispensed field for liquid vial products should be addressed to accurately analyze adherence for LAIs. The issue of adherence calculation for multidose vial products remains a concern but was beyond the scope of this research.

SPONSORSHIP: This research was conducted by Janssen Scientific Affairs, LLC, Titusville, NJ, without external funding.

■ **Adherence to Proposed ACR Treatment Guidelines for Gout**

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BACKGROUND: Although gout is a relatively common condition, treatment is often not ideal, with many patients continuing to experience multiple flares and some developing complications associated with the disease. To improve patient care, the American College of Rheumatology (ACR) recently proposed a draft set of recommendations for treating patients with gout.

OBJECTIVE: To assess the percentage of patients who meet the recently proposed treatment guidelines in a cohort of patients using xanthine oxidase (XO) inhibitor therapy.

METHODS: Data were assessed from a quantitative survey of U.S. physicians about gout disease management and oversampling for rheumatologists. Laboratory and clinical data were confirmed through chart audits using a structured case report form. The sample was restricted to patients treated with allopurinol or febuxostat. Type and initial allopurinol/febuxostat dose, presence of kidney disease, use of prophylactic medication, serum uric acid (sUA) level, physician type (rheumatologist vs. primary care physician [PCPI]), and patient sociodemographic factors were recorded/abstracted. Descriptive statistics were used to describe the number of patients initiating urate-lowering therapy (ULT) with anti-inflammatory prophylactic medication, titration of allopurinol, having a follow-up sUA and achieving sUA <6 mg per dL within 12 months of treatment initiation. Results are presented overall and by physician type.

RESULTS: The sample included 125 rheumatologists and 124 PCPs. Of the 1,245 patients with gout, 858 (69%) were treated with an XO inhibitor: 621 (72.4%) were treated with allopurinol and 237 (27.6%) were treated with febuxostat. Rheumatologists managed the care for 500 (58.3%) patients, and PCPs managed the care for 358 (41.7%) patients. Rheumatologists used an anti-inflammatory prophylactic treatment (nonsteroidal anti-inflammatory drugs [NSAIDs]/colchicine/corticosteroids) in 67% of cases, and only 37% of cases treated by PCPs received prophylactic therapy. A follow-up sUA assessment in the 1 year following the allopurinol/febuxostat initiation was done in 68% and 53% of patients managed by rheumatologists and PCPs, respectively. Rheumatologists were more likely to start with a lower dose of allopurinol (185 mg) versus PCPs (208 mg; $P<0.01$), and only 8% of patients treated by a PCP and 29% of patients treated by rheumatologists were titrated above 300 mg of allopurinol ($P<0.01$). Within 12 months of the allopurinol/febuxostat treatment, only 50% of patients managed by rheumatologists and 36% of patients managed by PCPs achieved an sUA of <6 mg per dL (among those who had an sUA level checked). There was no statistically significant difference between allopurinol (45%) and febuxostat (41%) in the proportion of patients reaching the sUA target ($P=0.26$).

CONCLUSIONS: Adherence to draft ACR guidelines vary by physician type with no more than 50% of patients achieving sUA <6 mg per dL within 12 months of XO therapy. Significant opportunities exist to improve care for all patients regardless of physician specialty, including use of prophylactic treatment, dose titration of ULT, and/or effective treatment strategies to bring patients to sUA goal.

SPONSORSHIP: This research was funded by Ardea Inc., San Diego, CA.

Association Between Pregabalin Access Restrictions and Pain-Related Health Care Utilization and Expenditures in Medicare Supplemental Health Plans

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BACKGROUND: Prior studies of pregabalin prior authorization programs in Medicaid and commercial health plans (Margolis et al., 2009; 2010) have, respectively, provided evidence associating pregabalin access restrictions with either increased or insignificantly affected pain-related health care utilization and expenditures in patients with painful diabetic peripheral neuropathy (pDPN) or post-herpetic neuralgia (PHN).

OBJECTIVE: To examine the association between pain-related health care utilization and expenditures and pregabalin prior authorization (PA) or step therapy (ST) access restrictions in patients with pDPN, PHN, or fibromyalgia (FM), with Medicare supplemental insurance.

METHODS: Retrospective, cross-sectional study using data from a large Medicare supplemental health care claims database. Selected patients were aged 65 or older, continuously enrolled in a single prescription carrier throughout calendar years 2008 (baseline) and 2009 (follow-up), had ≥ 1 medical claim with an ICD-9-CM diagnosis code for DPN, PHN, or FM, followed within 60 days by a medication or pain intervention procedure used in treating pDPN, PHN, or FM during 2008-2009. Patients were classified based on their prescription carriers' pregabalin access policies during 2008-2009: PA required (PA group); ST required (ST group); unrestricted access (unrestricted group). Follow-up period pain-related health care utilization and expenditures in the PA and ST groups were compared with the unrestricted group using generalized linear models adjusted for baseline demographics and clinical characteristics. PHN patients were combined with pDPN patients due to low sample size.

RESULTS: The pDPN/PHN sample comprised 24,362 patients with pDPN only, 4,327 with PHN only, and 1,615 with both pDPN and PHN; 2,277 in the PA group, 1,478 in the ST group, and 26,513 in the unrestricted group. The FM sample comprised 25,246 patients: 1,917 in the PA group, 1,830 in the ST group, and 21,499 in the unrestricted group. In the pDPN/PHN sample, when compared with the unrestricted group: adjusted odds of pregabalin use were significantly lower in the PA group (OR=0.589, 95% CI=0.496-0.700, $P<0.001$) and insignificantly higher in the ST group (OR=1.122, 95% CI=0.963-1.307, $P=0.140$); adjusted pain-related expenditures were significantly lower in the PA group (predicted cost difference=-\$533, cost ratio=0.716, 95% CI=0.653-0.784, $P<0.001$) and insignificantly higher in the step therapy group (predicted cost difference=\$74, cost ratio=1.039, 95% CI= 0.944-1.145, $P=0.431$). In the FM sample, when compared with the unrestricted group: adjusted odds of pregabalin use were significantly lower in the PA group (OR=0.675, 95% CI=0.553-0.824, $P<0.001$) and the ST group (OR=0.774, 95% CI=0.644-0.930, $P=0.006$); adjusted pain-related expenditures were insignificantly lower in the PA group (predicted cost difference=-\$65, cost ratio=0.960, 95% CI=0.795-1.160, $P=0.674$) and insignificantly higher in the step therapy group (predicted cost difference=\$60, cost ratio=1.037, 95% CI=0.964-1.115, $P=0.331$).

CONCLUSIONS: In general congruence with prior research, pregabalin access restrictions were, in most cases, associated with lower odds of pregabalin use but not overall savings on pain-related health care expenditures. This study's methodology was limited by its cross-sectional design, which is less internally valid for policy evaluation than the difference-in-difference designs employed by the 2 prior studies of pregabalin access restrictions.

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

Cardiovascular Events and LDL Cholesterol Lowering Associated with High-Potency Statin Therapies in a Real-World Setting

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BACKGROUND: To our knowledge, no single study has evaluated differences in cardiovascular event rates among the 3 most commonly used statins within the same real-world population. With generic compounds projected to capture 95% of the statin market share, questions arise as to whether branded statins offer clinical benefits over available generics.

OBJECTIVE: To assess the real-world outcomes on cardiovascular events following initiation of therapy with 3 commonly prescribed high-potency statins and 1 statin/cholesterol absorption inhibitor combination by identifying potential differences in cardiovascular event rates and risk of event by type of statin, and to measure the effect of specific statin therapies on the reduction of low-density lipoprotein cholesterol (LDL-C) levels.

METHODS: The dataset for this observational, retrospective, administrative claims analysis was created using pharmacy and medical claims, and laboratory results from 13 geographically distributed major U.S. health plans. Patients aged 18-63 years who were taking statin therapy were divided into primary (no documented cardiovascular events 12 months pre-index) and secondary (≥ 1 documented cardiovascular event 12 months pre-index) prevention. The primary outcome measure was the occurrence of a cardiovascular event (i.e., myocardial infarction, coronary heart disease, coronary artery bypass graft, angioplasty, angina/ischemic heart disease, cerebrovascular disease, transient ischemic attack, aortic aneurysm, or congestive heart failure). LDL-C level was measured pre-index to establish a baseline value and again 28 days post-index for the LDL-C reduction analysis, a secondary endpoint.

RESULTS: For the primary prevention group (214,066 patients), cardiovascular event rates were 0.9% rosuvastatin, 1.0% atorvastatin, 0.9% simvastatin, 0.9% simvastatin/ezetimibe. All statins reduced LDL-C levels by approximately one-third: 32.3% rosuvastatin, 33.9% atorvastatin, 33.9% simvastatin, 28.4% simvastatin/ezetimibe. For the group as a whole, the average pre-index LDL-C level was 146 mg per dL, which fell to 91.9 mg per dL post-index. In the secondary prevention group (22,594 patients), 6.2% (1,410 patients) experienced a cardiovascular event: 6.1% rosuvastatin, 6.2% atorvastatin, 6.3% simvastatin, 5.5% simvastatin/ezetimibe. Changes in LDL-C levels were similar for all statin treatment groups, decreasing by 28.2% for rosuvastatin, 27.9% for atorvastatin, 28.3% for simvastatin, and 24.3% for simvastatin/ezetimibe. The average LDL-C levels fell from 128.5 mg per dL at baseline to 85.1 mg per dL post-index. All post-index LDL-C levels were below recommended target levels. Choice of statin therapy used was not associated with a difference in cardiovascular events in either the primary or secondary prevention groups (table).

CONCLUSIONS: Despite differences in the potential LDL-C lowering effect of rosuvastatin, atorvastatin, simvastatin, and simvastatin/ezetimibe, we found no significant differences in cardiovascular event rates or changes in LDL-C levels in our real-world population, suggesting a classwide effect of statins when used at equivalent LDL-lowering doses. These data provide important information regarding expected clinically meaningful outcomes from these high-potency therapies as they are used in real-world practice.

SPONSORSHIP: This research was funded by WellPoint, Inc., Indianapolis, IN, and HealthCore, Inc., Wilmington, DE.

TABLE Cardiovascular Events and LDL

Factor	Hazard Ratio	95% CI	P Value
Primary prevention group			
Atorvastatin	0.96	0.789-1.168	0.68
Rosuvastatin	1.075	0.729-1.585	0.72
Simvastatin/ezetimibe	1.284	0.761-2.168	0.35
Secondary prevention group			
Atorvastatin	0.967	0.735-1.274	0.81
Rosuvastatin	0.908	0.589-1.399	0.66
Simvastatin/ezetimibe	1.074	0.588-1.960	0.82

Referent: simvastatin.

CI = confidence interval; LDL = low-density lipoprotein.

Comorbidity Burden, Health Care Resource Utilization, and Health Care Costs Among Medicare Advantage Members with Alzheimer's Disease

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BACKGROUND: The prevalence of Alzheimer's disease (AD) in the United States was estimated at 5.4 million individuals in 2011. Based on future expectations around the growing aged population, AD represents a serious public health issue.

OBJECTIVE: To examine and compare comorbidity burden, health care resource utilization (HCRU), and associated costs in the Medicare population of newly diagnosed AD members versus non-AD members (controls).

METHODS: This was a retrospective cohort study utilizing Humana Medicare Advantage Prescription Drug plan (MAPD) member claims data collected between January 1, 2007, and June 30, 2011. Members newly diagnosed with AD and with 36 months of continuous enrollment (12-month pre-index, 24-month post-index) were matched 1:2 to non-AD controls on age, gender, race/ethnicity, geographic region, and plan year of enrollment. Comorbidity burden (RxRisk-V score, Charlson Comorbidity Index score [CCI]), HCRU (outpatient, inpatient, emergency department, home health service, skilled nursing facility), and associated health care costs were compared between cohorts.

RESULTS: A total of 3,374 members with AD were identified and matched to 6,748 non-AD controls. The mean age (SD) of members diagnosed with AD was 79.4 (\pm 7.9) years, and 62.5% (n=2,108) were female. Comorbidity burden and health care costs are summarized in the table. Pre-index comorbidity burden was similar between-groups when measured using the RxRisk-V ($P=0.058$), while the pre-index CCI was higher among AD members ($P<0.001$). AD members displayed greater comorbidity burden than their non-AD counterparts on both measures during post-index years 1 and 2 (all between-group $P<0.001$). HCRU was significantly higher for AD members during the pre-index period, and post-index years 1 and 2 (all $P<0.001$). Similarly, mean annual per member total health care costs and medical costs were significantly higher for the AD cohort compared with the non-AD cohort during all time frames examined (all $P<0.001$). While pharmacy costs were greater among AD members during each year of post-index follow-up ($P<0.001$), there was no difference during the pre-index period ($P=0.254$).

CONCLUSIONS: Members diagnosed with AD demonstrated greater comorbidity burden, health care resource utilization, and direct health

TABLE Mean Per-Member Health Care Costs and Mean (SD) Comorbidity Index Scores During Pre-Index Year, Post-Index Year 1, and Post-Index Year 2 for Members Diagnosed with AD and Matched Non-AD Controls^a

	AD Members (n=3,374)			Non-AD Controls (n=6,748)		
	Pre-Index	Year 1	Year 2	Pre-Index	Year 1	Year 2
Health care costs						
Total health care costs (\$)	9,517	14,066	11,740	6,605	6,968	6,982
Total medical costs (\$)	7,799	11,449	9,006	4,953	5,313	5,349
Total pharmacy costs (\$)	1,718	2,616	2,734	1,651	1,655	1,633
Comorbidity burden						
RxRisk-V score	4.48 (3.23)	5.05 (3.34)	5.03 (3.35)	4.36 (2.89)	4.60 (2.97)	4.77 (3.03)
Deyo-Charlson score	1.41 (1.85)	1.90 (2.11)	1.83 (2.13)	1.15 (1.71)	1.35 (1.88)	1.50 (2.01)

^aAll between-group differences at individual time points are statistically significant (*t* test of means, $P<0.001$), with exception of RxRisk-V score ($P=0.058$) and pharmacy costs ($P=0.254$) during the pre-index period. All costs are adjusted to 2011 dollars based on the medical care component of the Consumer Price Index.

AD = Alzheimer's disease; SD = standard deviation.

care costs compared with matched non-AD controls. These findings demonstrate the significant clinical and financial impact associated with AD in a Medicare population.

SPONSORSHIP: This research was conducted by Pfizer Inc., New York, NY; Humana Inc., Cincinnati, OH; and Competitive Health Analytics, Inc., Louisville, KY.

Comparison of Compliance with Fingolimod and Other First-Line Disease-Modifying Treatments Among Patients with Multiple Sclerosis

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BACKGROUND: Disease-modifying therapies (DMTs) are used to treat multiple sclerosis (MS) by decreasing the number and severity of relapses and delaying progression of the disease. Adherence to DMTs is essential for the reduction of MS relapses and progression. Patients with lower adherence rates experience more inpatient visits and higher MS-related medical costs. Fingolimod, the first oral DMT approved by the FDA, may improve the access to and compliance with MS treatment when compared with injectable DMTs.

OBJECTIVE: To compare compliance with fingolimod and other first-line DMTs indicated for the treatment of MS.

METHODS: Using pharmacy claims from Medco Health Solutions, Inc., patients who initiated 1 of the DMTs between October 2010 and February 2011 were identified: fingolimod (Gilenya), interferon beta-1b (Betaseron, Extavia), subcutaneous interferon beta-1a (Rebif), glatiramer acetate (Copaxone), and intramuscular interferon beta-1a (Avonex). Initiation was defined as no prescription fill for the same medication in the prior 12 months. Patients who filled only 1 prescription of the index DMT were excluded because they may have terminated the treatment due to intolerance or adverse effects. Compliance with the index DMT was measured via proportion of days covered (PDC) and

medication possession ratio (MPR) based on prescriptions filled during the 12 months after the second dispense of the index medication. Logistic regression models were estimated to compare patient compliance with different DMT treatments.

RESULTS: Of the 1,891 MS patients who initiated DMT, 13.1% initiated fingolimod, 10.7% interferon beta-1b, 20.0% intramuscular interferon beta-1a, 18.8% subcutaneous interferon beta-1a, and 37.4% glatiramer acetate. Patients initiating fingolimod had the highest MPR and PDC values among the DMT cohorts in both experienced DMT users (fingolimod: mean MPR=0.92, 90.5% with MPR≥0.8; mean PDC=0.83, 73.7% with PDC≥0.8) and naïve users (fingolimod: mean MPR=0.90, 87.4% with MPR≥0.8; mean PDC=0.80, 66.7% with PDC≥0.8). After controlling for baseline demographics and characteristics, fingolimod was associated with significantly higher likelihood of PDC≥0.8 or MPR≥0.8 than other DMTs.

CONCLUSIONS: Patients who initiated the oral DMT fingolimod had better adherence to treatment than patients who initiated other first-line DMTs, and the association was stronger in experienced users than in naïve users. Limitations to this study include application of claims data and lack of clinical measurements.

SPONSORSHIP: This research was conducted by Novartis Pharmaceuticals Corporation, East Hanover, NJ, without external funding.

DMT	# of Patients	PDC ≥ 0.8		MPR ≥ 0.8	
		Odds Ratio	95% Confidence Interval	Odds Ratio	95% Confidence Interval
Fingolimod, experienced users	152	Referent		Referent	
Interferon beta-1b, experienced users	35	0.244	(0.112-0.534)	0.237	(0.091-0.622)
Intramuscular interferon beta-1a, experienced users	66	0.449	(0.241-0.834)	0.392	(0.170-0.904)
Subcutaneous interferon beta-1a, experienced users	98	0.364	(0.209-0.632)	0.265	(0.128-0.548)
Glatiramer acetate, experienced users	115	0.606	(0.356-1.034)	0.614	(0.283-1.328)
Fingolimod, naïve users	96	0.739	(0.419-1.304)	0.736	(0.323-1.675)
Interferon beta-1b, naïve users	167	0.308	(0.189-0.501)	0.291	(0.150-0.563)
Intramuscular interferon beta-1a, naïve users	313	0.423	(0.274-0.655)	0.408	(0.218-0.764)
Subcutaneous interferon beta-1a, naïve users	257	0.400	(0.255-0.627)	0.433	(0.227-0.826)
Glatiramer acetate, naïve users	592	0.459	(0.306-0.691)	0.462	(0.254-0.840)

^aControlled for age, gender, region of residence, requirement of prior authorization, copayment, type of pharmacy dispensing the index prescription (specialty pharmacy vs. retailers), and whether index drug prescriptions have been filled via mail-in orders.

DMT = disease-modifying therapies; MPR = medication possession ratio; PDC = proportion of days covered.

Comparison of Pharmacy Costs After Switching to Emtricitabine/Rilpivirine/Tenofovir DF Single-Tablet Regimen from a Ritonavir-Boosted Protease Inhibitor and 2 Nucleoside Reverse Transcriptase Inhibitors

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BACKGROUND: Antiretroviral (ARV) regimen simplification improves quality of life and long-term medication adherence and persistency while reducing risks for human immunodeficiency virus (HIV) virologic failure and decreasing financial costs. Emtricitabine/rilpivirine/tenofovir DF (FTC/RPV/TDF) is a well-tolerated, once-daily single-tablet regimen (STR) treatment option. This is the first study to evaluate the efficacy, safety, and costs of switching from ritonavir-boosted protease inhibitor (PI+RTV)-based highly active antiretroviral therapy (HAART) to a simplified regimen of FTC/RPV/TDF STR.

OBJECTIVE: To evaluate the efficacy, safety, and costs of switching from PI+RTV-based HAART to FTC/RPV/TDF.

METHODS: This was a randomized, open-label, multicenter, international, 48-week study to evaluate the safety and efficacy associated with switching from PI+RTV regimens to FTC/RPV/TDF in virologically suppressed (HIV RNA < 50 copies/mL) HIV-1 infected persons. Eligible participants were randomized 2:1 to switch to FTC/RPV/TDF or maintain their current PI+RTV regimens. The primary endpoint was noninferiority (12% margin) of FTC/RPV/TDF compared with PI+RTV regimens in maintaining plasma HIV-1 RNA < 50 copies/mL at Week 24 using the Snapshot analysis. Estimates of pharmacy costs assume all study participants remained on therapy for 24 weeks; wholesale acquisition cost (WAC) were based on February 1, 2012, First Data Bank published rates.

RESULTS: A total of 476 participants were randomized and received at least 1 dose of the study drug (317 FTC/RPV/TDF; 159 PI+RTV).

Comparison of Pharmacy Costs After Switching			
PI + RTV Regimens	Participants	WAC/Participant for 24 Weeks (\$)	Total PI + RTV Cost (\$)
LPV/RTV	58	4,078	236,524
ATV+RTV	54	6,896	372,384
DRV+RTV	33	7,201	237,633
fAMP+RTV	12	7,129	85,548
SQV+RTV	2	7,984	15,968
Totals	159		948,057

Mean PI + RTV WAC = \$948,057/159 participants = \$5,963.

NRTI Regimens	Participants	WAC/Participant for 24 Weeks (\$)	Total NRTI Cost (\$)
FTC/TDF	130	6,511	846,430
ABC/3TC	24	5,472	131,328
ZDV/3TC	5	5,062	25,310
Totals	159		1,003,068

Mean NRTI WAC = \$1,003,068/159 participants = \$6,309.

WAC for PI + RTV regimen/participant for 24 weeks = \$5,963 + \$6,309 = \$12,272.

WAC for FTC/RPV/TDF/participant for 24 weeks = \$10,275.

WAC difference between FTC/RPV/TDF and PI + RTV/participant for 24 weeks = \$1,997.

FTC/RPV/TDF = emtricitabine/rilpivirine/tenofovir DF; NRTI = nucleoside reverse transcriptase inhibitors; PI + RTV = ritonavir-boosted protease inhibitor; WAC = wholesale acquisition cost.

Baseline characteristics were similar. Switching to FTC/RPV/TDF was noninferior to maintaining a PI+RTV regimen (93.4% vs. 89.9%) at Week 24 for HIV RNA <50 copies/mL (95% CI [-2.0%, 8.9%]). The costs for FTC/PRV/TDF and PI+RTV regimens were \$10,275 and \$12,272 for 24 weeks of therapy, respectively, representing a savings of \$1,997 (16%) per FTC/RPV/TDF participant over the 24-week study period (table).

CONCLUSIONS: Switching to the FTC/RPV/TDF STR from a PI+RTV regimen in virologically suppressed HIV-1-infected participants maintained HIV suppression and saved \$1,997 (16%) in medication costs per participant over 24 weeks per WAC evaluation.

SPONSORSHIP: This research was conducted by Gilead Sciences, Foster City, CA, without external funding.

■ Comparisons of Costs and Clinical Outcomes in Hypertensive Patients Treated with Chlorthalidone or Hydrochlorothiazide

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BACKGROUND: Hydrochlorothiazide (HCTZ) is a diuretic frequently prescribed to treat hypertension. However, clinical studies indicate that chlorthalidone (CLD) has a longer duration of action and is 1.5-2 times more potent than HCTZ.

OBJECTIVE: To compare clinical and economic outcomes between hypertensive patients treated with CLD versus HCTZ.

METHODS: The I3 claims database was used to identify adults with hypertension (ICD-9-CM codes 401-405) who had at least 2 prescriptions for CLD or HCTZ between January 2000 and June 2008. Patients had to be continuously enrolled for at least 6 months before and 24 months after their first prescription of either study drug. We matched the HCTZ and CLD cohorts in a 5:1 ratio using propensity scores. Using chi-square and Wilcoxon tests, we compared hypertension-related complications, resource utilization, and average health care costs between the cohorts over a 2-year follow-up period.

RESULTS: Our sample included 634 patients taking CLD and 3,170 taking HCTZ. Compared with the HCTZ group, the CLD group had significantly lower rates of hypertension-related complications (19.9% vs. 23.6%, $P=0.044$) and significantly lower total health care costs (\$1,141 vs. \$1,252 per month, $P=0.026$); this result was primarily driven by the lower medical costs for the CLD group (\$921 vs. \$1,017 per month, $P=0.046$). Hypertension-related medical costs were significantly lower for patients treated with CLD versus those treated with HCTZ (\$179 vs. \$227 per month, $P=0.045$). Moreover, the CLD group had fewer patients who had hospitalizations (22.1% vs. 23.3%, $P=0.502$) or emergency department visits (17.7% vs. 18.6%, $P=0.575$) than the HCTZ group although the differences were not significant.

CONCLUSIONS: Hypertensive patients treated with CLD had fewer hypertension-related complications and incurred lower medical and total health care costs than patients treated with HCTZ over 2 years. The clinical and economic benefits of CLD for the treatment of patients with hypertension should be further studied.

SPONSORSHIP: This research was funded by Takeda Pharmaceuticals U.S.A., Inc., Deerfield, IL.

■ Comparisons of Costs and Clinical Outcomes in Patients Treated with Angiotensin Receptor Blockers Plus Chlorthalidone or Hydrochlorothiazide

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BACKGROUND: Combination therapies for hypertension are recommended for patients whose blood pressure is >20/10 mm Hg above goal. When used in combination, angiotensin receptor blockers (ARBs) are more frequently paired with hydrochlorothiazide (HCTZ) than with chlorthalidone (CLD), although physicians often perceive HCTZ and CLD to be interchangeable.

OBJECTIVE: To compare costs and clinical outcomes between ARB+CLD and ARB+HCTZ.

METHODS: Patients with a diagnosis of essential hypertension (ICD-9 code 401) before they received an ARB+CLD or an ARB+HCTZ were retrospectively identified using 1999-2007 Integrated-Health-Care-Information-Services Database covering approximately 25 million lives in the United States. Other criteria were use of only CLD or HCTZ within 30 days of the ARB, at least 1 refill of study drug, and continuous enrollment in a health plan for 6 months before and 12 months after the start of therapy. We matched the ARB+HCTZ and ARB+CLD cohorts in a 5:1 ratio using propensity score matching (greedy method) based on baseline characteristics. We compared cumulative 1-year medical, pharmacy, and total costs, adjusted to 2007 dollars, between the groups using a Wilcoxon test. We compared hospitalization and urgent-care rates using a Kaplan-Meier survival method. Data were censored at the end of their availability or at 3 years.

RESULTS: A total of 836 patients received an ARB+CLD, and 4,180 received an ARB+HCTZ. At 1 year, compared with the ARB+HCTZ group, the ARB+CLD group had significantly lower medical (\$5,374 vs. \$5,507, $P=0.005$) and total (\$7,927 vs. \$8,063, $P=0.008$) costs, a significantly lower rate of urgent care use (19.6% vs. 23.5%, $P=0.002$), and fewer hospitalizations (10.9% vs. 11.5%, $P=0.313$), although the latter was not statistically significant.

CONCLUSIONS: Medical and total health care costs and urgent care rates were lower for patients receiving an ARB+CLD than for patients receiving an ARB+HCTZ. A study limitation was selection bias, which was minimized with matching.

SPONSORSHIP: This research was funded by Takeda Pharmaceuticals U.S.A., Inc., Deerfield, IL.

■ Cost-Effectiveness of Multiple Sclerosis Therapies: An Indirect Comparison

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BACKGROUND: Cost-effectiveness (CE) models are developed to determine the most efficient treatment option based on best available data. A major challenge to CE models in multiple sclerosis (MS) is heterogeneity in randomized clinical trials (RCTs).

OBJECTIVE: To adapt an existing CE model comparing fingolimod with other first-line disease-modifying treatments (DMTs) using results of a mixed treatment comparison (MTC).

METHODS: The original model compared the cost per relapse avoided for first-line DMTs based on relative relapse reduction (RRR) from RCTs. Mixed treatment comparison (MTC) meta-analyses were performed on the annualized relapse rate (ARR) endpoint to produce relative effect estimates between all the first-line treatments for relapsing remitting multiple sclerosis (RRMS) that adjusted for differences in trial populations and endpoint definitions. The original model was adapted to include the MTC results as efficacy inputs in place of the RRR from the clinical trials and using prices as of July 2012. Results of the adapted model were compared with the original model. Sensitivity analyses were also performed using confidence intervals from the MTC.

RESULTS: Adjusted RRR in the MTC compared with placebo were 57% for fingolimod, 35% for subcutaneous (SC) interferon (IFN) beta (β)-1b (Extavia/Betaseron), 38% for glatiramer acetate, 33% for SC IFN β -1a, and 17% for intramuscular (IM) IFN β -1a. In the original model (using August 2011 prices), the cost per relapse avoided were \$74,843 for fingolimod, \$94,423 for SC IFN β -1b (Extavia), \$102,530 for SC IFN β -1b (Betaseron), \$124,512 for glatiramer acetate, \$108,940 for SC IFN β -1a, and \$197,073 IM IFN β -1a. In the re-analysis using the MTC inputs, the costs per relapse avoided were \$83,853 for fingolimod, \$104,376 for SC IFN β -1b (Extavia), \$113,049 for SC IFN β -1b (Betaseron), \$108,081 for glatiramer acetate, \$121,424 for SC IFN β -1a, and \$237,872 IM IFN β -1a. Sensitivity analyses showed that these results were robust and the rank-order of the results remained unaffected by any changes in the efficacy input.

CONCLUSIONS: Fingolimod remained the lowest cost per relapse avoided among all first-line DMTs after adjusting for MTC of efficacy results and using July 2012 pricing.

SPONSORSHIP: This research was conducted by Novartis Pharmaceuticals Corporation, East Hanover, NJ, without external funding.

Direct and Indirect Costs Associated with Relapse of Multiple Sclerosis

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BACKGROUND: Multiple sclerosis (MS) has been generally characterized by steady progression, with unpredictable relapses that often involve complex pharmaceutical and rehabilitative interventions. Early onset and frequency of MS relapses have been associated with a greater risk of more rapid progression to a severe level of disability.

OBJECTIVE: To assess the direct and indirect cost burden associated with MS relapses of different severities.

METHODS: Medical and pharmacy claims (1999-2011) from 60 self-insured U.S. companies were analyzed. Adult patients with ≥ 2 diagnosis claims of MS (ICD-9-CM: 340.x) were selected. A ≥ 6 months baseline period of eligibility preceding the first MS diagnosis (index date) was

required. Recorded relapses and costs were assessed during a follow-up of 12 months after the index date. MS patients with relapse(s) were categorized according to the most severe definition of relapse occurring during the follow-up. The low/moderate severity relapse cohort was defined as patients with ≥ 1 MS-related outpatient or emergency room visit followed by ≥ 1 IV or oral corticosteroid claim within 7 days. The high severity relapse cohort was defined as patients with ≥ 1 MS-related hospitalization with MS as the primary diagnosis. All-cause and MS-related direct and indirect costs of the nonrelapse cohort were compared with the low/moderate and high severity relapse cohorts. MS-related costs were defined as the subset of claims with a diagnosis of MS. Indirect costs included disability and medically related absenteeism costs.

RESULTS: A total of 9,421 MS patients (nonrelapse: n=7,686; low/moderate severity relapse: n=1,220; high severity relapse: n=515) were identified. Mean (SD) age for the nonrelapse, low/moderate, and high severity cohorts were 50.3 (13.8), 45.1 (11.4), and 50.7 (15.9) years, respectively; 72.0%, 75.2%, and 72.8% were female. Compared with the nonrelapse cohort, the low/moderate severity relapse and the high severity relapse cohorts incurred significantly higher annual all-cause direct costs (\$28,348 vs. \$17,545 cost difference=\$10,803, $P<0.01$; \$41,969 vs. \$17,545 cost difference=\$24,424, $P<0.01$) and MS-related direct costs (\$18,981 vs. \$8,803 cost difference=\$10,178, $P<0.01$; \$29,355 vs. \$8,803 cost difference=\$20,552, $P<0.01$). Low/moderate and high severity MS relapses were also associated with significantly higher indirect costs relative to nonrelapse MS patients (table). Of note, MS-related costs represented an important proportion (40%-75%) of all-cause direct and indirect costs and increased with MS relapse severity (table).

CONCLUSIONS: MS relapses are associated with a significant direct and indirect cost burden for patient and society. Providing therapeutic interventions that can decrease the number and severity of MS relapses will translate into a positive cost-benefit approach.

SPONSORSHIP: This research was funded by Novartis Pharmaceuticals Corporation, East Hanover, NJ.

Discontinuation Rates Among Atypical Antipsychotics for Schizophrenia: An Indirect Treatment Comparison

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BACKGROUND: Formulary decision makers seek comparative effectiveness data from various sources, including prospective comparative effectiveness trials, retrospective studies, indirect treatment comparisons, and network meta-analyses. The Clinical Antipsychotic Trial of Intervention Effectiveness (CATIE) study is a head-to-head trial of atypical antipsychotics (AAPs) comparing the older AAPs: olanzapine, risperidone, quetiapine, and ziprasidone. However, AAPs such as aripiprazole or lurasidone were not included in the CATIE study.

OBJECTIVE: To conduct an indirect treatment comparison to assess the estimated rates of (a) all-cause discontinuations and (b) discontinuations due to lack of efficacy for aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, and ziprasidone for subsequent cost-effectiveness modeling of AAPs in patients with schizophrenia using a Markov cohort decision analytic model.

METHODS: An indirect comparison of treatments from 3 separate parallel-group comparison studies was conducted to estimate rates of (a) all-cause discontinuations and (b) discontinuations due to lack of efficacy. Discontinuation rates among olanzapine, quetiapine, risperidone, and ziprasidone patients at 18 months from CATIE were converted into annualized discontinuation rates assuming a continuous

TABLE Direct and Indirect Costs for Nonrelapse and Relapse MS Patients

Annual Health Care Costs (U.S. \$2,011)	Nonrelapse MS	Relapse MS	
		Low/Moderate Severity	High Severity
Direct costs			
Number of patients, n	7,686	1,220	515
All-cause, mean (\$)	17,545	28,348 ^a	41,969 ^b
MS-related, mean (\$)	8,803	18,981 ^a	29,355 ^b
Ratio MS-related/all-cause (%)	50.2	67.0	69.9
Indirect costs			
Number of patients, n	1,687	322	84
All-cause, mean (\$)	4,146	5,610 ^a	9,226 ^b
MS-related, mean (\$)	1,613	3,238 ^a	6,939 ^b
Ratio MS-related/all-cause (%)	38.9	57.7	75.2

^aDenotes statistically significant comparison ($P<0.01$) of Nonrelapse MS versus Low/Moderate Severity Relapse MS.

^bDenotes statistically significant comparison ($P<0.01$) of Nonrelapse MS versus High Severity Relapse MS.

TABLE Discontinuation Rates Among Atypical Antipsychotics for Schizophrenia

	Aripiprazole	Lurasidone	Olanzapine	Quetiapine	Risperidone	Ziprasidone
Total discontinuation (%)	66.2	53.4	49.1	67.8	58.8	64.9
Discontinuation due to lack of efficacy (%)	18.3	14.3	9.9	19.6	19.2	16.8

exponential function. Data for lurasidone were obtained from a multiregional, 12-month, double-blind, parallel-group comparison study versus quetiapine (Loebel et al., 2010). The hazard ratio for lurasidone versus quetiapine was used to estimate the annual discontinuation rates of lurasidone versus other CATIE AAPs. Data for aripiprazole were obtained from a published 52-week open-label comparison with olanzapine in patients with chronic schizophrenia (Chrzanowski et al., 2006). All-cause discontinuations and discontinuations due to lack of efficacy were used to estimate the annual discontinuation rates of aripiprazole versus other CATIE AAPs.

RESULTS: Indirect comparison of the AAPs indicated that olanzapine and lurasidone had the lowest all-cause discontinuation rate: 49.1% and 53.4%, respectively, and the lowest discontinuation rate due to lack of efficacy: 9.9% and 14.3%, respectively (table). All-cause discontinuation rates were found to be highest among quetiapine (67.8%) and aripiprazole (66.2%) patients.

CONCLUSIONS: This indirect treatment comparison indicated that the estimated all-cause discontinuation rates and discontinuations due to lack of efficacy were lowest for lurasidone and olanzapine compared with aripiprazole, quetiapine, and ziprasidone. Results from this analysis are important, given that treatment discontinuations are believed to reflect AAP effectiveness in clinical practice.

SPONSORSHIP: This research was funded by Sunovion Pharmaceuticals, Inc., Marlborough, MA.

■ Economic Burden of Warfarin Underutilization in Adults with Nonvalvular Atrial Fibrillation

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BACKGROUND: Despite warfarin's well-established efficacy in stroke prevention in atrial fibrillation (AF), previous studies consistently show that oral anticoagulation (OAC) is often underutilized in this population.

OBJECTIVE: To estimate the economic burden associated with suboptimal warfarin exposure in a commercially insured AF population with moderate to high stroke risk.

METHODS: We conducted a retrospective cohort analysis of the MarketScan database (2003-2007), including Medicare beneficiaries with secondary commercial insurance, to estimate costs and consequences of warfarin underuse in adults newly diagnosed with AF. Subjects with valvular or transient AF, CHADS₂ < 2, prior warfarin use, high bleeding risk per published bleeding risk schemes, or contraindications to OAC were excluded. Prescription claims, days of supply, and timing of prothrombin time/international normalized ratio (PT/INR) claims were used to calculate the proportion of days covered (PDC) by warfarin after AF diagnosis. Warfarin exposure was categorized as none (PDC=0), low (PDC≤0.80), or high (PDC>0.80). Descriptive statistics were used to examine stroke and bleeding rates in patients receiving (PDC>0) and not receiving (PDC=0) warfarin. The effects of PDC on health care resource use and costs during 18 months after AF index diagnosis were assessed using multivariate negative binomial regression

and generalized linear models with gamma distribution, respectively.

RESULTS: Only 53% of 13,289 patients included in the analysis received warfarin. Patients who received warfarin had significantly lower rates of ischemic stroke (1.77 vs. 4.41, $P<0.001$) and transient ischemic attack (0.61 vs. 1.77, $P<0.001$) and higher rates of major gastrointestinal bleed (1.87 vs. 1.41, $P=0.003$) but similar intracranial (0.61 vs. 0.54, $P=0.30$) and other bleeds (0.28 vs. 0.22, $P=0.24$) per 100 person-years, compared with patients who did not receive warfarin. Patients with low PDC had similar likelihood of inpatient and emergency department (ED) service utilization compared with patients who did not receive warfarin but were 21% more likely ($P<0.001$) to incur an outpatient visit during follow-up, which was presumably related to increased PT/INR monitoring. Patients with high PDC were 28% less likely ($P<0.001$) to incur hospitalization and 16% less likely ($P=0.019$) to incur ED visits, but 32% more likely ($P<0.001$) to incur outpatient visits than patients who did not receive warfarin. Low PDC was associated with 10% lower inpatient cost ($P<0.001$) and similar ED and outpatient costs compared with patients who did not receive warfarin. High PDC was associated with 12% lower inpatient cost ($P<0.001$), similar ED cost, and 27% lower outpatient cost ($P<0.001$) compared with patients who did not receive warfarin. Overall, total costs were 13% lower for patients with high PDC ($P<0.001$) but similar for patients with low PDC as compared with patients who did not receive warfarin.

CONCLUSIONS: OAC is underutilized in patients with AF. In those with intermediate or high risk of stroke and low or moderate risk of bleeding, OAC provided a stroke benefit without a significant increase in the frequency of intracranial bleeds. High warfarin PDC resulted in cost reduction compared with no warfarin exposure, which supports guideline recommendations for thromboprophylaxis and efforts to ensure adherence in this specific group of patients.

SPONSORSHIP: This research was funded by Daiichi Sankyo, Inc., Parsippany, NJ.

■ Exacerbation Rates and Costs in Treated Chronic Bronchitis Patients with a History of Exacerbation: A Managed Care Perspective

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BACKGROUND: Little research is available on chronic obstructive pulmonary disease (COPD) exacerbation rates and costs among managed care patients treated with COPD maintenance medications for chronic bronchitis (CB) using real-world data.

OBJECTIVE: To estimate COPD exacerbation rates and costs among managed care treated CB patients who have a history of exacerbations.

METHODS: A retrospective analysis was conducted using administrative claims data from 13 geographically dispersed commercial health plans, representing 45 million U.S. lives. Inclusion criteria were as follows: age ≥ 40 years, ≥ 2 years of continuous health plan enrollment, ≥ 1 hospitalization or emergency department (ED) visit or ≥ 2 outpatient visits with CB diagnosis (ICD-9-CM 491.xx) from January 1, 2004, to May

31, 2011, ≥ 2 pharmacy fills for COPD medications during the follow-up year (first fill served as index date), and a history of exacerbation (≥ 1 moderate or severe exacerbation during 1 year pre-index). COPD exacerbations were categorized as severe (hospitalization with COPD as primary diagnosis) or moderate (ED visit with a primary COPD diagnosis or an oral corticosteroid filled within 7 days of a COPD-related office visit). When multiple exacerbations occurred within a 14-day window, only 1 was counted. Subgroup analysis was performed on patients with a history of ≥ 2 exacerbations.

RESULTS: 4,349 treated CB patients (52.7% female, mean age 68.3 ± 10.8 years) met study inclusion criteria. During the follow-up year, mean number of COPD maintenance medication fills was 8.9 ± 6.9 per patient. 57.4% experienced moderate or severe exacerbations (33.9% experienced severe exacerbations). Mean number of exacerbations was 1.6 ± 1.0 . Mean exacerbation-related health care costs were $\$7,374 \pm \$19,904$ per any exacerbation and $\$17,164 \pm \$28,726$ per severe exacerbation. Among patients with ≥ 2 exacerbations during the pre-index year, 69.5% experienced moderate or severe exacerbations (44.0% experienced severe exacerbations) during follow-up. Mean number of exacerbations was 2.6 ± 1.1 . Mean exacerbation-related costs were $\$7,372 \pm \$15,401$ per any exacerbation and $\$17,195 \pm \$24,948$ per severe exacerbation. Among overall population, pre-index exacerbation rate was the most significant predictor of follow-up exacerbation rates ($\beta=0.2098$, $P<0.0001$) and exacerbation costs ($\beta=0.1632$, $P<0.0001$).

CONCLUSIONS: Despite treatment with COPD maintenance medications, patients with prior exacerbations continued to have exacerbations during follow-up. Patients with prior exacerbation history have unmet needs and may require additional treatment strategies to reduce exacerbations and associated costs.

SPONSORSHIP: This research was conducted by Forest Research Institute, Jersey City, NJ, without external funding.

■ First-Line Chemotherapy Treatment Patterns, Treatment Outcomes, and Cost Among Elderly Advanced Non-Small Cell Lung Cancer Patients

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BACKGROUND: Data on treatment patterns and costs of first-line chemotherapies among patients 66 years or older with advanced non-small cell lung cancer (NSCLC) in a real-world setting are limited.

OBJECTIVE: To describe first-line chemotherapy treatment patterns and costs among elderly advanced NSCLC patients.

METHODS: Using the most currently available data in 2011 from the Surveillance and Epidemiology End Results-Medicare (SEER-Medicare) database, we identified patients newly diagnosed with stage IIIB/IV NSCLC from January 2002 through December 2007 who received intravenously administered (IV) chemotherapy. Patients were required to be aged 66+ years with no prior history of any cancer and to have continuous Part A and B Medicare coverage for the entire study period. Patients were followed from 1 year before the date of their first chemotherapy claim through death or December 31, 2009. First-line regimens were identified using claims-based algorithms (using HCPCS J-codes) developed in collaboration with clinical experts. Treatment patterns (30+ day gap in therapy, regimen modification [dropping 1 treatment from a doublet/triplet], therapy discontinuation, switch to a second-line IV chemotherapy regimen), adverse events (AEs), disease-related symptoms (DRS), and all-cause health care costs (2010 dollars) were assessed. A generalized linear model was estimated to predict per-patient per-month (PPPM) all-cause costs during first-line therapy; covariates included

selected AEs/DRSs, age, sex, race, region, Charlson score, stage at diagnosis, type of first-line regimen (i.e., monotherapy, doublet, or triplet therapy), and mortality during first-line therapy.

RESULTS: 8,368 patients met the inclusion criteria (mean age $74 + 5$ years, 55% male) with average follow-up of $14 + 15$ months. Platinum+taxane (53%), platinum+gemcitabine (16%), and taxane therapy (5%) were the most frequently prescribed IV chemotherapies. Average duration of first-line therapy was $4.2 + 2.8$ months. During first-line therapy, 19% of patients had a gap in therapy, 11% had a regimen modification, and 36% switched to second-line IV therapy. 64% of patients discontinued first-line therapy, of whom 92% died during therapy or within 2.8 months (median) of discontinuation. Common AEs included dehydration (40%), infusion reaction (39%), and anemia (39%). Serious AEs included bacterial/fungal infections (18%), hemorrhage (13%), and thromboembolic events (17%). DRSs included dyspnea (41%), chest pain (27%), and cough (13%). Mean monthly all-cause costs during first-line therapy were $\$6,461 \pm \$5,922$, 40% of which were inpatient costs. Claims noting AEs/DRS accounted for 48% of costs. In multivariate analysis, presence of selected AEs/DRS (e.g., chest pain, deep vein thrombosis, dehydration, hemorrhage, infection, thromboembolic events, and respiratory failure), triplet therapy, and death were associated with significantly ($P<0.05$) higher costs.

CONCLUSIONS: Platinum-based therapies were found to be administered most frequently in this elderly advanced NSCLC population. Treatment discontinuation and AEs were found to be common. Selected AEs and triplet therapy were associated with higher costs.

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

■ Health Care Resource Utilization Associated with Uncontrolled Serum Uric Acid in Patients with Gout

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BACKGROUND: The impact of high serum uric acid (sUA) on the health care resource utilization in patients with gout has not been well documented in the literature.

OBJECTIVE: To evaluate the impact of uncontrolled sUA on resource utilization among patients with gout using data from the U.S. Veterans Affairs Network.

METHODS: Adult male patients (age > 18 years) with at least 2 gout diagnoses (ICD-9 CM: 274.xx) and 2 sUA measurements between January 1, 2002, and January 1, 2011, were selected from the Veterans Integrated Services Network (VISN) 16 database. The study period from index date until the end of eligibility was divided into 6-month cycles to allow for a longitudinal design. Any cycle with sUA level > 7 mg/dL was considered uncontrolled while sUA ≤ 7 was considered to be controlled. A sensitivity analysis was subsequently performed using 6 mg/dL as threshold (sUA ≤ 6 as controlled). Logistic regression was used to obtain the odds ratio (OR) and Poisson regression model was used to obtain the incident rate ratio (IRR) for all-cause and gout-related hospital and outpatient visits. All regression models used sUA levels and gout-related medications as time-varying covariates and adjusted for repeated measures within subjects while also controlling for demographic information, baseline comorbidities, and resource use at baseline.

RESULTS: A majority of the 2,553 patients selected for the study were white (52%); average age was 63.5 years; mean body mass index (BMI) was 31.1 kg/m²; and average follow-up time was approximately 6 years. Hypertension (94%), hyperlipidemia (69%), cardiovascular diseases

(33%), diabetes (23%), renal disease (12%), and smoking (8%) were the most common comorbidities at baseline. Uncontrolled sUA (using >7 cut-off) was associated with an increased risk of all-cause hospitalization (OR: 1.25; 95% CI, 1.10 to 1.43), all-cause outpatient visits (OR: 1.32; 95% CI, 1.15 to 1.51), and increased number of all-cause hospitalizations (IRR: 1.23; 95% CI, 1.07 to 1.42). Similarly, the risk for gout-related hospitalization (OR: 1.49; 95% CI, 1.23 to 1.81), risk for gout-related outpatient visits (OR: 1.09; 95% CI, 1.02 to 1.18), the number of gout-related hospitalizations (IRR: 1.47; 95% CI, 1.22 to 1.78), and the number of gout-related outpatient visits (IRR: 1.12; 95% CI, 1.06 to 1.18) were also significantly higher for patients with uncontrolled sUA. All-cause outpatient visits associated with uncontrolled sUA were not statistically different from those with controlled sUA (IRR: 1.00; 95% CI, 0.95 to 1.05). Using 6 mg/dL as a cut-off point for controlled versus uncontrolled sUA levels exhibited similar trends in utilization.

CONCLUSIONS: In this retrospective study, gout patients with uncontrolled sUA utilized more hospital and outpatient care services than those with well-controlled sUA, imposing a greater burden on the health care system. A study limitation was that all enrollees were in the Veterans Affairs network, with a majority of male patients, which may reduce the representativeness of the study sample.

SPONSORSHIP: This research was funded by Takeda Pharmaceuticals U.S.A., Inc., Deerfield, IL, and Analysis Group, Inc., Chicago, IL.

Impact of a Self-Administration Training and Support Program on Site of Care in Patients with Hereditary Angioedema Receiving Nanofiltered C1 Esterase Inhibitor for Routine Prophylaxis

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BACKGROUND: In 2009, a plasma-derived nanofiltered C1 esterase inhibitor (C1 INH-nf) was FDA-approved for self-administration for the routine prophylaxis of swelling attacks in adolescents and adults with hereditary angioedema (HAE). Since HAE is a chronic genetic disease that may require twice weekly therapy, self-administration is an important option for these patients. An analysis of a patient database (n=516) to assess the site of care (SOC) was conducted in June 2010. Six months later, a self-administration training and support program led by skilled infusion nurses was implemented to educate eligible patients on self-administration of C1 INH-nf.

OBJECTIVE: To determine the impact of the self-administration training and support program of the SOC for patients receiving routine prophylactic C1 INH therapy.

METHODS: In early 2012, patient-reported demographic data from a dynamic C1 INH-nf database of HAE patients were examined. These results were compared with the 2010 analysis and reflect distributions of SOC for similar lengths of time before and after the initiation of the training and support program. Data were categorized and sorted; the results were based on descriptive statistics.

RESULTS: The SOC for patients receiving C1 INH-nf (n=789) was 75.8%, 16.1%, 8.1% at home, infusion center, and physician's office, respectively, compared with 47.1%, 23.3%, and 27.5% from the 2010 analysis. Of the 75.8% patients who infused at home, 57.9% self-administered; 26.6% were infused by a home health agency nurse; 14.7% were infused by a family member; and 0.8% were infused by other. Overall, self-administration was reported in 43.7% of patients compared with 20.0% from the 2010 analysis. Patients aged 30-64 years reported the highest percentage of home (60.8%) and self-administration (71.0%) overall. Per the previ-

ous analysis, no patients aged 12 years or younger or 65 years or older self-administered. However, in the current analysis, 10 patients aged 65 years or older learned to self-administer. Of the 234 patients enrolled in the program, 55% were successfully trained, and 13% were in the process of learning self-administration. Patients required an average of 5 visits to be successfully trained. Discontinuation rates of trained patients (5%) compared with untrained patients (10%) suggest that nonprogram patients were twice as likely to discontinue therapy.

CONCLUSIONS: These data suggest that a self-administration training and support program for HAE patients receiving routine prophylactic C1 INH therapy positively impacts the SOC in favor of home/self-administration as well as adherence to routine preventive therapy.

SPONSORSHIP: This research was conducted by ViroPharma Incorporated, Exton, PA, and Specialty Pharmacy Nursing Network, Inc., Sarasota, FL, without external funding.

Impact of a Step-Therapy Policy Restriction for Pregabalin on Health Care Utilization and Expenditures in a Commercial Population

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BACKGROUND: Prior research has examined the impact of prior authorization policies for pregabalin on health care resource utilization (HCRU) and associated expenditures in members from Medicaid and commercial health plans. Step therapy (ST) is a related formulary policy; however, the impact associated with implementation of a ST policy for pregabalin has not been examined.

OBJECTIVE: To compare year-over-year changes in HCRU and costs among commercial members with diabetic peripheral neuropathy (DPN), post-herpetic neuralgia (PHN), or fibromyalgia (FM) in a health plan implementing a pregabalin ST policy to similar members in health plans without pregabalin formulary restrictions.

METHODS: A retrospective, parallel-group, pre-/post-study design was used to examine outcomes associated with implementation of a ST policy on the use of pregabalin. Pharmacy and medical claims data from Humana ("restricted" cohort; ST implemented January 1, 2009) and Thomson Reuters MarketScan ("unrestricted" cohort) were used to conduct the analyses. Members aged 18-65 with ≥1 medical claim with an ICD-9-CM code for DPN, PHN, or FM during calendar years 2008 (baseline) or 2009 (follow-up), and a claim for a pain medication or pain intervention procedure were identified. The study cohorts were matched 1:1 on diagnosis and geographic region of residence. A difference-in-differences (DID) approach was used to examine year-over-year changes in disease-related and all-cause utilization and costs. The baseline to follow-up change in HCRU and costs was determined within each cohort, and the between-cohort DID was calculated as follows: DID=(Restricted cohort2009-Restricted cohort2008)-(Unrestricted cohort2009-Unrestricted cohort2008).

RESULTS: A total of 3,876 members was identified in the restricted cohort and matched to 3,876 members from the unrestricted cohort. The majority of members identified were diagnosed with FM (84.7%, n=3,284 in each cohort). Members in the unrestricted cohort were slightly older (mean ± SD: 49.0 years ± 10.4 vs. 47.6 years ± 10.5, P<0.001) and had a higher pharmacy-based comorbidity score (RxRisk-V score: 5.4±3.2 vs. 4.4±2.9, P<0.001) than members in the restricted cohort. The restricted cohort demonstrated a greater year-over-year decrease in the utilization of pregabalin compared with the unrestricted cohort (-2.6%, P=0.008). DID results were not significant for utilization of

gabapentin, opioids, nonopioid analgesics, antidepressants, muscle relaxants, or topical anesthetics. Compared with the unrestricted cohort, the restricted cohort experienced a greater increase in physical therapy use and disease-related outpatient utilization (3.7%, $P=0.010$, and 3.6%, $P=0.022$, respectively). DID calculations for all-cause total health care costs (\$-140, $P=0.832$), medical costs (\$-101, $P=0.867$), and pharmacy costs (\$-39, $P=0.806$) were not significant. Similarly, DID results were not significant for disease-related health care costs (\$86, $P=0.580$), medical costs (\$65, $P=0.598$), or pharmacy costs (\$21, $P=0.818$).

CONCLUSIONS: Consistent with prior research around pregabalin prior authorization policies in commercial health plans, this study found that implementation of a ST restriction resulted in lower pregabalin utilization, but the restriction was not associated with reductions in medical or pharmacy costs.

SPONSORSHIP: This research was funded by Pfizer Inc., New York, NY, and Humana, Inc., Louisville, KY.

Impact of an Extensive Pharmacist-Delivered Counseling Program on Patient Adherence to Target and Nontarget Chronic Medications

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BACKGROUND: Community pharmacists are well positioned to proactively counsel patients on the importance of medication adherence. Previous studies have shown that face-to-face interventions delivered by pharmacists can effectively increase medication adherence. Notably, the act of counseling patients on a specific target medication has been shown to improve patient adherence to that medication; it may also have the added benefit of increasing their adherence to other chronic medications.

OBJECTIVE: To determine the impact of an extensive pharmacist-delivered counseling program on patient adherence to target and nontarget chronic medications.

METHODS: This was a *post hoc* analysis of a retail pharmacy pilot study that randomly enrolled patients filling atorvastatin, pregabalin, and tolterodine between October 2008 and March 2009 to an intervention group or a usual care control group. Patients in the intervention group received enhanced pharmacist counseling that included adherence education, coaching, and reminder aids. Those who were new-to-therapy (NTT) received a NTT counseling session and were eligible for a first refill counseling session, and continuing therapy patients received 1 counseling session. A 6-month pre-index period was used to determine if patients were NTT or continuing on the target medications and to evaluate baseline group differences. One-year adherence rates for the 3 target medications as well as all nontarget chronic medications were assessed based on proportion of days covered (PDC). A general linear model was used to adjust PDC to control for age, gender, pre-index pill count, and number of chronic medications.

RESULTS: There were 3,329 intervention and 2,313 control patients included in the analysis. The average age of the intervention and control patients was 55.7 years ($SD\pm 13.8$) and 54.1 years ($SD\pm 14.6$), respectively. For target medications, the PDC at 1 year was 0.40 for the intervention group and 0.30 for the control group ($P<0.001$). For nontarget chronic medications, the PDC was 0.42 for the intervention group versus 0.37 for the control group ($P<0.001$). For NTT patients, PDC in the intervention group was 0.30 versus 0.22 for the control group ($P<0.001$) for target medications, and 0.38 versus 0.35 ($P=0.002$) for nontarget medications. For continuing patients, PDC in the intervention group

was 0.51 versus 0.39 for the control group ($P<0.001$) for target medications, and 0.46 versus 0.40 ($P<0.001$) for nontarget chronic medications. These results show that patients receiving counseling had 32.7% greater adherence to target medications than patients in the control group; they also exhibited 12.2% greater adherence to nontarget chronic medications. Compared with patients in the control group, patients receiving the intervention who were NTT had 36.8% and 8.7% greater adherence to target medications and nontarget medications, respectively, and continuing patients had 30.5% and 15.2% greater adherence to target medications and nontarget medications, respectively.

CONCLUSIONS: Patients participating in an extensive pharmacist-delivered counseling program demonstrated improved adherence to target medications. Furthermore, patients generalized their improved adherence behavior, to a lesser extent, to nontarget chronic medications that were not directly addressed by the intervention.

SPONSORSHIP: This research was funded by Walgreen Co., Deerfield, IL, and Pfizer Inc., New York, NY.

Impact of the Patient Protection and Affordable Care Act Provision on Contraception as a Preventive Benefit: Contraception Costs for Commercial Health Plans

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BACKGROUND: Provisions of the Patient Protection and Affordable Care Act (PPACA) require health plans to cover contraceptive methods and counseling as a preventive service without cost sharing. Comments by the U.S. Department of Health and Human Services suggested that the cost of PPACA's required contraceptive coverage would be outweighed by the savings associated with reducing the number of unintended pregnancies. The literature does not contain information on how PPACA will impact costs of covering contraceptives from a health plan perspective. As the rules are currently not finalized at the time of writing, it is unclear whether all or just some of the currently approved and available contraceptive methods will be considered preventive.

OBJECTIVE: To quantify the per member per month (PMPM) cost of eliminating member cost sharing on contraception under 3 benefit design scenarios and to explore the elasticity between cost sharing and utilization for contraceptive methods.

METHODS: Data from the Thompson Reuters MarketScan Commercial Claims Database for 2009, trended to 2012, on female enrollees were used in the analysis. Per-member and per-patient costs and utilization for 6 contraception methods—oral contraceptives (OC), vaginal rings, implantable rods, injectables, intrauterine devices (IUD), and sterilization—were identified through National Drug Code (NDC) or procedure codes. We modeled the impact of the preventive contraception coverage rule under 3 benefit design scenarios: zero cost sharing for (a) generic products only, (b) generic products and products without a generic alternative, and (c) all generic and branded products. We also analyzed the elasticity between cost sharing and utilization for these methods. Linear regression was used to estimate elasticity curves from the data. Elasticity factors were applied to contraception utilization in the 3 scenarios to project change in net PMPM costs.

RESULTS: Our analysis estimated that the national average cost increase to payers of contraception coverage due to the inclusion of contraception as a preventive service without cost sharing will range from \$0.43 (scenario 1) to \$1.02 (scenario 3) PMPM. Four of the 6 contraception methods showed price elasticity: OC, vaginal rings, injectables, and IUD. Evidence for elasticity for implantable rods and female

TABLE PMPM Impact of Preventive Contraception Services Provision

	Scenario 1 (\$)	Scenario 2 (\$)	Scenario 3 (\$)
Net cost pre-reform	2.39	2.39	2.39
Net cost post-reform	2.82	3.00	3.41
Net impact	0.43	0.61	1.02

PMPM = per member per month.

sterilization was not conclusive. The number of IUD users per 1,000 women of childbearing age increased as member cost sharing decreased. For OC, vaginal rings, and injectables, there was an increase in utilization with decreased cost sharing through improved compliance of existing users rather than an increase in the number of users. The cost-sharing gap between the branded and generic OC may also affect the use of OCs.

CONCLUSIONS: Providing contraception methods as preventive health services with no cost sharing results in a modest increase in contraception costs to payers, which will vary depending on the final rule's details.

SPONSORSHIP: This research was conducted by Bayer HealthCare Pharmaceuticals Inc., Wayne, NJ, without external funding.

■ Is History of Patient Adherence to Asthma Controller Medication Associated with Initial Choice of Prescription for Inhaled Corticosteroid and Long-Acting β2-Adrenergic Agonist Combination Therapy?

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BACKGROUND: Patient history of past adherence to prescribed asthma controller regimen may be a marker of future adherence. Physicians may consider previous patient compliance in their choice of treatments, especially if they perceive ease of use with type of inhaler associated with adherence.

OBJECTIVE: To evaluate the association between patients' adherence to prior asthma controller medication and choice of therapy initiation with budesonide/formoterol combination (BFC) or fluticasone/salmeterol combination (FSC).

METHODS: In a retrospective analysis of HealthCore Integrated Research Database, asthma patients aged 12-64 years with ≥ 1 pharmacy claim for inhaled corticosteroid/long-acting β2-adrenergic agonist (ICS/LABA) between June 1, 2007, and August 31, 2011, with ≥ 12 months' continuous enrollment before therapy initiation (index date) were identified. Patients with chronic obstructive pulmonary disease and other respiratory diseases or prescription fills for > 1 type of ICS/LABA therapy were excluded. Adherence was measured using medication possession ratio (MPR) for patients with ≥ 1 pre-index controller prescription. MPR was assessed for monotherapies (ICS, LABA, leukotriene receptor antagonist [LTRA], theophylline, omalizumab) and treatments prescribed together (ICS+LABA, ICS+LTRA, and LABA+LTRA). Composite-weighted MPR measure, ranging from 0-1, was created based on percentage of time each medication was used. Patients were considered adherent if MPR > 0.80.

RESULTS: 9,706 BFC and 27,975 FSC patients were identified. Mean age was 40 years for BFC patients and 38 years for FSC patients. Overall, 19% and 14% of BFC and FSC patients, respectively, had ≥ 1 prescription fill for LTRA and ICS, while < 5% of patients filled prescriptions for

all other asthma controller medications. ICS and LTRA monotherapies were prescribed together for 6% of patients. Composite-weighted MPRs were comparable between BFC and FSC patients (n, mean ± SD, median: 4537, 0.81 ± 0.23, 0.91 vs. 10,163, 0.82 ± 0.24, 0.95). Mean difference (-0.005) was not statistically significant between cohorts (95% CI, -0.013 to 0.0031; P=0.221). 64% of BFC and 65% of FSC patients were adherent (MPR > 0.80) to their controller therapies (OR=0.92; 95% CI, 0.85-0.99, P=0.023).

CONCLUSIONS: Adherence to prior controller therapy in asthma patients was similar between BFC and FSC cohorts and does not appear to have an impact on physician choice of type of combination therapy initiated. Other factors, including patient preferences and formulary access, may affect the physician's choice of prescribing these agents for asthma management.

SPONSORSHIP: This research was conducted by AstraZeneca, LP, Wilmington, DE, without external funding.

■ Medication Therapy Management: Methods to Increase Comprehensive Medication Review Participation, Phase 2

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BACKGROUND: Current Centers for Medicare and Medicaid Services' (CMS) guidelines require Part D sponsors to offer a Comprehensive Medication Review (CMR) to each beneficiary participating in a Medication Therapy Management Program (MTMP). A CMR is a review of a beneficiary's medications that is intended to aid in assessing medication therapy and optimizing patient outcomes. CMS has recently adopted the Pharmacy Quality Alliance (PQA) MTM Completion Rate as a performance metric by which program sponsors will be evaluated. Beginning with calendar year 2013, health plans' MTM CMR Completion Rate will be displayed on the CMS website using 2011 data. In 2014, the MTM CMR Completion Rate will be a STAR metric using 2012 data. Sponsors of MTMPs and/or their MTMP providers are responsible for creating innovative processes to increase CMR completion rates in order to improve health outcomes and maximize quality bonus payments associated with this measure.

OBJECTIVE: To evaluate process improvements implemented by an MTMP call center that were designed to increase the rate of MTMP beneficiaries participating in a CMR.

METHODS: The industry average of CMR completion rates in 2010 have been reported to be just over 8% (9.6% for Medicare Advantage Prescription Drug [MAPD] plans and 6.6% for Medicare Prescription Drug Plans [PDP]). Assumptions of reasonable performance have been hypothesized to be between 10% and 15%. Process improvements were implemented by an MTMP call center to minimize barriers to completing CMRs, increase the completion rates, and ultimately maximize future quality bonus payments associated with this metric. Changes include utilization of prior year's claims data to increase the pool of MTMP beneficiaries qualifying in the first quarter of the year; eliminating any wait period after members qualify for the MTMP prior to providing services; offering a CMR upon every Targeted Medication Review (TMR) member outreach; increased number of clinical interventions that trigger TMRs; and ongoing monitoring of CMR completion rates throughout the year.

RESULTS: In calendar year 2011, prior to implementing additional process changes, a total of 153,560 beneficiaries participated in the MTM program, with 10,636 members completing a CMR, for a total participation rate of 6.93%. Through the first quarter of the 2012 program

year, 247,478 members have qualified for the MTMP. Of those members, 6,982 members have completed a CMR. Based on first-quarter experience, the process changes are expected to result in a CMR participation rate greater than 10%. Updated results will be provided through the third quarter of 2012.

CONCLUSIONS: This program is associated with a projected 44% increase in the participation rate of CMRs.

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

Methods for Improving Outcomes and Increasing Fill Rates for Antiplatelet Therapy After Stent Implantation

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BACKGROUND: Antiplatelet therapy following bare metal or drug eluting stent implantation is crucial in preventing further cardiovascular events. Following hospital discharge, a patient who delays filling antiplatelet therapy, is nonadherent to therapy, or discontinues therapy early may be at risk for an adverse cardiovascular outcome.

OBJECTIVE: To decrease the time to first fill of antiplatelet medication, prevent early discontinuation of therapy, decrease vessel restenting and new stents, decrease cardiac related hospitalizations, and emergency department visits.

METHODS: From January 1, 2009, through December 31, 2009, 248 members insured by Geisinger Health Plan were identified as having a stent implantation requiring antiplatelet therapy. Members as part of the pre-intervention group were followed 1 year post-stent implantation to evaluate outcomes through electronic health record documentation and pharmacy and medical claims. The intervention group patients (n=429) were identified through discharge summaries from hospitals included inside and outside of the Geisinger Health System clinical enterprise. Patients were discharged alive following stent placement in ≥ 1 coronary artery from February 2011 to February 2012. The pre-intervention group was used as a comparator for the year prior to intervention group. Antiplatelet medications included were clopidogrel, prasugrel, and ticagrelor. The offer to counsel and provide the medication prior to discharge was made by inpatient pharmacists. Upon discharge, a Geisinger Health Plan pharmacist, an adherence pharmacy technician, or a case manager offered additional counseling and addressed adherence barriers for 1 year post-stent placement or until discontinuation of therapy as recommended by physician. Satisfaction surveys were sent to members upon completion of therapy for program evaluation and process improvement feedback.

RESULTS: Significant differences among members receiving medication prior to or upon discharge were observed comparing the pre-intervention group (n=248) with the intervention group (n=429), 52% versus 93%, respectively. No claims submitted for medication decreased from 21% in the pre-intervention group to <1% in the intervention group. One member receiving medication following drug-eluting stent has discontinued, while rate of discontinuation for bare metal stent is approximately 19%. Among the bare metal stent population, there were varying prescribing habits for length of therapy and reasons of discontinuation. Length of therapy ranged from 2 weeks and beyond, and observed reasons for discontinuation were initiation of anticoagulation therapy, surgery, therapy completed per physician, and financial barriers. At day 30 post-stent, the intervention group cardiac-related hospitalization and emergency department visits were decreased by approximately 50%,

TABLE Rates Per 1,000 Patients

	Days Post-Stent	Pre-Intervention (# of Patients)	Post-Intervention (# of Patients)
Restenting/revascularization	7	24	5
	30	28	26
Emergency department/hospitalizations	7	149	55
	30	69	52

while revascularization and new stents were decreased by approximately 23% when compared with the pre-intervention group. Feedback from member surveys showed overwhelming satisfaction with the program and gratefulness on behalf of members for the health plan's dedication to their overall health.

CONCLUSIONS: This study shows that pre-discharge counseling and offering to fill medication, as well as consistent post-discharge contact improves patient outcomes. Potential limitations of this study were that claims data and electronic health record notes were highly utilized and all of the intervention patients have not reached 1-year post-discharge.

SPONSORSHIP: This research was conducted by Geisinger Health Plan, Danville, PA, without external funding.

Multiple Sclerosis Specialty Drug Utilizers Cost of Care Trends 2008 to 2010: An Integrated Medical and Pharmacy Claims Analysis

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BACKGROUND: In 2011, multiple sclerosis (MS) drugs accounted for 3.6% of all pharmacy benefit (Rx) costs and the average per prescription cost was \$3,135, an increase of 15.2% from 2010, among a 9-million member commercially insured cohort. It is unknown if the increases in MS drug costs are associated with decreases in medical costs.

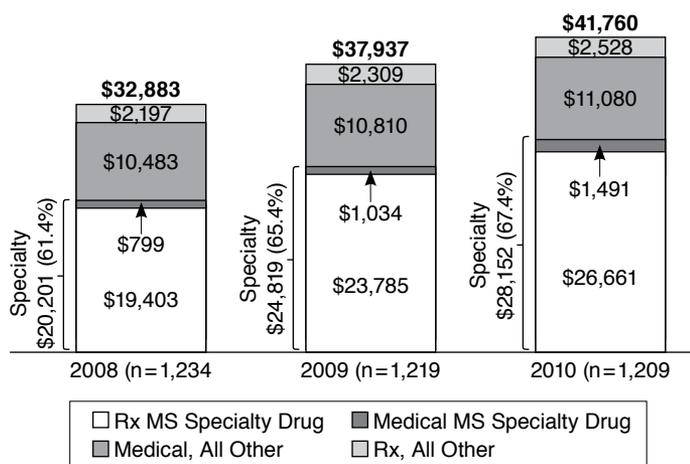
OBJECTIVE: To describe the cost of care trends among commercially insured individuals utilizing an MS specialty drug stratified by specialty and nonspecialty costs within the medical and Rx benefits.

METHODS: Integrated Rx and medical claims data from 1.2 million commercially insured members were queried. Members were required to be age 0 to 64 and continuously enrolled for a full year during 2008, 2009, or 2010. To define a member as having an MS diagnosis, the following criteria were used: (a) 2 or more medical claims with an MS ICD-9 diagnosis code, (b) 1 medical claim with MS and 1 MS drug claim, or (c) 2 or more MS drug claims. All MS drugs were considered specialty drugs and included the following: glatiramer, interferon beta-1a and 1b, natalizumab, dalfampridine, and fingolimod. Each year, the prevalence of members with an MS diagnosis and MS drug treatment was identified. Among members using MS drugs, the annual average member total cost of care was calculated (PMPY). Total cost of care was also separated into 4 categories: medical MS drug, medical all other, Rx MS drug, and Rx all other. Costs were the total paid amount, which includes both the individual out-of-pocket and insurer payments. Descriptive statistics were used to describe the annual total cost of care and spending in each of the 4 categories. The compound annual growth rate (CAGR) was used to describe cost trends.

RESULTS: MS diagnosis prevalence was 17 per 10,000 continuously enrolled members in 2008 (1,742 of 1,038,638) and did not change through 2010. MS drug utilization among members with a diagnosis was consistent over the 3 years at a rate of 1,234 (70.8%) of 1,742

FIGURE

Annual Average Cost of Care for Multiple Sclerosis Patients Treated with Specialty Drugs^a



^aCommercially insured members continuously enrolling during analysis year. MS= multiple sclerosis; Rx= pharmacy benefit.

members in 2008 and 1,209 (71.8%) of 1,685 members in 2010. Although MS drug utilization remained constant, the total cost of care CAGR was 12.7% from 2008 to 2010 (figure). All other medical costs were \$10,483 in 2008 and increased to \$11,080 in 2010, CAGR 2.8%. Combined MS medical and Rx specialty drug costs accounted for \$20,201 (61.4%) of \$32,883 total cost of care in 2008 and increased to 67.4% in 2010 (\$28,152 of \$41,760), CAGR 18.1%. The medical and Rx specialty drug CAGRs over the 3-year period were 36.6% and 17.2%, respectively. MS drug costs were 95% from the Rx benefit.

CONCLUSIONS: In 2010, MS medical and Rx specialty drug costs were more than two-thirds of the total cost of care. The fastest growing category within the total cost of care was specialty drugs to treat MS, at 6.5 times the rate of all other medical costs (CAGR 18.1% vs. 2.8%). As drug utilization remained relatively unchanged and more than 95% of MS drug expenditures were from the Rx benefit, most of the increase in spending was due to manufacturer price increases. The increasing MS drug costs do not appear to be associated with decreasing medical costs. Health plans and insurers need to have a full understanding of where dollars are being spent in conditions such as MS and how to best manage the increasing burden of specialty drug costs. More research in other specialty conditions is necessary to broaden the knowledge base among specialty care.

SPONSORSHIP: This research was conducted by Prime Therapeutics, LLC, Eagan, MN, without external funding.

Nonadherence with Oral 5-ASA Therapy and Disease Burden with Ulcerative Colitis

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BACKGROUND: Ulcerative colitis (UC) is 1 of the 2 major types of inflammatory bowel disease (IBD). First-line treatment with 5-aminosalicylic acid (5-ASA) is recommended for mild-to-moderate disease. Systematic literature review has shown that UC is a costly disease, with hospitalizations contributing significantly to direct medical costs. There

is little published literature assessing medication adherence and its association with emergency room visits and inpatient hospitalization using medical claim data.

OBJECTIVE: To evaluate the prevalence of nonadherence with oral 5-ASA therapy and its association with UC-related and all-cause disease burden in UC patients.

METHODS: IMS LifeLink Health Plan claims data (January 2007 to June 2011) were analyzed. Adult patients (18 years or older) were selected if they met the following criteria: (a) initiated at least 1 oral 5-ASA prescription fill (index date) during July 2007 to July 2010; (b) presence of at least 1 diagnosis of UC (ICD-9-CM code=556.x [ulcerative colitis]) in the 6 months prior to or the 12 months post-index date; (c) continuous enrollment in both health and pharmacy plans for at least 6 months prior to and the 12 months post-index; (d) no prescription fill for 5-ASAs, corticosteroids, and immunosuppressive/biologic agents 6 months prior to index date. Patients with a diagnosis of Crohn's disease (ICD-9-CM: 555.x [regional enteritis]) or irritable bowel syndrome (ICD-9-CM: 564.1 [irritable bowel syndrome, irritable colon, spastic colon]) in the 6 months prior to and the 12 months post-index date were excluded. Nonadherence was determined by a proportion of days covered (PDC) <0.8 for any 5-ASA. Disease burden was defined as emergency department or inpatient visits. Multiple logistic regression models were used to assess nonadherence with oral 5-ASA and other risk factors associated with UC-related and all-cause disease burden.

RESULTS: We identified 5,964 UC patients. Mean age was 48 years; 53% were female. Overall, 79% of patients were nonadherent with oral 5-ASA treatment; 10% had UC-related disease burden; and 28% had all-cause disease burden. When compared with patients who adhered with 5-ASA treatment, nonadherers were more likely to have UC-related burden (OR=1.41, 95% CI=1.12-1.77) or all-cause disease burden (OR=1.35, CI=1.16-1.57). Other factors significantly associated with UC-related/all-cause disease burden included noncommercial payer type ([OR=1.25, CI=1.02-1.54]/[OR=1.25, CI=1.08-1.45]); comorbidities (≥2 comorbidities: [OR=2.00, CI=1.62-2.47]/[OR=2.75, CI=2.38-3.18]; 1 comorbidity: [OR=1.36, CI=1.09-1.70]/[OR=1.57, CI=1.36-1.82]); more severe UC as measured by corticosteroid use ([OR=3.39, CI=2.82-4.09]/[OR=2.18, CI=1.92-2.46]); or immunosuppressive/biologic agents use ([OR=2.11, CI=1.61-2.76]/[OR=1.48, CI=1.18-1.85]) in post-index date. Additionally, age older than 65 years (OR=1.28, CI=1.07-1.54); female gender (OR=1.24, CI=1.10-1.39); patients from different regions (Midwest: OR=1.29, CI=1.06-1.56; West: OR=1.47, CI=1.17-1.86 as compared with Northeast); and specialist care use (OR=1.18, CI=1.04-1.34) were significantly associated with all-cause disease burden.

CONCLUSIONS: Prevalence of nonadherence with oral 5-ASA treatment was high as reflected in these administrative claims of UC patients. Nonadherence with 5-ASA treatment was significantly associated with UC-related or all-cause disease burden. These associations reinforce the importance of improving medication adherence as a strategy to avoid potential emergency department or inpatient hospitalization events.

SPONSORSHIP: This research was conducted by Shire Development LLC, Wayne, PA, without external funding.

Pain Characteristics, Related Treatment Patterns, and Health-Related Quality of Life Among Patients with Painful Diabetic Peripheral Neuropathy

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BACKGROUND: Pain is a debilitating symptom of diabetic peripheral neuropathy affecting 10%-20% of diabetics annually. Opioids are

reserved for combination therapy or second-line use when treatment with other therapies, such as antidepressants or anticonvulsants, provides insufficient pain relief. Research efforts have focused on disease burden of painful diabetic peripheral neuropathy (pDPN), yet little has been done to understand pain characteristics, related treatment, and health-related quality of life (HRQoL) in this population.

OBJECTIVE: To evaluate pain characteristics, treatment patterns, and HRQoL in patients with pDPN.

METHODS: A nationally represented U.S. sample of adults (N=75,000) who completed the 2011 National Health and Wellness Survey (NHWS) online and reported both a diagnosis of "neuropathic pain as a result of diabetes," and pain in the past month were included. Patients were excluded if they were receiving pain medication primarily for cancer, migraine, dental, or menstrual pain. Pain characteristics (3-level severity, frequency, and intensity in the past week), related treatments, and HRQoL collected using the Short Form Health Survey (SF-12 v2; i.e., Mental Component Summary [MCS] and Physical Component Summary [PCS] scores) were reported descriptively.

RESULTS: Of the 1,625 pDPN patients (mean/median age=60/62 years; 64.4% males; 79.3% whites) included in the analysis, 68.6% were diagnosed by their primary care physicians, with an average pain duration of 6.17 years. Sleep difficulties (43.5%), depression (36.9%), and anxiety (21.7%) were frequently reported comorbidities, while many patients reported diagnoses of arthritis (46.1%), back (36.4%), and joint (30.2%) pain. When asked about the cause of pain in the past month, 70.2% reported neuropathic pain followed by arthritis (51.9%), joint (50.3%), and back (48.7%) pain. Overall, patients reported an average pain intensity of 5.88, and the majority (65.3%) experienced pain daily. Nearly 75% rated their neuropathic pain as moderate to severe, and only 56.4% were currently treating with a prescription analgesic. Among prescription users, more than half used monotherapy, most commonly opioids (32.3%), anticonvulsants (14%), or nonsteroidal anti-inflammatory drugs (NSAIDs; 8.5%), while about two-fifths used combination therapy. Most common combinations included anticonvulsants/opioids (16.4%), opioids/NSAIDs (16.6%), or opioids/other drugs (12.1%). Opioid users, which comprised the majority of prescription users, were primarily using such treatment for back (47.9%), neuropathic (29.1%), or arthritis (21.7%) pain. As for the HRQoL measure, pDPN patients reported high activity impairment (69.2%) and had lower MCS and PCS scores (45.17 and 33.28, respectively), relative to the general population (mean score=50).

CONCLUSIONS: Patients with painful diabetic peripheral neuropathy commonly have other pain conditions and use opioids either alone or in combination for their neuropathic and nociceptive pain. Despite having moderate-to-severe neuropathic pain, only about half of the studied population is treated with prescription pain medications, which may have contributed to lower HRQoL. Further analyses of these data will assess the impact of treatment on other patient-reported outcomes.

SPONSORSHIP: This research was conducted by Janssen Scientific Affairs, LLC, Raritan, NJ, without external funding.

■ Prescription of Inhaled Corticosteroids and GOLD Severity Stage Among Patients with Chronic Obstructive Pulmonary Disease

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) treatment guidelines recommend that maintenance inhaled corticosteroid (ICS) therapy be reserved for patients at high risk, that is, severe or very severe airflow limitation (Global Initiative for Obstructive Lung Disease

[GOLD] III or IV) and repeated exacerbations. Reports in different populations indicate that ICS may be overutilized in patients with less severe disease. This is of concern, given the potential adverse effects of ICS use in patients with COPD.

OBJECTIVE: To describe the pattern of ICS prescriptions according to COPD severity based on GOLD 2010 stages using the General Electric Centricity electronic medical record (GE EMR) database.

METHODS: A retrospective cohort study was conducted using data from the GE EMR database (2005-2009) that contains around 21 million patients from 45 states and 30,000 clinicians (85% are primary care). Patients with at least 1 forced expiratory volume in 1 second (FEV1) result test between January 1, 2005, and December 31, 2009, were included with the date of first spirometry testing as the index date. Additional inclusion criteria included the following: age ≥40, diagnosis of COPD (ICD-9: 491.xx, 492.xx, 496.xx) prior to the index date, 1 year of GE system history post-index, and no diagnosis of asthma (ICD-9: 493.xx) in the study period. Patients were staged using FEV1% predicted values based on the GOLD 2010 guidelines. Prescription use of ICS was summarized by GOLD 2010 COPD stage.

RESULTS: 6,478 COPD patients were identified for inclusion into this study (59% >65 years, 48% female, mean FEV1% predicted: 63%). Among them, 24% were classified as mild COPD; 42% were classified as moderate COPD; 25% were classified as severe COPD; and 9% were classified as very severe. ICS therapy was prescribed for 35% (n=554) of mild patients and 39% (n=1,073) of moderate patients.

CONCLUSIONS: A high percentage of patients in mild-to-moderate COPD were prescribed ICS therapy by their physicians in the GE database. Use of ICS therapy in these stages of COPD is inconsistent with the GOLD 2010 guidelines recommendations.

SPONSORSHIP: This research was conducted by Novartis Pharmaceutical Corporation, East Hanover, NJ, without external funding.

■ Prevalence of Opioid Abuse and Related Costs in a Commercial Managed Care Population

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BACKGROUND: While treatment with opioids is an important component of pain management, increased use of these medications has been accompanied by a dramatic increase in the rate of opioid drug abuse. Although the prevalence of diagnosed opioid abuse in managed care claims is relatively small, opioid abuse-related costs are significant and have not been documented extensively.

OBJECTIVE: To measure the prevalence and resource use/cost burden of diagnosed opioid abuse in Humana commercial members.

METHODS: This study was a retrospective analysis of claims data for Humana commercial members (January 1, 2007, to June 30, 2011). Overall prevalence of opioid abuse was assessed using ICD-9 codes indicating opioid abuse/dependence (304.0X, 304.7X, 305.5X, 965.0X). To assess incremental resource use and costs related to diagnosed opioid abuse among members with opioid use, those with an ICD-9 claim for abuse (cases) between January 1, 2008, and June 30, 2010, were matched 1:2 with members with opioid use but no abuse (controls). Matching was based on line of business, region, enrollment period, age, and gender. The date of diagnosed opioid abuse is defined as the index date, and resource use, comorbidities, and costs were examined 12 months pre- and post-index date. Exclusion criteria were ASO members, pregnancy, an opioid abuse diagnosis in the pre-index period, and members not

continuously enrolled during the entire study period. Multivariate analyses were conducted using generalized linear modeling (GLM) with log-transformed abuse-related costs as the dependent variable.

RESULTS: The 6-month prevalence (per 1,000) of diagnosed opioid abuse increased from 0.84 in 1st half of 2008 to 1.15 in 1st half of 2010, while the prevalence of opioid use decreased from 118 to 115 per 1,000 during the same time period. Opioid abusers (cases) were similar to nonabusers (controls) in terms of age (63.0 vs. 63.1), gender distribution (56% female), and region (78% South). Compared with nonabuse controls, opioid abuse cases had a significantly higher mean RxRisk score (5.2 vs. 3.2, $P<0.001$), number of opioid prescriptions (14.1 vs. 2.4, $P<0.001$), and total number of pain medication prescriptions during the pre-index period (25.8 vs. 5.5, $P<0.001$). Opioid abuse cases also reported significantly higher substance abuse (53 vs. 8%, $P<0.001$), psychiatric diagnoses (73 vs. 17%, $P<0.001$), and hepatitis (3.1 vs. 0.3%, $P<0.001$) in the pre-index period than nonabuser controls. In the pre-index period, total abuse-related costs were \$3,185 higher in abusers ($P<0.001$), whereas all-cause direct costs were \$17,068 higher ($P<0.001$). In the post-index period, total abuse-related costs were \$2,236 higher in abusers ($P<0.001$), whereas all-cause direct costs were \$16,258 higher ($P<0.001$). In the multivariate model, adjusted costs were 270% higher for opioid abusers than nonabuser controls, 172% higher for members living in the West region (compared with the South), and were 124% higher for females ($P<0.001$). Costs were also more likely to be higher for members with pain-related conditions (126%, $P<0.001$) and higher RxRisk scores (124%, $P<0.001$).

CONCLUSIONS: Members with diagnosed opioid abuse in the Humana commercial population experienced significantly higher health care-related costs than nonabusers. To our knowledge, this study provides the first published estimates of diagnosed opioid abuse and its cost burden in the Humana commercial membership.

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Quality Care Improvement Through Engaged Provider Response to Medication Therapy Management Recommendations

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BACKGROUND: A variety of Medication Therapy Management (MTM) programs have evolved over the past 6 years. Programs are challenged to engage providers by identifying important patient issues with variable access to clinical data.

OBJECTIVE: To (a) evaluate the impact of pharmacist clinical recommendations on the quality of vulnerable elder care, (b) measure provider response to recommendations, and (c) determine the impact of adding the number of MTM recommendation responses as a component of an existing provider quality bonus program.

METHODS: MTM at Providence Health Plans is provided by in-house clinical pharmacists. These pharmacists complete a Comprehensive Medication Review (CMR) or Individual Targeted Medication Review (I-TMR) for 100% of the almost 4,000 members enrolled. For both types of reviews, the pharmacist examines prescription and medical claims and, when accessible, provider electronic medical records. For a CMR, the pharmacist contacts the member by phone, discussing medical history, medication-related questions, and issues related to health status. If the member declines a conversation, the completed evaluation is called an I-TMR. Following both types of reviews, recommendations are sent to providers focusing on up to 3 key concerns. For this analysis, the

impact on patient quality was measured for members who were continuously enrolled in MTM and could act as their own control. In 2011, an addition to the existing quality bonus was offered to providers who returned any response to at least 80% of MTM recommendations sent to them. In this review, the percentage of provider responses received in 2010 and 2011 were compared to measure increased provider engagement and evaluate medication changes expected based on provider responses received.

RESULTS: The 1,631 members continuously enrolled from 2009 through 2011 were included for analysis. In 2010, 1,443 identified issues led to recommendations. In 2011, 2,698 provider recommendations were made. In a chronically ill population that had grown a year older, a number of clinical measures improved or remained stable from 2010 to 2011. The number of individuals with documented hemoglobin A1c (A1c) values remained stable (507 vs. 504), the percentage of members with A1c $<8\%$ increasing 1.9% (86.0% to 87.9%). The rates of use of at least 1 high-risk medication (HRM; 36.4% vs. 34.5%) and the use of 2 or more HRMs (9.7% vs. 8.9%) both decreased. The percentage of members diagnosed with rheumatoid arthritis who also were dispensed a disease-modifying antirheumatic drug grew from 69.0% to 73.1%. Members also remained persistent on chronic medications: angiotensin-converting enzyme inhibitors (96.7% to 95.9%), digoxin (96.4% to 98.7%), diuretics (95.9% to 94.8%), and anticoagulants (70.1% to 70.1%). Comparing data from 2010 to 2011, there was a 7% increase in both the percentage of providers responding to recommendations (63% to 70%) and in provider agreement to consider a change in treatment (50% to 57%).

CONCLUSIONS: A pharmacist with member-specific care plan recommendations that result from medical as well as pharmacy data can lead to stronger provider engagement and improvements in quality measures while meeting Medicare MTM requirements.

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

Resource Utilization and Costs of Multiple Sclerosis Patients with High Relapse Rate Using a Claims Database

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BACKGROUND: Multiple sclerosis (MS) is a chronic disease that affects adults. Multiple relapses can indicate high disease activity (HDA) and can restrict the individual's life, resulting in a major financial burden and high health care resource utilization. There are very few studies evaluating the impact of HDA on outcomes using real-world claims data.

OBJECTIVE: To identify HDA MS patients and compare the differences in resource utilization and costs between HDA and non-HDA patients, controlling for baseline demographics and comorbidities

METHODS: A retrospective longitudinal study was conducted using MarketScan commercial claim and Medicare database. Patients included had at least 1 ICD-9 for MS (340.XX) in 2009 and 1 in the prior year, were 18 years or older in 2009, and had continuous enrollment in the year of 2009 and 2010. HDA was defined in 2009 as having 2 relapses in the year, and relapse was defined according to Chastek 2010 algorithm. Multivariate analyses were conducted to compare all-cause and MS-specific emergency room (ER) and hospitalizations (logistic regression) and all-cause costs (Gamma regression with log link) in 2010 between HDA and non-HDA patients, controlling for age, gender, geographic region, health plan type, employment status, Charlson

comorbidity index (CCI), MS symptoms, and disease-modifying treatment (DMT) use in 2009.

RESULTS: 19,219 patients met the study criteria. 94.71% (n = 18,202) had less than 2 relapses and 5.29% (n = 1,017) had more than 2 relapses in 2009. HDA patients were younger (50 vs. 52 years) and less likely to be employed (50.15% vs. 56.47%). Mean CCI was 0.82 for HDA (vs. 0.56). HDA patients had more MS symptoms (82.1% vs. 68.8%) and were more likely to use DMT in 2009 (67.7% vs. 63.6%, $P=0.008$). Unadjusted results in 2010 showed that HDA patients had more all-cause and MS-specific hospitalizations (23.21% vs. 11.43% and 7.37% vs. 1.63%) and ER visits (32.84% vs. 22.70% and 15.24% vs. 7.6%) compared with non-HDA patients. After adjusting for patient demographics, CCI, MS symptoms, and DMT use, HDA patients were more likely to be hospitalized (OR all-cause: 2.2 95% CI: 1.8, 2.5; OR MS specific: 3.9, 95% CI: 2.9; 5.1) and have ER visits (OR all-cause: 1.5, 95% CI: 1.3; 1.7; OR MS specific: 1.9, 95% CI: 1.6; 2.3) than non-HDA patients. Mean unadjusted total all-cause cost (excluding DMT drug costs) for the HDA group was US\$30,286 compared with US\$14,568 for the non-HDA group. Adjusted cost difference between HDA and non-HDA was \$12,648 (\$27,700 vs. \$15,052; 95% CI: \$10,568; 15,035; $P<0.0001$) for all.

CONCLUSIONS: Patients with 2 or more relapses annually have high resource utilization and are more costly. After adjusting for differences in patient characteristics, the results were robust. Two or more relapses annually seems to be indicative of HDA; however, a more robust algorithm needs to be developed to also incorporate clinical aspects of the HDA definition.

SPONSORSHIP: This research was conducted by Novartis Pharmaceuticals Corporation, East Hanover, NJ without external funding.

Retrospective Analysis of Drug Therapy Continuation Following Implementation of a Limited Pharmacy Network

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BACKGROUND: Restricted pharmacy networks, where 1 or more retail pharmacy chains are excluded from coverage, are growing in popularity with pharmacy benefit programs. These networks are attractive to payers due to the cost savings achieved with low member disruption; however, there is little research showing how limiting member access to retail pharmacies affects clinical outcomes.

OBJECTIVE: To measure drug therapy continuation rates for prescription drug utilizers within a payer client that implemented a restricted pharmacy network.

METHODS: A large employer client implemented a restricted pharmacy network where 1 national retail pharmacy chain was excluded from coverage. Affected members received a letter identifying 3 pharmacy alternatives near their homes with instructions on transferring their prescriptions. A pre-/post-analysis was conducted on continuously enrolled members who filled 2 or more prescriptions for maintenance medications and where at least 1 prescription was filled at the pharmacy chain to be excluded upon implementation of the restricted network. Members were tracked for 6 months prior to and 6 months after the implementation of the restricted pharmacy network. Members who filled at least 1 prescription for a drug in the same therapeutic class during the post-period were identified as having continued their drug therapy. Members with no fill for a drug in the same therapeutic class during the post-period were identified as discontinuing drug therapy. The percentage of members continuing drug therapy was calculated both overall and at the therapeutic class level with further analysis of continuation by age, sex, and distance to the nearest alternative pharmacy.

TABLE

Therapy Continuation Rates: Top 10 Therapeutic Classes by Number of Utilizers in the Pre-Period

Therapeutic Class	% Utilizers Continued Therapy	% Utilizers Discontinued Therapy
HMG-CoA reductase inhibitors	94.5	5.5
Beta blockers cardio-selective	95.5	4.5
Antihypertensive combinations	94.9	5.1
Proton pump inhibitors	93.3	6.7
Ace inhibitors	94.4	5.6
Nonsteroidal anti-inflammatory agents	93.1	6.9
Calcium channel blockers	93.6	6.4
Thyroid hormones	96.3	3.7
Biguanides	95.9	4.1
Selective serotonin reuptake inhibitors	93.7	6.3

RESULTS: A total of 12,713 members met the inclusion criteria for the pre-period. Of these members, 11,843 (93.2%) continued, and 870 (6.8%) did not continue their drug therapy during the post-period. Therapy continuation rates ranged from 93.1% to 96.3% of utilizers within the top 10 therapeutic classes. Therapeutic classes with the lowest continuation rates included valproic acid (82.5%), combination contraceptives-oral (86.9%), antihistamines-nonsedating (87.6%), steroid inhalants (89.5%), and antineoplastic-hormonal and related (89.9%). All other therapeutic classes had continuation rates of 90.0% or higher. Although members who continued therapy were significantly older ($t=12.7$, $P=0.004$; 59.8 vs. 53.3 years), distance to a network pharmacy ($t=1.2$, $P=0.218$; 1.3 vs. 1.4 miles) and member sex ($\chi^2=.02$, $P=0.883$) had no impact on likelihood of therapy continuation.

CONCLUSIONS: Most members who used a soon-to-be noncovered retail pharmacy successfully transitioned to a pharmacy alternative post-implementation of a restricted pharmacy network. Additional outreach targeted to specific age groups and within certain therapeutic classes may lead to higher continuation rates for plans considering this strategy.

SPONSORSHIP: This research was conducted by CVS Caremark, Woonsocket, RI, without external funding.

Retrospective Analysis of Generic Dispensing Rates, Gross Cost, and Drug Therapy Continuation Rates Following Implementation of a Value Formulary

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BACKGROUND: With many factors contributing to overall increasing health care costs, payer clients are seeking ways to save on their prescription benefits. The implementation of a Value Formulary, a closed but therapeutically comprehensive formulary focusing on generic coverage with brand coverage where clinically necessary, can drive significant savings for payer clients. The Value Formulary complies with health care reform on preventative therapy and applies utilization management tools including prior authorization, step therapy, and quantity limits where appropriate. The Value Formulary is a clinically sound tool that may be used to drive generic utilization and overall cost savings; however, there is little research on the impact of therapy continuation rates with implementation of such formularies.

OBJECTIVE: To measure pre- and post-generic dispensing rates (GDR), gross costs, and drug therapy continuation rates for prescription drug

TABLE Therapy Continuation Rates

Condition	CAD	DM	HF	HTN	Asthma	CHO
2010-2011 therapy continuation rates (%)	70.0	89.0	92.0	87.0	64.0	86.0
2011-2012 therapy continuation rates (%)	79.0	86.0	75.0	87.0	50.0	83.0
P value	0.282	0.231	0.010	0.975	0.034	0.171

Members may overlap in more than 1 disease state. The year 2010 includes paid claims from September 15, 2010, through December 31, 2010. The year 2011 includes paid claims from January 1, 2011, through March 31, 2011.

CAD = coronary artery disease; DM = diabetes; HF = heart failure; HTN = hypertension; CHO = hyperlipidemia.

utilizers within an employer payer client who implemented a Value Formulary.

METHODS: A pre- and post-analysis was conducted from 2011 through the first quarter of 2012. GDR and gross cost per member per month (PMPM) were calculated. To assess therapy continuation, members that were continuously eligible were evaluated, and claims history for maintenance medications were compared 3 months prior to and 3 months after the implementation. Members who filled at least 1 maintenance prescription in the same therapeutic class during the post-period were identified as having continued their drug therapy. Members with no fill for a maintenance prescription in the same therapeutic class were identified as having discontinued their drug therapy. The percent of members continuing drug therapy was calculated for 6 common chronic conditions and compared with previous therapy continuation rates.

RESULTS: Based on utilization, GDR increased from 73.0% in 2011 to 87.0% in 2012 ($t=51.2$, $P=0.001$). In addition, gross cost PMPM was significantly reduced from \$75 PMPM to \$56 PMPM ($t=9.4$, $P=0.003$). Therapy continuation rates ranged from 50.0% to 87.0% within the 6 common chronic conditions (table). Therapy continuation rates from 2010 to 2011 were similar when compared with therapy continuation rates from 2011 to 2012 with the exception of heart failure and asthma.

CONCLUSIONS: Implementation of the Value Formulary showed a statistically significant increase in GDR and decrease in gross cost PMPM compared with a traditional formulary. Most members continued their maintenance drug therapy in the 6 common chronic conditions analyzed. Additional outreach targeted within certain therapeutic classes, as well as improved point of sale messaging, may lead to higher continuation rates for plans considering this strategy.

SPONSORSHIP: This research was conducted by CVS Caremark, Pittsburgh, PA, without external funding.

Single-Pill Versus Loose-Dose Combination Triple Therapy for Hypertensive Patients: Managed Care Formulary Impact

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BACKGROUND: Hypertension is a pervasive chronic illness in the United States that requires sustained treatment in order to avoid morbidity and mortality. Most patients with hypertension require 2 or more agents to achieve adequate blood pressure (BP) control; many require 3 or more agents. BP control is strongly associated with reduced cardiovascular disease risk and, in turn, lower medical care costs. However, a major obstacle to BP goal attainment is poor regimen adherence and persistence, which are exacerbated by regimen complexity.

OBJECTIVE: To estimate the managed care budget impact of regimen simplification via greater use of triple-agent single-pill combination (SPC) regimens (valsartan/amlodipine/hydrochlorothiazide or olmesartan/amlodipine/hydrochlorothiazide) within a formulary of comparable 2- and 3-pill loose-dose combination (LDC) regimens (angiotensin II receptor blockers [ARB] + amlodipine + hydrochlorothiazide) for hypertensive patients not controlled on dual therapy.

METHODS: We used a budget-impact model to consider the impact of increasing the use of triple-therapy SPC regimens for hypertensive patients not controlled on dual therapy. Our analysis assumes that 10,568 patients in a hypothetical plan size of 5 million would be eligible for triple antihypertensive therapy as a 1-, 2-, or 3-pill daily regimen of ARB + amlodipine/hydrochlorothiazide. Price, market share, and tier/copay for each aforementioned antihypertensive agent was obtained from published sources, as were percent of patients with 30- versus 90-day refill schedules. Adherence and persistence with therapy vary by regimen type, which, in turn, influence pharmacy costs, cardiovascular outcomes, and medical care costs.

RESULTS: Among hypertensive patients not controlled on dual therapy, our model estimated that a doubling of SPC triple-therapy use (to 31% from 16%) within a formulary of 1-, 2-, and 3-pill alternative regimens would result in higher pharmacy costs (\$7.0 million vs. \$6.2 million), fewer cardiovascular events (311 vs. 313), and lower medical care costs (\$67.1 million vs. \$67.5 million) over the course of 1 year. Taken together, the model projects a net-neutral economic impact from the health plan perspective (\$0.005 lower per-member-per-month costs with 31% use of SPC therapy).

CONCLUSIONS: Improved patient adherence/persistence with SPC triple antihypertension therapy is associated with better cardiovascular outcomes and reduced medical care costs, which offset incremental drug acquisition costs.

SPONSORSHIP: This research was funded by Daiichi Sankyo, Inc., Parsippany, NJ.

Statin Medication Adherence Association with Hospitalizations or Emergency Room Visits and Total Cost of Care over 2 Years

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BACKGROUND: Poor medication adherence has been reported to be associated with worse medical outcomes and increased medical costs. However, minimal data are available quantifying outcome and cost differences in members adherent and nonadherent to statin medications among commercially insured individuals followed for more than 1 year.

OBJECTIVE: To examine the association between medication adherence, hospitalization or emergency room (ER) visits, medical costs, and pharmacy costs among individuals adherent and nonadherent to their statin medications.

METHODS: Retrospective pharmacy and medical claims data from a 1.2 million member commercial plan were queried to identify members continuously enrolled from 2007 through 2010. Members were required to have either 2 separate hypercholesterolemia office visit claims or a hypercholesterolemia-related hospitalization claim in 2008. The members' first 2008 medical encounter was defined as the index date. Members were required to have a statin supply on index date or a high risk condition diagnosis in the year prior to index date. High-risk conditions were defined as diabetes mellitus (DM), coronary artery disease (CAD), embolic stroke, or peripheral vascular disease (PVD). All

TABLE Multiple Sclerosis Specialty Drug

2-Year Outcomes Assessment	Adherent (PDC ≥80%) n = 21,693	Nonadherent (PDC <80%) n = 24,176	P Value ^a
Unadjusted all cause hospitalization/ER visit	26.5%	29.1%	<0.0001
All medical costs ^b , \$ (SD)	12,487 (7,490)	13,254 (9,016)	<0.0001
All pharmacy costs, \$ (SD)	5,585 (3,409)	3,979 (2,595)	<0.0001
Total cost of care (medical and pharmacy), \$ (SD)	18,034 (10,481)	17,225 (11,172)	<0.0001

^aHospitalization/ER visit rate compared by log-rank test and costs compared by GLM.

^bAll medical costs are allowed amounts (plan and member paid) from all facility and professional claims including office visits, hospitalizations, procedures, laboratory testing, and ancillary.

ER=emergency room; GLM=generalized linear model; PDC=proportion of days covered; SD=standard deviation.

members were followed for 2 years after their 2008 index dates. All statin drug claims were assessed to identify members as adherent (proportion of days covered [PDC] ≥80%) or nonadherent (PDC <80%). All medical and pharmacy claim total allowed amounts (plan and member) were summed to determine total cost of care. The Kaplan-Meier method was used for observed hospitalization- and ER-rate calculation and association with adherence was analyzed using a Cox proportional hazard regression model with adjustment for age; gender; zip-code derived income and education; Charlson Comorbidity score; existence of baseline depression or bipolar disorder; DM, CAD, PVD, or embolic stroke; and high-deductible health plan enrollment. Cost analyses were performed using the generalized linear model (GLM) with Gamma log link and adjusted for the same covariates.

RESULTS: Of the 45,869 members meeting all inclusion criteria, 21,693 (47.3%) were adherent and 24,176 (52.7%) nonadherent during the 2-year follow-up. The adherent group was associated with a significantly lower hospitalization/ER visit rate (HR of 0.91, 95% CI, 0.87 to 0.94), significantly lower medical costs (\$767), but higher pharmacy costs \$1,606, and higher total cost of care \$809.

CONCLUSIONS: In this 2-year total cost of care analysis, individuals adherent to statin medication had an associated unadjusted 2.6 percentage point lower hospitalization/ER visit rate, which remained significantly lower risk in the multivariate Cox model. Although medical costs were significantly lower, higher pharmacy costs resulted in higher total costs of care. Future analyses are required to determine if longer follow-up will identify lower total cost of care among members adherent to their statin medications.

SPONSORSHIP: This research was conducted by Prime Therapeutics, LLC, Eagan, MN, without external funding.

The Identification and Exclusion of Non-FDA Approved Drugs in a Commercial 3-Tier Open Formulary

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BACKGROUND: The FDA estimates that there are several thousand illegal, unapproved drugs that are on the market today. This estimate is composed of drugs that contain several hundred different active ingredients in various strengths, combinations, and dosage forms. The

TABLE Pharmacy Claims & Unique Members

Total Claims-Unapproved Drugs	Unique Utilizing Members	Plan-Paid Savings
83,006	35,938	Approximately \$3.0 million

FDA estimates that unapproved drugs represent approximately 2% of all prescriptions dispensed in the United States.

OBJECTIVE: The FDA has described the widespread utilization of unapproved drugs as a significant public health issue and has increased resources and activities to remove these products from the market. The majority of Blue Cross and Blue Shield of Florida's (BCBSF) commercial pharmacy members have a 3-tier open formulary for their pharmacy benefits. BCBSF completed a retrospective analysis of 2009 commercial pharmacy claims to identify pharmacy claims for selected unapproved drugs and unique utilizing members. The results of this analysis were that BCBSF paid for more than 50,000 claims in 2009 for these unapproved drugs for approximately 28,000 members. To help ensure the health and safety of our members, BCBSF in conjunction with our pharmacy benefit management company (PBM), Prime Therapeutics, determined that the development of a repeatable process to identify and exclude unapproved prescription drugs from our 3-tier open formulary on an ongoing basis was needed.

METHODS: The FDA does not maintain a list of unapproved drugs. Development of an unapproved drug list requires a manual case by case review of specific drugs. However, the FDA databases do allow for verification of the approval status of a drug by utilizing the National Drug Code Directory. After the initial unapproved list was compiled by BCBSF, a retrospective pharmacy claims analysis was completed to validate the exclusion list. This analysis included all paid commercial pharmacy claims in 2009 and identified almost 36,000 members that had a claim for at least 1 of the unapproved drugs on the exclusion list. The table lists the total unapproved drug claim counts and unique utilizing members from this analysis as well as estimated plan-paid savings. The plan-paid savings is based on the annualized spend for these drugs in 2009.

RESULTS: The non-FDA approved exclusions were implemented for all BCBSF pharmacy plans on January 1, 2010. Prior to implementation of the drug exclusions, BCBSF completed extensive communications to our members and providers. Our network pharmacies also received detailed communications with all drugs listed that would no longer be covered in addition to point-of-sale messaging.

CONCLUSIONS: Since the initial identification and exclusion of unapproved drugs was implemented on January 1, 2010, BCBSF has expanded the exclusion list 4 times. Additional unapproved drugs were added to the exclusion list in April and October 2010 as well as in April and October 2011. Through the case-by-case review process, BCBSF identified and implemented the exclusion or removal of approximately 800 drugs and topical products from BCBSF's open formulary in 2010. BCBSF's goal is to continue this ongoing process supported by our PBM, Prime Therapeutics, to identify additional illegally marketed drugs and topical products for removal from our open formulary. Health plans working in conjunction with the FDA have a vital role in reducing the utilization of unapproved drugs and ultimately improving medication safety for consumers in the United States.

SPONSORSHIP: This research was conducted by Blue Cross and Blue Shield of Florida, Jacksonville, FL, without external funding.

■ The Role of Community Pharmacy Disease Management Programs in a Value-Based Insurance Design: Results from Kroger Pharmacy Coaching Programs

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BACKGROUND: Pharmacist-provided care improves patient outcomes, resulting in fewer emergency room visits, fewer inpatient hospitalizations, better guideline concordant care, and lower health care costs. By lowering out-of-pocket expenses to plan participants, value-based insurance design improves medication adherence and outcomes.

OBJECTIVE: To determine if a combined approach of medication copay waiver/reduction and disease management improves clinical outcomes for active employees and retirees of self-insured employers in Cincinnati, Ohio.

METHODS: From 2008-2010, specially trained Kroger pharmacists enrolled eligible employees from the City of Cincinnati and The Kroger Company into either (a) a Diabetes Coaching Program (DCP) or (b) a Heart Healthy Coaching Program (HHCP). Participants were seen every 1 to 3 months for medication therapy management and health-related counseling. Blood pressure and body mass index (BMI) were assessed every visit, while hemoglobin A1c (A1c) and a total lipid panel were analyzed every 3 to 6 months. Patients received waived/reduced copays on all disease-related medications for active participation in the program.

RESULTS: There were 478 and 468 patients enrolled in the DCP and HHCP from 2008-2010, respectively. Average A1c values for patients enrolled in the DCP dropped from 7.60 at the time of program enrollment to 6.93 1 year after enrollment. The proportion of patients in the DCP with an A1c less than 7 rose from 46.5% at the time of enrollment to 62.3% 1 year after enrollment. DCP patients' average low-density lipoprotein (LDL) levels and systolic blood pressure dropped from 92.28 to 82.24 and 135.05 to 130.11 during the same time period, respectively. For patients enrolled in the HHCP, average LDL levels and systolic blood pressure dropped from 103.75 to 98.50 and 134.05 to 127.03 from the time of program enrollment to 1 year after enrollment, respectively.

CONCLUSIONS: Community pharmacy disease management programs in conjunction with a value-based insurance design can lead to improved patient outcomes.

SPONSORSHIP: This research was conducted by University of Cincinnati, Cincinnati, OH, without external funding.

■ Understanding Reasons for Nonadherence to Atypical Antipsychotic Medications in Claims Data: Results from a Pilot Study

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BACKGROUND: Atypical antipsychotics are indicated for the treatment numerous conditions, including schizophrenia and bipolar disorder. Adherence in both patient populations remains a challenge, with numerous studies reporting high percentages of non- or partially adherent patients. Lower adherence to antipsychotic medications is linked to a greater risk for hospitalizations and emergency room (ER) visits. By identifying specific patient-reported barriers, health plans can design targeted interventions aimed at improving adherence in this patient population.

OBJECTIVE: To identify patient-reported barriers and reasons for atypical antipsychotic medication nonadherence in claims data.

METHODS: Using a large health plan pharmacy database (approximately 1.2 million lives), health plan members with at least 3 prescriptions for

the same oral atypical antipsychotic (AA) prescriptions in Q3 and Q4 of 2011 were identified. From this patient population, nonadherent patients were identified (medication possession ratio [MPR] <0.80) during the measurement year. Additional exclusion criteria included <18 years of age, long-acting injectable drugs, and oral solutions of AAs. A group of nurses and pharmacists implemented a telephonic intervention program in order to capture specific barriers reported in this patient population, with the ultimate goal of improving adherence. Upon initial outreach, 40 randomly chosen patients were identified for this analysis. Baseline characteristics were measured for the pilot patients between 2011-2012.

RESULTS: The mean age of this population was 44.0 years, and 47.5% were female. Baseline mean MPR was reported as 0.55. Patients had an average of 5.75 AA drug dispensings throughout the study period. 67.5% of patients had a gap in therapy of >45 days with an average of a 68.5-day maximum gap in therapy. Mean out-of-pocket costs for AAs were shown to be \$38.07 (standard deviation: 67.08) for the baseline period. Of the 40 patients surveyed, 77.5% did not feel that there were any issues with taking the medications as prescribed. Additionally, 20.0% of patients cited out-of-pocket cost as a barrier, followed by side effects (17.5%) and a doctor change in therapy (17.5%) for reasons for low adherence. 12.5% of patients did not perceive the drug to be effective, and 5.0% cited forgetfulness and supply issues (out of stock) as a barrier.

CONCLUSIONS: The majority of surveyed patients did not feel that there were any issues with nonadherence to their AA medications. These results are inconsistent with the claims data and are a potential educational opportunity for future outreach to these patients.

SPONSORSHIP: This research was conducted by CDMI Health, Newport, RI, without external funding.

■ Utilization of Augmentation Agents for the Treatment of Depression: Analysis of a Psychiatric Electronic Medical Record Dataset

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BACKGROUND: The American Psychiatric Association (APA) recommends consideration of treatment augmentation for patients with depression after 4-8 weeks of inadequate response to initial antidepressant treatment. However, limited real-world data exist on implementation of augmentation strategies in this population.

OBJECTIVE: To examine the real-world utilization of augmentation agents in depression and assess demographic and clinical characteristics of patients receiving these agents.

METHODS: A cross-sectional design was used. Patients without psychosis/psychotic features initiating augmentation therapy for treatment of depression between January 2001 and June 2011 were identified from a psychiatric electronic medical record (EMR) dataset (MindLinc). Augmentation was defined as the prescription of a combination of antidepressants or an antidepressant in conjunction with an agent that is not conventionally used as first-line monotherapy (i.e., atypical antipsychotics, mood stabilizers/anticonvulsants, or stimulants). Patient demographics and clinical profile, psychiatric drug utilization patterns, and site characteristics were obtained from EMR data. Clinical severity of patients at the time of augmentation was documented using the Clinical Global Impressions-Severity (CGI-S) scale. Logistic regression models were used to assess the clinical and demographic predictors of type of augmentation agent (in a multivariate framework). Augmentation with an atypical antipsychotic was used as the reference category for the analyses, since it constitutes the only FDA-approved augmentation option.

RESULTS: A total of 3,209 patients initiated augmentation therapy for depression with most receiving treatment in an academic center (54.1%) or community mental health center (32.7%). Patients were 70.7% white and 69.8% female, with a mean age of 43.8 years. Most patients augmented with a combination of antidepressants (75%), followed by atypical antipsychotics (11.1%), mood stabilizers/anticonvulsants (8.3%), and stimulants (5.2%). Within combination antidepressants, patients most commonly received an SSRI (selective serotonin reuptake inhibitor) in combination with bupropion (23.1%) followed by SSRI+serotonin modulator or norepinephrine-serotonin modulator (15.9%). Patients receiving atypical antipsychotic augmentation most commonly received quetiapine (39.6%) or aripiprazole (31.2%). Gabapentin (39.1%) and lamotrigine (21.4%) were the most common mood stabilizers/anticonvulsants; methamphetamine (55.7%) and dextroamphetamine (35.3%) were the most common stimulants. Logistic regression demonstrated that baseline clinical severity of patients was the strongest and most consistent predictor of the augmentation strategy adopted. Compared with patients with mild symptoms (CGI-S: 2-3), patients with severe clinical symptoms (CGI-S: 5-7) were 2.75 times more likely to receive an atypical antipsychotic versus combination of antidepressant (95% CI=1.87-4.04). These severe patients were also more likely to receive atypical antipsychotics compared with mood stabilizers (OR=3.35, 95% CI=1.90-5.91) or stimulants (OR=4.05, 95% CI=1.78-9.21). Regression results also indicated that male patients, nonwhites, those with concomitant psychiatric diagnoses, and users of benzodiazepines were significantly more likely to receive augmentation with an atypical antipsychotic.

CONCLUSIONS: Clinicians primarily prescribe a combination of antidepressants for augmentation of initial antidepressant treatment and appear to disproportionately use atypical antipsychotics, the only approved augmentation option, for patients with severe depression.

SPONSORSHIP: This research was funded by Bristol-Myers Squibb, Princeton, NJ, and Otsuka Pharmaceutical Co., Ltd, Tokyo, Japan.

■ Utilization Patterns of Biologics Before and After Implementation of a Managed Care Step-Therapy Policy

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BACKGROUND: Significant increases in the use of step-edit policies affecting intravenously (IV) delivered biologics in the rheumatology, gastroenterology, and dermatology therapeutic areas are being implemented in an attempt to reduce utilization and costs in new patients initiating biologics. Published evidence on the effect of these policies on overall utilization of services is limited.

OBJECTIVE: To assess utilization patterns of abatacept (ABT), adali-

mumab (ADA), certolizumab (CTZ), etanercept (ETA) and infliximab (IFX) before and after the implementation of a step-therapy policy.

METHODS: The Wolters Kluwer Source Rx and Medical databases from January 1, 2006, through April 30, 2011, were used to conduct a longitudinal descriptive analysis of the number of patients with biologic claims within 365 days before and after step-edit implementation. Available data included payer, prescription (Rx), diagnosis (Dx) and procedure (Px) information with unique anonymized patient identifiers associated with each claim. To be included in the analysis, patients were required to have at least 1 National Drug Code (NDC) or Healthcare Common Procedure Coding System (HCPCS) billed claim for ABT, ADA, CTZ, ETA or IFX, regardless of indication, at any time during the study period (365 days pre- and post-index). To establish a proxy for eligibility, patients were required to have at least 1 prescription claim (any type) and medical claim (all cause) more than 1 year before and after the policy change date (index). The number and percentage of patients receiving a biologic was described in quarterly increments for the 365 days before and after implementation of the policy change. The analysis was stratified by product. Quarters 1-4 constituted the 365-day pre-index period and quarters 5-8 constituted the 365-day post-index period.

RESULTS: A total of 252 patients who were members of 4 different plans that implemented a policy change and who met the analysis criteria were included. The majority of patients (71.4%) had a claim for a biologic during the first quarter (i.e., constituted an existing patient population not likely to be impacted by a new step-therapy policy change focused on new patients). 87.3% of the patients in the pre-index and 75.4% in the post-index periods received only 1 biologic. Less than 10% of patients initiated therapy in any of quarters 2-8, with the percentages of patients initiating therapy declining each quarter. The percentage of patients by product in the pre- /post-index periods were 3.2%/4.4% (ABT); 37.6%/37.6% (ADA); 0.8%/2.0% (CTZ); 44.8%/38.4% (ETA); 9.6%/11.6% (IFX); and 92.0%/84.8% (Overall). Percentage changes were +37.5% (ABT); 0.0% (ADA); +150.0% (CTZ); -14.3% (ETA); +20.8% (IFX); and -7.8% (Overall). Eligibility had to be established based on plan information in the pharmacy claims data. This may lead to an under-representation of patients with low utilization rates. These data contained relatively few patients who initiated therapy after the policy change, who would be the typical patients impacted by the change to a new step-therapy policy.

CONCLUSIONS: Policies designed to reduce overall patient proportions using infusion biologics did not appear to have the desired effect in this population.

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