Abstracts From Professional Poster Presentations at AMCP’s 2005 Educational Conference

The following poster presentations have been prepared for the Academy of Managed Care Pharmacy’s 2005 Educational Conference, October 5-8, 2005, in Nashville, Tennessee. Poster presentations are selected by the Program Planning Committee from proposals that are submitted to AMCP. Authors of posters are responsible for the accuracy and completeness of 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 individuals who are scheduled to present at the meeting are underlined.

■■ ANALYSIS OF THE CLINICAL AND ECONOMIC IMPACT OF A STEP-THERAPY SEQUENCE ON NONSEDATING ANTIHISTAMINE FAILURE RATES
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INTRODUCTION: The purpose of this study is to determine baseline failure rates for secondary nonsedating antihistamines (NSAs) and the clinical and economic outcomes of a step-therapy sequence after patients have received prior treatment with over-the-counter (OTC) loratadine.

METHODS: To establish a baseline, a retrospective study of patients who failed OTC loratadine was conducted, reviewing physician prescribing habits for subsequent therapy with secondary NSAs or other allergy therapies. Subsequently, a step-therapy sequence was implemented in which patients who failed OTC loratadine were required to try and fail intranasal corticosteroids and intranasal antihistamines before receiving secondary NSA therapy. These prescribing methods were compared for clinical outcomes and economic impact in a managed care setting.

RESULTS: Prior retrospective analysis demonstrated that 1,713 members received at least one prescription for OTC loratadine from January 1, 2004, through March 31, 2005. The goal of the step therapy was to reduce the number of prior authorizations (PAs) by requiring failure with an alternative therapeutic class of agents. Of those members, 349 required PA to obtain approval for use of an alternative NSA. The estimated potential savings, with a 50% reduction in failure rates, would amount to approximately $30,000 per year in this population.

CONCLUSIONS: Several published clinical studies have demonstrated that there is a high secondary failure rate when using one NSA after another NSA has already been tried. Implementing step therapy (failure of OTC loratadine and additional failure of a nasal antihistamine [Astelin] and a formulary corticosteroid) before applying secondary NSA therapy would provide potential cost savings in a managed care population.

■■ ANEMIA TREATMENT COSTS IN CANCER PATIENTS TREATED WITH EPOETIN ALFA OR DARBEPOETIN ALFA IN A MANAGED CARE POPULATION
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INTRODUCTION: Anemia management with epoetin alfa (EPO) or darbepoetin alfa (DARB) is a common occurrence in cancer patients in managed care populations. This study compares anemia-related costs in cancer patients receiving EPO and DARB.

METHODS: Administrative medical, lab, and pharmacy claims from more than 30 diverse managed care plans were examined. Cancer patients aged 18 years and older with at least 1 medical claim for EPO or DARB from January 2003 through February 2004 were identified. Patients continuously eligible for benefits for at least 3 months prior to and 4 months after the date of the initial claim were included. Only patients new to therapy (no EPO or DARB claims during the 3 months prior to initiating therapy) and those with at least 1 additional medical claim for the index agent were included in the study. Costs were evaluated on a per-patient-month (PPM) basis, for patients with at least 28 days of therapy.

RESULTS: 6,584 cancer patients (EPO 4,535; DARB 2,049) were identified. The EPO group was older, had a higher proportion of men, and had higher baseline rates of cardiac, respiratory, digestive, and neurologic comorbidities. A higher proportion of EPO patients was initiated in the hospital outpatient setting than DARB patients (EPO 21%, DARB 6%). Treatment duration was similar between the groups (EPO 77 days, DARB 78 days), with a higher number of injections of erythropoietic agent in the EPO group (EPO 8.4, DARB 6.5). Transfusion rates were similar between groups (EPO 6.6%, DARB 5.9%). Compared with DARB patients, EPO patients had lower erythropoietic agent drug cost (EPO $2,057 vs. DARB $2,462, $P < .0001).

CONCLUSIONS: Despite lower rates of baseline comorbidities, similar treatment duration and fewer injections, the DARB group incurred a 20% greater drug cost for anemia treatment compared with EPO in this large managed care population.
ASSESSING THE IMPACT OF GLYCEMIC CONTROL ON HEALTH RESOURCE UTILIZATION AND COSTS OVER A 1-YEAR PERIOD

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INTRODUCTION: The relationship between glycemic control and health resource utilization and costs was evaluated in a cohort of managed care members with diabetes over a 1-year period.

METHODS: A retrospective analysis was conducted on a nationally representative administrative claims database of managed care enrollees aged 18 to 64 years between 2000 and 2002. Patients with an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code diagnosis of diabetes who were continuously enrolled for at least 365 days of follow-up were included. Glycemic control was measured by using the average score of ≥2 glycated hemoglobin (A1c) tests. Selected comorbidities were controlled for using multiple logistic regression techniques. Resource utilization (hospitalizations, emergency department (ED) visits, office visits, pharmacy, and laboratory tests) was assessed in the entire study cohort as well as in subpopulations with health care encounters for 7 diabetes-related conditions (cardiovascular disease, hypoglycemia, nephropathy, neuropathy, retinopathy, embolic stroke, and transient ischemic attack).

RESULTS: A total of 20,914 subjects (mean age 52 years) met the inclusion criteria for analysis. Overall, a positive statistical relationship was observed between increasing A1c level and total direct medical cost over a 1-year period. In patients with an A1c level of <7, the average total direct medical cost was $1,418.69; corresponding costs in patients with A1c levels 7 to <8.5%, 8.5% to 10%, and >10% were $1,867.53, $2,382.26, and $2,904.33, respectively. The relationship extended to rates of hospitalizations, ED visits, and office visits, and the number of prescriptions for diabetes-related drugs. Similar trends were evident in the subpopulations, with a positive statistical relationship observed between increasing A1c level and both total direct medical cost and hospitalization rate in all 7 subpopulations.

CONCLUSIONS: Tighter glycemic control is associated with lower medical costs during a 1-year period. By promoting ways to improve glycemic control in their members with diabetes, such as optimizing drug therapy and high-risk member diabetes case management, health insurers may benefit from averted medical costs, even in the short term.

BUDGET IMPACT MODEL FOR Erlotinib (Tarceva) IN ADVANCED NON–SMALL-CELL LUNG CANCER

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OBJECTIVE: To develop a tool that can be used by health care plans to assess the budgetary impact of covering erlotinib for treating patients, aged 18-65 years, with stage IIIB/IV non–small-cell lung cancer (NSCLC) who have failed at least 1 prior chemotherapy regimen.

METHODS: An Excel-based decision model was developed to assess costs and outcomes for a formulary that includes U.S. Food and Drug Administration-approved and National Comprehensive Cancer Network guideline-recommended treatment options, comparing a formulary with erlotinib versus without erlotinib. The model considers second- and third-line treatments and includes differential outcomes that may influence direct medical costs (grade 3/4 adverse effects of treatment such as neutropenia and anemia). The incidence of advanced NSCLC and adverse effects related to treatment (all agents) are based on the Surveillance, Epidemiology, and End Results Cancer Registry and published results of clinical trials. Drug and treatment costs are obtained from publicly available sources. One-way and multiway uncertainty analyses were used to evaluate the impact of varying assumptions and data values on outcomes.

RESULTS: The base case considers a health plan of 500,000 enrollees. Assuming that erlotinib represents 22% of second-line treatments and 50% of third-line, total costs of treating Stage IIIB/IV NSCLC patients over 1 year are $418,710 without erlotinib and $388,226 with erlotinib (difference: $30,484; 90% CI, $8,722-$90,170). Erlotinib lowers costs compared with standard chemotherapy through reductions in standard chemotherapy-related infusion costs and costs of managing adverse events. Sensitivity analyses demonstrate that the budget impact is most sensitive to the incidence of NSCLC, the proportion of patients receiving treatment, the proportion receiving erlotinib versus standard agents, the cost of erlotinib, and duration of treatment. Outcomes were relatively insensitive to the incidence of serious erlotinib-related adverse events.

CONCLUSION: Adding erlotinib as a second- and third-line treatment option may reduce total health plan costs compared with standard therapy.
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CLINICAL AND FINANCIAL IMPACT OF ERYTHROPOIETIN: A STUDY OF PRE–END-STAGE RENAL DISEASE PATIENTS IN A HIGH-RISK SPECIALTY-CASE COORDINATION PROGRAM

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OBJECTIVE: To assess the clinical and financial impact of erythropoietin (EPO) in the management of anemic patients with chronic kidney disease (CKD).

METHODS: A retrospective cohort study of 4,097 predialysis CKD patients enrolled in a specialty coordination program of the AvMed Health Plans, a not-for-profit health maintenance organization, from January 2000 and December 2003. Administrative databases were used to examine the clinical characteristics and health care costs of the group. Two hundred seventy-one members received EPO, but after those with aplastic anemia or renal transplants were eliminated as well as those undergoing chemotherapy, hemodialysis, or peritoneal dialysis, the final study group had 52 patients with 52 case-matched controls. Clinical and demographic characteristics of both the case and control groups were virtually identical to nationally reported data for CKD patients.

RESULTS: CKD patients experienced a continuous deterioration of renal function over time (creatinine clearance fell 16.3% over 9 months, P < .0001), accompanied by a progressive 5-fold increase in global per-member-per-month (PMPM) health care expenditures over the 3-year period prior to the initiation of EPO therapy (r² = .651, P < .0001). Following EPO therapy, renal function was effectively stabilized, measured by creatinine clearance, and sustained over a mean follow-up time of 9 months. Mean hemoglobin levels fell from 11.52 g/dL (± 1.56 SD) to 9.90 g/dL prior to EPO therapy and were corrected to starting levels (11.52 g/dL ± 1.44 SD) with the use of EPO. The rise in PMPM expenditures was halted and remained stable over the 9-month mean follow-up period. Health care expenditures were comprehensive, including all drug costs.

CONCLUSIONS: Treatment with EPO in anemic patients with predialysis CKD is clinically effective and is associated with a stabilization of both the progression of renal disease and global PMPM costs.

CMS COMPETITIVE DRUG ACQUISITION PROGRAM: SHAPING FUTURE MCO PROCESSES?

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INTRODUCTION: This case study details the Centers for Medicare & Medicaid Services (CMS) Competitive (Drug) Acquisition Program (CAP) processes that become effective January 1, 2006, and explores the potential impact on managed care organization processes.

METHODS: The primary objective of the case study was 2-fold: to develop a process model of the CMS CAP for Part B drugs as it relates to physician providers, and to explore the potential for those government processes to shape managed care organization (MCO) processes in the near future. Government sources and physician interviews and observations were utilized to create the CAP process model. MCO interviews and relevant survey results were utilized to create a likely future scenario for the MCO process changes.

RESULTS: The case study identified sequential processes that are required of physician providers who will participate in the CMS CAP. Although the CAP processes were initially designated as primarily administrative in nature, the physician practice personnel involved professional clinical labor as well as clinical labor in more than 50% of practices interviewed. More than 70% of practices interviewed indicated they planned to adopt the government-mandated process as their primary model. A significant portion of physician practices indicated they intended to request specific changes from MCOs in the next contracting cycle. When the framework for potential changes, constructed utilizing physician responses, was ranked using a 5-point scoring system, 3 particular categories emerged as most likely to impact MCO processes in the near future.

CONCLUSIONS: CAP stipulates a series of mandatory processes for participating physician providers. This case study's model demonstrates that processes utilized by the government model have a significant potential for migrating to MCOs in the near future. Process changes will most likely be triggered by provider requests and/or negotiations when contract expiration dates are pending. The model also demonstrates that the processes utilized are capable of being successfully replicated.

COMPARISON OF HEALTH CARE UTILIZATION AND INCIDENCE OF ADVERSE EVENTS OF LEVETIRACETAM WITH GABAPENTIN IN EPILEPTIC PATIENTS USING A RETROSPECTIVE CLAIMS ANALYSIS

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OBJECTIVE: To compare health care utilization and incidence of adverse events (AEs) in epileptic patients initiating levetiracetam (LEV) or gabapentin (GBP).

METHODS: A retrospective cohort analysis of epileptic patients was conducted using data from a U.S. claims database. Patients without any LEV or GBP prescription for 6 months prior to therapy initiation were followed for 3 months to 1 year (July 2001-December 2003). GBP patients were matched to LEV patients by clinical characteristics, seizure, and therapy types. Comparison of health care utilizations used Wilcoxon rank-sum tests. Risk of AEs was assessed using Cox proportional hazards models.

RESULTS: Treatment groups (n = 816 in each) were comparable:
mean age ~39 years, ~63% women, 64% generalized seizures, 65% adjunctive therapy. LEV patients refilled their prescriptions more often than GBP (mean/patient/year: 8.3 vs. 6.0, P<0.001). Utilization was significantly lower in LEV than in GBP for physician office visits (18.1 vs. 20.8, P<0.01), emergency room visits (8.5 vs. 11.0, P<0.01), other outpatient visits (35.7 vs. 40.6, P<0.05), and medications other than antiepileptics (24.4% vs. 36.5, P<0.001). Diagnostic tests and inpatient services were comparable (not significant) in both groups. Absence of AEs during follow-up was 38% for LEV versus 29% for GBP (P<0.001). Risk of AEs was significantly lower in LEV than GBP: hazard ratio: 0.76, 95% confidence interval, 0.68-0.86, P<0.001; median time to first AE: 42 days LEV, 28 days GBP.

CONCLUSION: LEV patients showed lower utilization of most common health care services than GBP patients. Rate and risk of AEs were significantly lower in LEV despite a higher refill rate relative to GBP.

COST-EFFECTIVENESS AND BUDGETARY IMPACT OF BIOLOGIC THERAPIES FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS

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OBJECTIVE: To calculate, from the payer perspective, the relative cost-effectiveness and budget impact of efalizumab and etanercept for psoriasis in a million-member health plan.

METHODS: We used information on dosing and treatment-related utilization from product labeling information and subsequent clinical trials for 2 biologic drugs (efalizumab and etanercept) indicated for moderate-to-severe plaque psoriasis to construct a cost-effectiveness model that calculates cost per patient with a successful outcome. Success was defined as achieving a ≥75% improvement in the Psoriasis Area and Severity Index score (PASI 75) after 24 weeks of treatment. Cost of treatment was determined by adding costs in 4 categories: (1) drugs (average wholesale price), (2) administration, (3) monitoring (platelet counts or tuberculosis test), and (4) adverse events. For budget impact, we assumed that a million-member plan would have 2,000 adults with moderate-to-severe plaque psoriasis and 200 would use biologic therapy. To calculate cost, we assumed 100% of etanercept users stepped down their dose from 100 mg/week (weeks 1-12) to 50 mg/week (weeks 13-52) as recommended in the product labeling.

RESULTS: Cost per PASI 75 responder was $20,438 for efalizumab and $24,351 for etanercept. Projected annual treatment costs were $3.8 million for efalizumab and $4.7 million for etanercept, assuming all patients step down and continue at 50 mg/week for 40 weeks. Annual treatment costs increased if patients on etanercept had lower step-down rates: $5.4 million (75%); $6.1 million (50%); and $6.8 million (25%).

CONCLUSIONS: Efalizumab is more cost effective than etanercept. The budget impact of etanercept is unpredictable since it is unknown how many patients will step down from 100 mg/week to 50 mg/week. Efalizumab dosing is stable and predictable. Cost-effectiveness and dosing stability may be particular advantages when efficacy and safety are comparable and the ability to accurately predict drug costs is a key consideration.

COST-EFFECTIVENESS OF LINEZOLID VERSUS VANCOMYCIN IN THE TREATMENT OF COMPLICATED SKIN AND SOFT-TISSUE INFECTION DUE TO PROVEN OR SUSPECTED MRSA IN PATIENTS AGED 65 YEARS OR OLDER

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INTRODUCTION: We estimated costs of treating complicated skin and soft tissue infections (cSSTI) with linezolid (LZD) versus vancomycin in a subset of patients aged >65 years enrolled in the largest clinical trial of cSSTI due to proven or suspected methicillin-resistant staphylococcus aureus (MRSA).

METHODS: Clinical trial patients aged >65 years and admitted to U.S. hospitals with cSSTI due to proven or suspected MRSA were included in these analyses. Infection-related costs were estimated by applying nationally representative 2003 per-diem hospital costs for days in medical/surgical, intensive care, or step-down units. Costs of administering intravenous (IV) therapy were applied to IV treatment duration. Medications were valued at wholesale acquisition cost. Hospitalization costs and total costs (hospital plus outpatient) were estimated. Cure rates were determined from the subset of patients who were clinically evaluable.

RESULTS: Of the 717 patients in the clinical trial, 163 were aged >65 years (87 LZD, 76 vancomycin). No significant clinical or demographic differences at baseline were observed between groups. Average hospitalization costs for patients treated with LZD were $4,511 versus $6,478 for vancomycin (P<0.001). Average total costs for patients treated with LZD was $6,009 versus $7,329 for vancomycin (P=0.03). Average length of stay for LZD patients was 6.8 days compared with 10.3 days for patients treated with vancomycin (P<0.001). No significant differences were observed in clinical cure rates between linezolid and vancomycin (LZD = 89%, vancomycin = 81%, P = 0.2).

CONCLUSION: Treatment with linezolid (IV/orally) for cSSTI due to proven or suspected MRSA in patients aged >65 years results in lower hospital and total costs compared with vancomycin. Clinical cure rates were similar in both groups. Lower costs for patients treated with linezolid are enabled by transition to oral therapy and earlier hospital discharge.
the association of length of exposure to cyclooxygenase-2 inhibitors (COX-2s) and the risk of cardiac events. This study determines the impact of extended exposure to COX-2s among high-risk Medicaid patients and is based on a previous propensity-adjusted model that showed no added risk of cardiac events in COX-2 versus nonsteroidal anti-inflammatory drug (NSAID) users in this Medicaid population.

**METHODS:** Selecting COX-2 users alone, we analyzed all medical and prescription claims of all continuously enrolled Medicaid patients, with at least 1 prescription for a COX-2 between January 1, 2000, and January 1, 2003, and no such prescriptions in the first 6 months. We used both direct adjustment and propensity score methods and assessed length of exposure to COX-2s as a risk factor for postuse cardiac events, defining risk as a categorical variable (<30, 30-59, 60-89, 90-119, and >120 days), then as a continuous variable (divided by 30). The models are adjusted for age, gender, race, location (urban/suburban/rural), and clinical risk factors.

**RESULTS:** A total of 1,784 patients used COX-2s, 25% for fewer than 30 days. From the categorical analysis, there is a concomitant 5.5% significant increase in postuse cardiac events. For the direct adjusted model, there is a concomitant 5.5% significant increase in postuse cardiac events.

**CONCLUSION:** Among Medicaid COX-2 users, the risk of cardiac events is associated with longer exposure to COX-2s only when exposure is categorized in 30-day increments but not when used as a continuous variable, suggesting a nonlinear relationship between exposure and events.

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**DEPRESSION COMPLIANCE RETROSPECTIVE CASE ANALYSIS**

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**OBJECTIVE:** To review and document nonspecific, nonbranded drug therapy of patients being treated for depression with issues related to noncompliance. The study was to determine the causes of the noncompliance and provide recommendations for better compliance.

**METHODS:** A managed care database was used to identify patients receiving drug therapy for depression during 2003. There were no time limits for treatment on drug therapy. A total of 150 patients who were identified were sent a letter by their physicians and asked to participate in a discussion about their therapy with a registered pharmacist. The patients who responded to the letter were asked to:

- a) provide demographic information such as age, gender, etc.;
- b) indicate chronic disease states, number of prescriptions taken each day;
- c) provide the name of medication used for depression therapy;
- d) identify a stressful event in the last 12 months;
- e) rank themselves according to a self-reported medication-taking behavior scale;
- f) discuss whether they skip doses due to cost;
- g) discuss whether they experience embarrassment because of medication; and
- h) discuss whether they are receiving any counseling or group therapy.

**RESULTS:** There were 76 patients interviewed for this study. Despite treatment recommendations, 77.6% of the patients were noncompliant due to at least one reason, whether it was side effects, cost, or forgetfulness. A patient could have had more than one reason for being noncompliant. The results also showed that there was no correlation between noncompliance and the medication being taken for depression.

**CONCLUSIONS:** It can be concluded that, in this population, patient education regarding the value of their medications was to be encouraged. The results were shared with the physicians to increase their awareness of patients not properly taking their medications; 27.6% of patients were noncompliant due to side effects. A discussion with their physician regarding these unwanted side effects can determine if patients need to switch medications. The study showed that 51.3% of the patients admitted that they either skip doses, split their pills, or asked their physician for samples, so cost was a major issue with compliance. Patient-assistance program phone numbers for assistance and other discount card information was given to the staff to distribute to these patients. The other reason given for noncompliance was forgetfulness; 31.6% of patients admitted to being forgetful about taking their medication. Morisky tear-off sheets were placed in patient waiting areas for patients to privately score themselves for medication non-adherence and encourage them to discuss their results with a staff member.
DOSING DISTRIBUTION PATTERNS AND ASSOCIATED COSTS OF ERYTHROPOIETIC AGENTS IN PATIENTS WITH PREDIALYSIS CHRONIC KIDNEY DISEASE FROM 3 LARGE MANAGED CARE ORGANIZATIONS

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INTRODUCTION: Since few reports exist describing current dosing patterns of epoetin alfa (EPO) and darbepoetin alfa (DARB) in patients with predialysis chronic kidney disease (pCKD), this retrospective, observational study was performed to analyze dosing patterns and associated costs of EPO and DARB from a managed care practice perspective.

METHODS: Anemic pCKD patients who were aged ≥18 years, had >2 EPO or DARB claims, and were newly initiated on erythropoietic therapy between the fourth quarter of 2001 and the third quarter of 2004 were identified from medical claims of 3 regionally diverse health plans covering approximately 10.2 million lives. EPO and DARB use was identified via Healthcare Common Procedure Coding System (HCPCS) codes in medical claims with doses calculated using billed units. Dosing frequency, mean weekly dosing, and drug costs (using 2004 wholesale acquisition prices) were calculated for each group.

RESULTS: A total of 325 EPO and 163 DARB patients met the inclusion criteria. Mean age (years, EPO 69.5±13.8, DARB 69.6 ± 12.7, P=not significant NS), gender distribution (EPO 45.0% male, DARB 45.0% male, P=NS), and prevalence of comorbid conditions were similar between therapeutic groups. Weekly and extended (every Q 2 weeks [Ws]) dosing frequency were utilized in patients receiving EPO (QW: 23.4%, Q2W: 34.8%, >Q3W: 29.6%) and DARB (QW: 5.5%, Q2W: 46.0%, >Q3W: 44.5%), with an average interval between treatments of 18.6 ± 15.9 days for EPO and 20.7 ± 8.6 days for DARB patients. The average weighted weekly dose was 8,516 units for EPO and 57 mcg for DARB, which corresponded with estimated mean weekly costs of $100 for EPO and $241 for DARB. Similar dosing patterns and cost differences were observed for patients completing 4, 8, and 12 weeks of therapy.

CONCLUSIONS: Extended EPO and DARB dosing (> Q2W) was common among anemic pCKD patients. However, costs associated with these treatments differed between therapies, providing a cost advantage to those patients being administered EPO.

ECONOMIC BURDEN OF GOUT TO THE EMPLOYER

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OBJECTIVE: To determine the economic burden of gout associated with medical costs and work loss from an employer perspective.

METHODS: Medical, pharmacy, workers’ compensation (WC), short- and long-term disability (STD, LTD), and sick leave (SL) costs in employees with gout, as identified by an International Classification of Diseases, Ninth Revision (ICD-9) code of 274.xx, were examined in a database consisting of 2001 through 2004 claims, payroll, and demographic data from more than 250,000 employees from multiple large U.S.-based employers. Regression modeling was used to measure the cost differences between employees with gout and employees without gout while controlling for age, job tenure, gender, salary, region, and other factors.

RESULTS: Data were available for 1,171 employees with gout and a control group of (247,867) employees without gout. The gout group’s costs (per patient per year) were almost twice as high ($6,871 higher) summed across all direct medical and work loss measures (P <0.0001). The individual differences in medical and pharmacy costs were $1,401 and $427, respectively (both P<0.0001). Work absence costs had differences of $697 (WC, P < 0.0001), $358 (STD, P < 0.0001), -$25 (LTD, P<0.0001), and $307 (SL, P<0.0001).

CONCLUSIONS: The economic impact of gout can be costly to employers not only in terms of direct health care costs but also from potential work loss due to absenteeism. Interventions focused on identifying and managing the underlying cause of gout have the potential to produce significant savings in medical and pharmaceutical costs.

ECONOMIC EVALUATION OF CONTROLLED-RELEASE OXYCODONE (CRO [OXYCONTIN TABLETS]) VERSUS OXYCODONE/ACETAMINOPHEN (OXY/APAP [PERCOCET]) FOR OSTEOARTHRITIS PAIN OF THE HIP OR KNEE


INTRODUCTION: Controlled-release oxycodone (CRO) is efficacious for persistent moderate-to-severe osteoarthritis pain, based on well-controlled trials. Additionally, decision makers require evidence of effectiveness in routine practice and cost-effectiveness compared with standard therapy.

METHODS: An open-label, active-controlled, randomized, naturalistic 4-month study of analgesic effectiveness and cost-effectiveness of CRO versus oxycodone/acetaminophen (oxy/APAP) was conducted. Outcomes and resource use were
collected by telephone. Effectiveness was measured in 485 patients as the proportion having at least 20% improvement from baseline in Western Ontario and McMaster Universities Osteoarthritis Index pain score. Quality-adjusted life-years (QALYs) were calculated from Health Utilities Index-3 scores. Cost-effectiveness was measured as cost/patient improved and QALYs gained from societal and health care perspectives using generic oxy/APAP (base case). Uncertainty was evaluated using multiple 1-way sensitivity analyses and cost-effectiveness acceptability curves.

RESULTS: In the study, 62.2% versus 45.9% (P = 0.0003) of patients improved with CRO and oxy/APAP, respectively. Mean QALYs gained over 4 months with CRO compared with oxy/APAP was 0.0105 (P = 0.1673). Mean societal cost/patient over 4 months was US$6,792 versus US$6,929 (P = 0.3345) for CRO and oxy/APAP, respectively. CRO was both more effective and less costly than oxy/APAP, using the societal perspective (includes costs associated with time loss). Using a health care perspective (excludes costs associated with time loss), cost-effectiveness of CRO was US$4,500/patient improved and US$69,856/QALY gained.

CONCLUSIONS: From the societal perspective, CRO was both more effective and less costly than oxy/APAP. From the health care perspective, CRO, compared with generic oxy/APAP, fell within the acceptable range of cost-effectiveness if decision makers were willing to pay between US$50,000/QALY and US$100,000/QALY. These findings should be considered in decisions about treating osteoarthritis pain.

### EFFECTIVENESS OF A DIRECT-TO-PATIENT SPECIALTY PHARMACY COMPLIANCE PROGRAM


**INTRODUCTION:** The therapy persistence for patients enrolled in a hepatitis C direct-to-patient specialty pharmacy compliance program was compared with a retail distribution control group in a matched-pair cohort fashion.

**METHODS:** Patients new to hepatitis C therapy who enrolled in a Specialty Pharmacy Compliance Program (n = 279) were matched retrospectively in a 1 to 5 ratio with a control group of patients receiving therapy through a retail distribution channel and analyzed over a 1-year period. The primary end point was the percentage of patient persistence, defined as the percentage of patients in a given month of the study period who had drugs on hand as measured by prescription fill date and days supply. Secondary measures included compliance and length of therapy. Patients were excluded if they had any medication fills from a retail outlet during the study period.

**RESULTS:** Of the 279 patients enrolled, 227 were available for analysis. Beginning at 2 months, and extending each month to the end of the evaluation period, the specialty pharmacy cohort had significantly more persistence than the retail comparator group (P < 0.05). Specialty patients were also more compliant at 6 and 9 months and utilized 37% more units than did the control group over the same period.

**CONCLUSION:** A specialty pharmacy compliance program, including relationship marketing, call center support, and distribution of a hepatitis C product, improves patient persistence with therapy.

### EFFECTIVENESS OF DEPRESSION TREATMENT PREDICTS SUBSEQUENT HEALTH SERVICES COSTS

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**INTRODUCTION:** Numerous cross-sectional studies demonstrate a strong association between depression and use of health services, but few longitudinal studies have examined whether remission of depression is associated with decreased health services costs.

**METHODS:** Pooled data from 7 longitudinal studies of patients beginning depression treatment were used to examine the relationship between clinical outcomes of acute-phase treatment and health services costs over the subsequent 6 months. Clinical outcomes were assessed by structured telephone interviews. Health services costs were assessed using health plan accounting records.

**RESULTS:** Of 1,816 patients entering treatment and meeting criteria for major depressive episode, 29% had persistent major depression 3 to 4 months later, 37% were improved but did not meet criteria for remission, and 34% achieved remission of depression. Those with persistent depression had higher baseline depression scores and higher health services costs before beginning treatment. After adjustment for baseline differences, mean health services costs over the 6 months following acute-phase treatment were $2,106 (95% confidence interval [CI], $1,684-$2,545) for those achieving remission, $2,333 (95% CI, $1,940-$2,754) for those improved but not remitted, and $2,955 (95% CI, $2,452-$3,509) for those with persistent major depression. Average costs for depression treatment (antidepressant prescriptions, outpatient visits, mental health inpatient care) ranged from $431 in the remission group to $599 in the persistent depression group.

**CONCLUSIONS:** Clinical outcome of acute phase depression treatment predicts subsequent health services costs, and persistence of depression is associated with 40% higher costs compared with full remission. The excess costs associated with persistence of depression are nearly twice as great as spending on depression treatment.
EFFECTIVENESS OF ROSUVASTATIN COMPARED WITH OTHER STATIN THERAPIES ON TARGET LDL-CHOLESTEROL GOALS IN A USUAL-CARE SETTING

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OBJECTIVE: To evaluate current cholesterol management trends in clinical practice, low-dose lipoprotein cholesterol (LDL-C) goal attainment in patients treated with rosuvastatin compared with other statins was examined using aggressive therapeutic options suggested in the 2004 National Cholesterol Education Program (NCEP) Report (Grundy et al. Circulation. 2004;110: 227-29).

METHODS: Patients newly initiated on rosuvastatin, atorvastatin, simvastatin, pravastatin, lovastatin, or fluvastatin between August 1, 2003, and September 30, 2004, were identified from a Southeastern health plan's administrative claims with integrated lab results data for this retrospective, longitudinal cohort study. Patients were excluded if they had prior dyslipidemic therapy in the 12-month period preceding their initial statin fill. Patients with at least 1 preinitiation and postinitiation LDL-C level were followed until they switched, supplemented, or discontinued their initial statin. Administrative claims were utilized to assign patients an NCEP risk status and corresponding LDL-C goal. Adjusted LDL-C goal attainment odds ratios were calculated using multivariate regression techniques after controlling for baseline differences between groups.

RESULTS: From the identified cohort (N=3,139), patients receiving rosuvastatin were slightly younger and had lower mean doses compared with other statins (11 mg vs. 18-69 mg). LDL-C goal attainment was higher with rosuvastatin compared with other statins (58% vs. 29%-48%). After adjusting for age, gender, preindex LDL-C, NCEP risk status, and therapy duration, significantly (P <0.05) fewer patients achieved their LDL-C goals with atorvastatin (odds ratio [OR] = 0.66; confidence interval [CI], 0.49-0.89), simvastatin (OR = 0.53; CI, 0.38-0.74), pravastatin (OR = 0.22; CI, 0.15-0.33), fluvastatin (OR = 0.16; CI, 0.09-0.28), and lovastatin (OR = 0.32; CI, 0.22-0.46) compared with rosuvastatin. Furthermore, dose-stratified analysis revealed LDL-C goal attainment was significantly lower (P<0.05) with 10, 20, and 40 mg atorvastatin compared with 10 mg rosuvastatin (46%-48% vs. 57%).

CONCLUSION: Rosuvastatin patients were significantly more likely to attain their LDL-C goals compared with patients on other statins. These data are among the first to illustrate the effectiveness of rosuvastatin over other statins in a usual-care setting and reinforce findings from randomized controlled trials.

EFFECTS OF IMPLEMENTING A GENERIC MEDICATION STEP EDIT ON THE UTILIZATION AND COSTS OF ANTIDEPRESSANTS IN A MANAGED CARE ORGANIZATION

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OBJECTIVE: To evaluate the impact on utilization and costs of implementing a generic medication step edit in the antidepressant category in an integrated managed care organization (MCO). This report contains short-term results and an explanation of the methodology undertaken by this MCO. Long-term data will be presented in a follow-up abstract.

METHODS: Antidepressants do not significantly differ in their ability to treat depression or in their incidence of adverse events (with some interpatient variability). Initial clinical medication choices should be made based on cost considerations, with specific treatments being prescribed at the discretion of the treating provider. With the availability of multiple generic antidepressant medications, using them first will improve the cost-effectiveness of treatment and lower the cost of treatment for patients and MCOs. Of the selective serotonin reuptake inhibitors (SSRIs) currently on the market, fluoxetine (Prozac), paroxetine (Paxil), and citalopram (Celexa) are available generically. In addition to the SSRIs, 2 other agents are available generically. Bupropion SR (Wellbutrin) is a weak inhibitor of norepinephrine and dopamine uptake while mirtazapine (Remeron) is a serotonin, alpha-adrenergic, and histamine antagonist. Some of the antidepressants are U.S. Food and Drug Administration-labeled for additional indications other than treatment of depression. The vast majority of patients will both tolerate and respond to 1 of these 5 medications. On January 1, 2005, Intermountain Health Care (IHC) Health Plans and the IHC Behavioral Health Clinical Program introduced their GenericStart! Program. Under this program, for new starts, IHC Health Plans covers brand-name antidepressants only after a trial of a generic antidepressant medication (excluding tricyclic antidepressants, or TCAs). New starts are defined as members with no claims history of antidepressant treatment within the previous 6 months. Branded antidepressants were reevaluated for formulary positioning, with different copays being applicable after the edit was met. IHC Health Plans generally has a 3-tier benefit. Tier-1 is for generic medications and has the lowest copay. Tier-2 is for branded preferred medications, while tier-3 is reserved for branded non-preferred medications that have the highest copay. In addition, bupropion SR, citalopram, and paroxetine were added to IHC Health Plans GenericSample Program (fluoxetine had been available through this program since 2003). GenericSample is a program for IHC Health Plans members that eliminates a copay/coinsurance for the first fill of select generic prescriptions when filled at a participating retail pharmacy. If the member has not filled a prescription for the requested GenericSample drug...
in the previous 6 months, the prescribed GenericSample drug will not require a copay/coinsurance. All subsequent refills of that drug will require the usual generic (lowest) copay/coinsurance. Also, a recommendation for prescribing medications for the treatment of depression was sent to physicians that focused on the following messages: generic antidepressants offer a dramatic improvement in cost-effectiveness over their brand-name equivalents; they have an excellent efficacy and safety profile and low expense; they should be considered as the initial choice in a patient presenting with depression; most people respond within the first 4 to 6 weeks of treatment, but a substantial minority will respond after 8 to 12 weeks on an anti-depressant; and because the possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs, close supervision of high-risk patients should accompany drug therapy.

RESULTS: All generic medications were made available at tier-1, with 4 being available with a zero copay the first time they are filled. Paxil CR (paroxetine), Wellbutrin XL (bupropion), and Effexor XR (venlafaxine) remained at tier-2. Lexapro (escitalopram) and Cymbalta (duloxetine) remained at tier-3, while Zoloft (sertraline) moved from tier-2 to tier-3. Ingredient cost, the number of prescriptions, the ingredient cost per prescription, and the per-member-per-month (PMPM) cost for the antidepressants remained fairly consistent throughout 2004 (prior to the implementation of the GenericStar! Program). The ingredient cost, the number of prescriptions, the ingredient cost per prescription, and the PMPM costs for first-quarter 2004 were $5,403,976, $67,435, $80.14, and $4.22, respectively. For fourth-quarter 2004, the comparable numbers were $5,371,476, $67,028, $80.14, and $4.14. During first-quarter 2005, the first-quarter after the GenericStar! Program was implemented, the ingredient cost, the number of prescriptions, the ingredient cost per prescription, and the PMPM costs all decreased substantially. The respective values were $4,853,841, $62,689, $77.43, and $3.76. This was despite the fact that the average ingredient cost per prescription of the branded antidepressants continued to increase over the 5 reported quarters. As expected, the market share shifted more toward the generics during first-quarter 2005 compared with 2004. During first-quarter 2005, 3,928 prescriptions for generic antidepressants were filled through the GenericSample Program at an expense to the MCO of $22,891. This expense is very small compared with the savings generated through the increased use of generic antidepressants. Generic citalopram became available during fourth-quarter 2004. It had no impact on overall spend or utilization during that quarter. As the price of citalopram and the other generic antidepressants continue to decrease (and an MCO is able to place a maximum allowable cost) and the prices of the branded antidepressants continue to increase, there will be more of an impact on the category, and savings will continue to grow. The overall estimated annualized savings for this MCO due to this program exceeds $2 million.

CONCLUSIONS: Antidepressants are generally a top 5 most-utilized category for most MCOs. As more antidepressants become available generically, MCOs can implement utilization controls to improve formulary compliance and reduce costs to both the MCO and its members. The implications for the medical side should be negligible, while the long-term savings for the MCO should be significant. As more medications become available generically, this process can be expanded and built upon, especially in large disease categories such as the proton pump inhibitors or HMG-CoA reductase inhibitors (statins).

**EFFECTS OF IMPLEMENTING EDITS TO CORRECT DOZING INEFFICIENCIES AMONG THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS IN A MANAGED CARE ORGANIZATION**

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INTRODUCTION: The ability of managed care organizations (MCOs) to balance high-quality pharmaceutical care with improved cost efficiency is becoming increasingly more challenging because of a variety of issues. Certain drug categories are exhibiting inefficiencies regarding appropriate utilization and dosing regimens. With the atypical antipsychotics (aripiprazole [Abilify], olanzapine [Zyprexa], quetiapine [Seroquel], risperidone [Risperdal], and ziprasidone [Geodon]), there is substantial off-label use and suboptimal dosing. Dose optimization is one method of addressing the rising costs associated with the use of atypical antipsychotics. An example of atypical antipsychotic dose optimization would be recommending the administration of a single 10 mg tablet in place of two 5 mg tablets if a patient was prescribed 10 mg/day of olanzapine. Another example would be a claims edit that would ensure that one 4 mg tablet was dispensed if a patient was receiving four 1 mg risperidone tablets per day. The keys to implementing a dose-optimization program include (1) maintenance medication being available in multiple strengths, (2) clinical evidence (pharmacokinetics, study data) supporting once-daily administration being available, and (3) similar average wholesale price (AWP) among the different dosage strengths of each drug. This quality-based cost-containment approach ensures that patients still receive the same medication at the same daily dosage; however, the dosing regimen is simplified, which may improve compliance. Medically necessary exceptions (which are clinically supported) to this rule are always allowed.

OBJECTIVE: To evaluate the impact of inefficient dosing of atypical antipsychotics and the success of implementing a pharmacy claims edit in an integrated MCO. This report contains preliminary data and an explanation of the methodology.
undertaken by this MCO. Long-term data and atypical antipsychotic class results will be presented in a follow-up abstract. **METHODS:** In 2003, Intermountain Health Care (IHC) Health Plans began an investigation of the potential impact of implementing a dose optimization program involving the atypical antipsychotics. A prescribing efficiency analysis was conducted to identify the extent to which inefficient prescribing of olanzapine and risperidone was occurring at IHC. Based on the findings of this analysis, a pharmacy claims edit was put in place for all the atypical antipsychotics. This edit was designed to flag prescriptions at the pharmacy level for the atypical anti-psychotics in which inefficient dosing was present. Pharmacists were required to automatically optimize the dosing regimens based on predetermined algorithms. **RESULTS:** The average age of patients prescribed olanzapine and risperidone in this MCO was 38 years and 28 years, respectively. There were 880 members receiving olanzapine. The most commonly prescribed daily doses for olanzapine (representing 95% of the total sample, or 836 patients) that were incorporated into this cost analysis were 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg. Of the 46 members using 7.5 mg/day, only 35 (76%) were receiving one 7.5 mg tablet. Eight members (17%) were using two 2.5 mg tablets and three members (7%) were using one and a half 5 mg tablets. Of the 203 members using olanzapine 10 mg/day, 147 (73%) were receiving one 10 mg tablet, 47 (23%) were using two 5 mg tablets, 8 (4%) were using four 2.5 mg tablets, and 1 (≤1%) was using one 7.5 mg tablet in combination with one 2.5 mg tablet. The average number of days on medication per year was estimated at 230 for olanzapine-treated patients. The average cost per patient per day for olanzapine was $9.10, based on AWP. If the dosing was optimized to the appropriate strength of 1 tablet once daily, the average cost per patient per day would be $8.32, resulting in a savings of $0.78 per patient per day (or 8.5%). Multiplying this estimated savings per patient per day by the number of days on medication per year by an estimated 70% dose conversion would result in an estimated $112,000 annual savings, based on AWP. Other members using more than 160 mg/day to sign an MMA with IHC Health Plans. It requires the member to commit to using 1 physician and 1 pharmacy for his or her pain medications. The purpose of this agreement is to protect the health care providers' interests while ensuring that members are receiving the most appropriate treatment possible. Also, IHC Pharmacy Services works closely with an IHC case manager, who is available to assist where necessary. This protocol has been extended to other long-acting opioids (i.e., Duragesic, Kadian, Avinza) and people using multiple physicians and pharmacies for short-acting opioids. Prior to the changes being implemented, letters were sent to members, and letters and clinical information including specific lists of patients on high quantities of long-acting opioids or patients using other additional physicians to obtain pain medications or using multiple pharmacies were sent to health care professionals. In addition, pharmacists from the MCO educated health care professionals via clinical in-office presentations. **RESULTS:** For the 2 quarters prior to the changes, the number of OxyContin prescriptions totaled 2,417 and 2,495. By third-quarter 2004, this number had been decreased to 2,072. The daily average consumption for OxyContin 10 mg was reduced...
from a high of 3.16 prior to the change to a low of 2.78 after the change. The changes for OxyContin 20 mg, 40 mg, and 80 mg were 2.92 to 2.65, 3.12 to 2.91, and 5.37 to 3.08, respectively. Total ingredient cost for all quarters beginning with first quarter 2003 were $542,780, $540,862, $586,543, $599,669, $558,895, $539,674, and $567,567. This relative flat trend in ingredient cost was despite an average 15% price increase in OxyContin over the same time period. The number of members filling a prescription for OxyContin during first quarter 2003 was 964, in third quarter 2004, 863 members filled a prescription for OxyContin. Some members switched to other newer long-acting opioids such as Avinza or Kadian. Overall, the number of members using a long-acting opioid did not change. By third quarter 2004, more than 400 members had signed an MMA. Pharmacy Services and Case Management were actively coordinating care for nearly half of the members with an MMA. This coordinated effort ensures that costs are simply not shifted to facilities such as emergency rooms or to other agents.

CONCLUSIONS: The requirement of an MMA, in conjunction with quantity limits and case management, improves the appropriate use of potentially abused and very expensive opioids. Quantity limits aid in the identification of potential opioid misuse, and utilization numbers become more consistent with recommended guidelines. Members are not denied medication. They are only required to more appropriately use the health care system. Theoretically, overall care is improved by using 1 physician and 1 pharmacy. Overall costs are also decreased.

EMPLOYED RHEUMATOID ARTHRITIS PATIENTS EXPERIENCED DECREASED WORK LOSS ON ETANERCEPT TREATMENT

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OBJECTIVE: To assess the effects of etanercept on work loss in rheumatoid arthritis (RA) patients.

METHODS: Patients aged ≥18 years with active RA who started or switched to etanercept could enroll in RADIUS 2, a prospective, multicenter, observational study. Data on employment status and the number of times patients missed work for half a day or more in the past month were collected at every visit. Only patients who were on etanercept monotherapy (ETA) or etanercept combination therapy with methotrexate (ETA+MTX) were included in this analysis. Missing data were imputed using last observation carried forward. For patients who reported that they were “full-time,” “part-time,” “temporarily employed,” or “other” at baseline, the number of missed workdays was analyzed comparing baseline with month 6 and month 12 using the Wilcoxon Signed Rank Test. This analysis was based on data available through November 5, 2004.

RESULTS: At baseline, there were 1,146 patients on ETA and 1,659 patients on ETA+MTX. At baseline, 41%, 11%, 1%, and 4% of ETA patients and 45%, 10%, 1%, and 4% of ETA+MTX patients reported that they were “full-time,” “part-time,” “temporarily employed,” or “other,” respectively. The number of patients who had missed work for half a day or more in the past month because of their RA declined significantly from baseline (mean for ETA = 1.74, mean for ETA+MTX = 1.43) to month 6 (mean for ETA = 0.75, mean for ETA+MTX = 0.67) and to month 12 (mean for ETA = 0.91, mean for ETA+MTX = 0.71) (P <0.001 at both time points for both groups).

CONCLUSION: RA patients on etanercept, either with or without methotrexate, reported significantly fewer missed days of work after 6 or 12 months of treatment. These improvements may be translated into savings in indirect costs to society.

ESZOPICLONE COADMINISTERED WITH FLUOXETINE FOR INSOMNIA ASSOCIATED WITH MAJOR DEPRESSIVE DISORDER: EFFECTS ON SLEEP AND DEPRESSION

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INTRODUCTION: Insomnia and major depressive disorder (MDD) coexist; currently, no treatment standards exist that address hypnotic administration during antidepressant therapy. This study evaluated the efficacy of eszopiclone on insomnia in patients administered fluoxetine for MDD.

METHODS: Patients who met Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV) criteria for both MDD and insomnia received 10 weeks of fluoxetine QAM (every morning) and were randomized to nightly eszopiclone 3 mg (n=270) or placebo (n=275) for 8 weeks. Subjective sleep and daytime function were assessed weekly by telephone. Depression was assessed with the Hamilton Depression Rating Scale (HAMD17) every 4 weeks and with the Clinical Global Impression Improvement (CGI-I) and Severity scales (CGI-S). Depression response is ≥50% decrease from baseline HAMD17, and remission is HAMD17 ≤7.

RESULTS: Completion rates were similar. Compared with placebo, eszopiclone was associated with significantly decreased WASO (wake time after sleep onset) and increased TST (total sleep time) at each treatment week (P <0.05), significantly decreased latency at all time points (P <0.05) except week 8, higher ratings across the treatment period in sleep quality and depth (P <0.05), and higher ratings of daytime alertness, ability to concentrate, and physical well-being (P <0.05). Patients coadministered eszopiclone experienced significant reductions in HAMD17 total scores compared with placebo coadministration at Week 4 (P = 0.01) and Week 8 (P = 0.002). After removing HAMD17 insomnia items, differences remained significant at Week 8 (P <0.05). At Week 8, significantly more eszopiclone patients were responders (P <0.0011) and remitters (P <0.03).
Eszopiclone was well tolerated and associated with significantly improved sleep and daytime function in patients with insomnia and coexisting MDD.

**CONCLUSIONS:** In this study, patients coadministered eszopiclone and fluoxetine experienced statistically significant improvements in several insomnia and depression measures. Eszopiclone was well tolerated and associated with significantly improved sleep and daytime function in patients with insomnia and coexisting MDD.

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**EVALUATION OF COMORBIDITIES AND COSTS IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA AND CARDIOVASCULAR DISEASE**

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**INTRODUCTION:** To evaluate common comorbidities and annual costs in patients with benign prostatic hyperplasia (BPH) also having cardiovascular disease (CVD).

**METHODS:** A retrospective case-control analysis was conducted in a large, national, managed care database to assess comorbidities and costs for patients with BPH and CVD. The study population (cases) consisted of males, aged 35 years or older, having evidence of CVD within 6 months prior to the index BPH date (first identified BPH diagnosis) and having 18 months of continuous eligibility between January 1997 and June 2004. A control cohort was matched by age and index CVD date (first indication of CVD) at a maximum of 4:1 versus cases. Comorbidities, total costs, and CVD-related costs (adjusted to 2004 dollars) were evaluated over the 12-month period following the index BPH date (using the matched case’s index BPH date for the controls). Log-transformed costs were modeled using regression analyses, and differences in comorbidities between cohorts were assessed using chi-square tests.

**RESULTS:** 82,828 patients having BPH with CVD met inclusion criteria and were matched with 271,440 controls. Hyperlipidemia (60% vs. 47%), diabetes (23% vs. 20%), and erectile dysfunction (10% vs. 4%) were more common with cases (patients having BPH and CVD) than controls (all *P* <0.001). Average annual total costs were $7,810 for cases and $5,335 for controls. Average annual CVD costs were $2,204 for cases and $1,613 for controls. Controlling for potential confounders, average costs in the case cohort were 45% higher (*P*<0.001) for total costs and 46% higher for CVD-related costs compared with the control cohort (*P*<0.0001).

**CONCLUSIONS:** Patients having BPH with CVD are more frequently diagnosed with comorbidities and have higher costs when compared with a CVD-matched cohort. Although patients with CVD commonly have increased health care costs associated with their disease, this study highlights additional incremental costs among patients with BPH and CVD.

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**EVALUATION OF MEDICATION EFFICACY IN A MANAGED CARE ORGANIZATION WHEN USING 3 ORAL ANTIDIABETIC MEDICATIONS VERSUS METFORMIN PLUS INSULIN IN THE TREATMENT OF TYPE 2 DIABETES**

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**INTRODUCTION/BACKGROUND:** Controlling hyperglycemia reduces the risk of microvascular disease and alleviates the classic symptoms of diabetes mellitus including, but not limited to, polydipsia, polyphagia, and polyuria. As part of an integrated health system, health care providers work together to ensure that cost-effective treatment is part of a care process model for diabetic members. Direct member data need to be evaluated often in order to guarantee that the best service possible is being provided to health plan members.

**OBJECTIVE:** The primary objective of this study was to evaluate glycemic control in type 2 diabetic members on 3 oral anti-diabetic medications versus members using insulin plus oral metformin therapy.

**METHODOLOGY:** The health system’s electronic medical record system was used to identify a subset of type 2 diabetic members starting January 1, 2004, through December 31, 2004. These members were then assigned to 2 groups according to their medication regimen. The first group consisted of all members taking 3 different oral anti-diabetic medications. Members of this group needed to have at least 6 prescriptions adjudicated through the system throughout the calendar year. A combination medication (e.g., glyburide/metformin 2.5/500) counted as 2 different medications for the data pull. The second group consisted of all members using any class of insulin (long-acting, short-acting, or combination) therapy plus oral metformin. Members in this group required at least 6 prescriptions for metformin and at least 6 prescriptions for insulin.

In order to properly compare these groups, adherence was also reviewed in terms of “Total Length of Therapy,” “Medication Possession Ratio,” and “Persistence.” The primary objective was a comparison of the efficacy of treatment determined by A1c values between the 2 groups. A1c values were retrieved from the electronic medical record system and were reviewed and evaluated by 3 pharmacists and 1 computer data analyst. Results were tested for normality using the Anderson-Darling Normality test and found not to be normalized. The Mann-Whitney test was used to determine statistical difference between the groups.

**RESULTS:** **Glucose control:** The oral group (members taking 3 oral medications) contained 191 members. The insulin/
metformin group contained 138 members. The oral group showed better glucose control (median A1c = 7.37) compared with the metformin/insulin group (median A1c = 8.02). This difference was statistically different \((P=0.0004)\).

**Adherence and demographics of medication use:** The total length of therapy is the time from the first fill to the last fill, including the days supply from the last fill. The percentage of time the patient actually possesses the medication during the course of therapy is the medication possession ratio. It can be reported by the length of therapy of the patient or by a specific time period, such as 90, 180, or 365 days. The possession ratio reported here is the length of therapy (LOT), 180 days, and 365 days. (Remember that members were required to have at least 6 months of therapy.) Insulin is not reported in the insulin/metformin group with the medication possession ratio or the persistence measure because the correct insulin length of therapy is often hard to determine and/or is misrepresented when adjudicated at the point of sale. “Persistence” over time is one of the best measures of adherence; it measures how many patients continue to have their medications filled. Even if there is a gap in therapy, a patient is considered persistent until his last fill of medication.

**Conclusion:** In this retrospective analysis, hyperglycemia was better controlled, according to A1c values, in members taking 3 different oral medications compared with patients taking metformin and insulin together. This is despite similar adherence measures. The next step in this evaluation of these treatment regimens is to consider the cost-effectiveness of each group.

**Extent of Blood Pressure Control Among Diabetic Patients Within the Managed Care Setting**

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**Objective:** Diabetes is associated with a 2- to 10-fold increased risk of coronary events. Approximately 75% of cardiovascular disease in diabetic patients may be attributed to hypertension. The objective of this study is to determine and compare blood pressure (BP) control in patients with diabetes among 4 health plan populations.

**Methods:** A retrospective chart review of a random sample of diabetic patients (identified using Health Plan Employer Data and Information Set [HEDIS] specifications for the Comprehensive Diabetes Care measure) was conducted within 4 commercial health plans during 2004. The level of BP control was stratified by 4 criteria according to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: (1) diastolic (DBP) level >80 mm Hg, (2) systolic (SBP) level >130 mm Hg, (3) SBP >130 or DBP >80 mm Hg, and (4) BP <130/80 mm Hg, defined as controlled.

**Results:** Of the 1,260 usable patient records, 16.9% of the patients were aged 18-44 years, 73.6% were aged 45-64 years, and 9.5% were aged >65 years; 50.3% were female. More than 50% of diabetic patients in all plans had an SBP that met or exceeded 130 mm Hg (range 50.6%-57.7%), and more than 50% of diabetic patients in 3 of 4 plans had a DBP level that met or exceeded 80 mm Hg (range 34.8%-56.6%). In 2 of the 4 plans, fewer than one third of diabetic patients met the recommended BP target of <130/80 mm Hg (range 28.0%-42.5%).

**Conclusions:** Diabetic patients are frequently not treated to their BP goal, putting them at higher risk for cardiovascular complications. More aggressive treatment by physicians and education by health plans are needed to achieve BP goals for the diabetic population.

**Financial Impact of a Provider and Pharmacy Outreach Program Designed to Convert Members from Prescription to Over-the-Counter Proton Pump Inhibitors**

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**Introduction:** An outreach program was initiated to encourage the use of therapeutically equivalent, cost-effective over-the-counter (OTC) drugs.

**Methods:** Proton pump inhibitors (PPIs) are one of the most heavily promoted and prescribed therapeutic categories of medications in the United States. The introduction of Prilosec OTC in September of 2003 presented health plans with yet another opportunity to utilize therapeutically equivalent OTC products as a cost-effective alternative to available prescription medications. A “therapeutic alternative” outreach program was initiated in a Medicaid health plan where state regulations did not allow for the use of copays or tiers as incentives for formulary compliance among members. Medical providers were given the names of their patients who were currently being treated with prescription PPIs and asked to consider Prilosec OTC as a therapeutic option. The health plan’s pharmacy network was also notified of the program and requested to reevaluate inventory to help ensure product availability and to remind providers of the availability of Prilosec OTC as a formulary alternative when discussing patient therapy options. The PPI prior authorization requirements were lifted for Prilosec OTC during the first 6 months of therapy but remained in place for the prescription PPIs. Providers were given updated PPI utilization reports on their patients on a quarterly basis throughout 2004.

**Results:** Prior to implementing this program, the average cost for a one-month supply of a PPI was approximately $120. As the program progressed, that average cost decreased to approximately $52. Annual savings attributed to the program...
amounted to more than $3.6 million.

CONCLUSIONS: Despite product availability issues during 2004, a provider and pharmacy outreach program to encourage the use of Prilosec OTC was extremely successful. The promotion of OTC products as cost-effective alternatives to prescription products should be considered by health plans when identifying cost-containment solutions.

FINANCIAL IMPACT OF A PROVIDER EDUCATION PROGRAM ON THE APPROPRIATE USE AND DOSING OF ATYPICAL ANTIPSYCHOTICS

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INTRODUCTION: The impact, from a payer's perspective, of a provider education program on the appropriate use and dosing of atypical antipsychotics in a Medicaid population is evaluated.

METHODS: Atypical antipsychotics tend to be one of the most expensive classes of medications used by predominately Medicaid populations, if not the most expensive. Compounding resource issues faced by such health plans is the reality that atypicals are often not used in accordance with U.S. Food and Drug Administration labeling and recognized treatment guidelines, such as those created by the Texas Medication Algorithm Project (TMAP). Unjustified combination therapy with 2 or more atypical antipsychotics has become a common practice even though guidelines do not recommend this type of combination therapy until all other therapeutic options have been exhausted. A provider education program was developed to encourage prescribing patterns that are in accordance with the TMAP guidelines. Providers were faxed an illustrative algorithm of the guidelines and a report of their patients receiving duplicate therapy with atypical antipsychotics. They were asked to evaluate the patients’ current regimens and determine if there were opportunities for changes that would improve the patients’ care. A clinical pharmacist was available via telephone should the provider have any questions or would like to discuss an action plan for making changes to a patient’s regimen. Throughout 2004, these reports were sent every quarter, and results were evaluated routinely.

RESULTS: Prior to initiating the program, approximately 925 members were receiving combination therapy with 2 or more atypicals each month. By the end of the year, that number decreased to 634, and the total cost savings attributed to the program was approximately $1.1 million.

CONCLUSION: A provider education program on the appropriate use and dosing of atypical antipsychotics was successful in improving practice patterns and should be considered by health plans that experience similar prescribing patterns in their population.

FINANCIAL SAVINGS OF A GENERIC DRUG SAMPLING PROGRAM IN A MANAGED HEALTH CARE SETTING

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INTRODUCTION: A program was designed and implemented by a pharmacy benefits management (PBM) company to counter increasing drug costs and encourage the use of generic medications by its members.

METHODS: The program was available to health plan members with eligible pharmacy benefits in the participating states. PBM clinical pharmacists provided physician offices with sample request forms listing the 10 generic medications offered in the program. Physicians provided these forms to patients who had medical conditions that could be treated by one of the listed generic medications. The patient presented the request form along with a prescription to his or her pharmacy to receive a complimentary supply (up to $10) of the generic medication.

RESULTS: The retrospective analysis of pharmacy claims data from January 1, 2004, through December 31, 2004, was conducted to approximate the total savings associated with the program. A total savings of $1,101,675.61 was attributed to this program for 2004, with 18,866 participants. The average ingredient cost savings per prescription was $70.81 for the health plan and $26.86 in copayment dollars for the member.

CONCLUSION: Development and implementation of this generic drug sampling program provided a significant cost savings to the health plan and saved copay dollars for the members who continued to take these medications.

HEALTH CARE COSTS OF PATIENTS WITH PERSISTENT ASTHMA


INTRODUCTION: Health care costs of persistent asthma patients were compared with health care costs of individuals without asthma and across asthma severity levels within asthma patients.

METHODS: A persistent asthma patient sample (≥65 years) was selected from an administrative database (1999-2003). Patients were included in the sample if they met the following criteria: (1) had 1 asthma diagnosis (International Classification of Diseases, Ninth Revision [ICD-9]: 493.xx), (2) had no diagnosis of chronic obstructive pulmonary disease (COPD), (3) satisfied the 2005 Health Plan Employer Data and Information Set (HEDIS) criteria of persistent asthma between July 2002 and June 2003. The asthma sample was subsequently divided by asthma severity according to Leidy's Reliever and Oral Steroid Method, and recommended inhaled corticosteroids (ICS) dosage by asthma severity in the 2004 Global Initiative for Asthma guidelines for
asthma management. A matched sample of individuals without asthma (2 controls:1 patient) was randomly selected based on patient demographic characteristics. Annual health care costs, measured as payments to medical providers and pharmacies, were compared between asthma and nonasthma control samples, within the overall asthma sample by severity level, and limited to patients receiving long-term ICS treatment. Descriptive statistics were evaluated for statistical significance using paired t tests. Costs were adjusted to 2004 dollars using the medical Consumer Price Index.

RESULTS: An average asthma patient uses $6,452 in health care costs annually, whereas the cost for an average control individual with matching characteristics is $2,040 (difference: $4,412, P < 0.01). Severe asthma patients, compared with moderate and mild patients, had higher total direct health care costs ($7,933 vs. $6,314 and $4,840, respectively; P < 0.01). Health care cost of persistent asthma patients receiving long-term ICS treatment (severe: $7,635, moderate: $5,594, mild: $3,679) were lower compared with the average asthma patients of the same severity. The cost reduction ($1,161) was greatest in mild-persistent patients.

CONCLUSIONS: Persistent asthma is an expensive, chronic condition across all severity levels, with health care costs increasing as severity worsens. Long-term ICS treatment can reduce health care costs of asthma, especially in the mild-persistent patients.

HEALTH OUTCOMES OF MS PATIENTS MANAGED BY A SPECIALTY PHARMACY

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INTRODUCTION: Specialty pharmacies have well-established programs for providing multiple sclerosis (MS) medications and monitoring patients’ therapy adherence. Our specialty pharmacy expanded its program to include the assessment and evaluation of health outcomes.

METHODS: A prospective, open-label study was implemented with an Institutional Review Board-approved protocol in February 2003. The objective was to compare health outcomes between patients beginning therapy for MS with interferons (IFNs) and those beginning therapy for MS with the noninterferon, glatiramer acetate (GA). Consecutive MS patients were invited to participate in a telephone survey assessing general health status, depression (Center for Epidemiologic Studies Depression Scale), and fatigue (Fatigue Severity Scale and Daily-Fatigue Impact Scale). Verbal consent was provided for a baseline survey prior to beginning therapy; a mailed written informed consent form had to be returned prior to initiation of follow-up surveys at months 1, 3, 6, and 12. Included in this mailing was the Guy’s Neurological Disability Scale, which assessed the patients’ disabilities in 12 domains commonly affected by MS. Other variables thought to potentially impact the outcome measures were collected: concomitant medications, compliance with MS therapies, relapses, adverse events, and demographic characteristics.

RESULTS: A total of 103 patients completed 12 months of follow-up as of February 2005; 56 began therapy with IFN and 47 began with GA. Mean age was 45.9 years (range: 28 to 65 years); 88% were female and 85% were white. There were no statistically significant differences between the treated groups in disability, depression, or fatigue at baseline. However, there were significant or near-significant declines in fatigue severity, the impact of fatigue, and depression over the course of the 1-year study period.

CONCLUSIONS: Assessing health outcomes as part of a specialty pharmacy program allowed us to advise patients and their physicians about problematic symptoms. In addition, we tracked symptom change, showing reduced fatigue and depression over the 12-month period.

THE HIDDEN VALUE OF PRIOR AUTHORIZATION (PA): REIMBURSEMENT OUTCOMES AND ESTIMATED SAVINGS FOLLOWING A POINT-OF-SALE REJECTION FOR VARIOUS PA DRUGS

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INTRODUCTION: Although prior authorization (PA) is a popular drug- cost-containment tool, the approval rate of PA requests has been reported to be as high as 90%. Little is known, however, about the rate of successful PA application following a point-of-sale rejection and its attendant effect on drug use and costs. This study analyzed claims data for 8 drugs commonly requiring PA on Canadian employer-sponsored drug plans to determine the impact of PA on patient reimbursement outcomes and savings to the plan.

METHODS: Study drugs were grouped by therapy class: osteoarthritis (celecoxib, rofecoxib), erectile dysfunction (sildenafil, tadalafil), rheumatoid arthritis (etanercept, infliximab), and obesity (orlistat, sibutramine). All plans administered by ESI Canada, a large pharmacy benefit manager, with at least one of the study drugs managed on a PA program were included. Retrospective claims data for all patients (n = 4,510) with a point-of-sale rejection from October 2003 through September 2004 were examined. Patients reimbursed for the PA drug after the point-of-sale rejection were compared with those with no subsequent paid claims. The estimated decrease in drug costs was based on utilization patterns of patients reimbursed over the study period.

RESULTS: Overall, 27.5% of patients (1,240) with a point-of-sale rejection pursued reimbursement and were eventually approved. Approval rates varied by therapy class: 16.5% (erec-
The value of PA programs in managing drug utilization should be measured from the point-of-sale rejection. The rate at which patients seek reimbursement following a PA rejection varies by therapy class and has been found to be relatively low compared with the reported approval rate. This translates into savings for employer plans.

**IMPACT OF A CARDIOVASCULAR RISK REDUCTION PROGRAM ON LIPID GOAL ATTAINMENT**

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**INTRODUCTION:** A cardiovascular risk-reduction program was evaluated by comparing baseline Health Plan Employer Data and Information Set (HEDIS) cholesterol measures with comprehensive follow-up chart review.

**METHODS:** HEDIS 2004 low-density lipoprotein cholesterol (LDL-C) control was determined. The plan’s medical management nurses employed provider- and patient-directed interventions to address cardiovascular risk reduction and to increase awareness of the importance of cardiovascular medication adherence. Interventions included cardiovascular health screenings at employer health fairs, monthly patient education programs by mail, employer educational lunches, pharmacist-patient communication programs, and communication program for the plan’s staff and nurses. A follow-up chart review determined member cardiovascular risk factors and National Cholesterol Education Program (NCEP) goal attainment.

**RESULTS:** Baseline HEDIS measurements were 63.3% for LDL-C <130 mg/dL and 36.7% for LDL-C <100 mg/dL. Chart review was conducted on 356 members with a diagnosis of hyperlipidemia. LDL-C <100 mg/dL was documented in 51.0% of members with coronary heart disease or CHD risk equivalents, and LDL-C <130 mg/dL was documented in 73.2% of members with 2 or more cardiovascular risk factors. Overall NCEP goal attainment was achieved in 66.6% of members evaluated.

**CONCLUSIONS:** Provider- and patient-directed cardiovascular risk reduction interventions had a positive impact on member lipid goal attainment and may positively impact future HEDIS measures. Continued use of this multifaceted approach may result in overall improved cardiovascular health for the plan’s member population.

**IMPACT OF A TARGETED DISEASE INTERVENTION ON HMG-COA REDUCTASE INHIBITOR UTILIZATION IN PATIENTS WITH DIABETES**

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**INTRODUCTION:** In May 2004, Prescription Solutions implemented the HMG-CoA Reductase Inhibitor (Statin) Use in Diabetes Targeted Disease Intervention (TDI) to promote the proper use of these agents in patients with diabetes.

**METHODS:** This program was an interactive provider-based pharmacy intervention designed to increase awareness of diabetic dyslipidemia treatment recommendations from the National Cholesterol Education Program Adult Treatment Panel III and the American Diabetes Association. This program involved analysis of medical claims data to identify members who were diabetic or had a diabetes-related diagnosis. Provider-specific reports were generated listing patients who might benefit from lipid-lowering therapy, and on May 4, 2004, these reports were sent to physicians in the intervention cohort. The statin use of patients under the care of intervention and control physicians was then compared. It was hypothesized that members who were included in the intervention mailing would be more likely to initiate statin therapy after the intervention compared with those in the control group.

**RESULTS:** The Statin Use in Diabetes TDI was associated with a nearly 2-fold increase in the percentage of members who initiated statin therapy during the postintervention period. The statin initiation rate was significantly higher (one-sided test with P value = 0.0497) in the intervention cohort compared with the control cohort (13.2% vs. 7.7%), with an adjusted odds ratio of 1.8.

**CONCLUSIONS:** Patients whose physicians received TDI components were more likely to initiate statin therapy than patients in the control cohort. These data suggest that the Statin Use in Diabetes TDI had a positive impact on appropriate statin utilization within this high-risk patient population.

**IMPACT OF A TARGETED DISEASE INTERVENTION TO OPTIMIZE ANGIOTENSIN-CONVERTING ENZYME INHIBITOR AND ANGIOTENSIN RECEPTOR BLOCKER UTILIZATION WITHIN A MANAGED CARE ORGANIZATION**

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**INTRODUCTION:** An educational initiative was implemented to optimize angiotensin-converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) therapy in patients with diabetes.

**METHODS:** This pharmacy intervention highlighted the benefits of blood pressure control in patients with diabetes to physician providers. Educational materials presenting evidence from
published clinical trials and recommendations from the American Diabetes Association were sent to primary care physicians providing care to patients with diabetes. The mailing also included a report listing the provider’s patients with diabetes who had no history of ACEI or ARB utilization within the previous 6 months. Twenty percent of identified physicians were randomly selected as a control group and did not receive the intervention. Six months following the intervention, ACEI and ARB utilization of the previously identified patients under the care of intervention and control physicians was compared to evaluate the program’s impact. Patients not continuously enrolled through the postintervention review period were excluded from the evaluation analysis.

RESULTS: A total of 2,621 physicians were identified who provided care to 29,224 patients with diabetes who previously receiving an ACEI or ARB. A total of 24,997 patients were available for follow-up analysis. The ACEI and ARB educational initiative was associated with a significant increase in the percentage of members initiating ACEI or ARB therapy during the postintervention period. Within the intervened cohort, 3,635 of 20,045 patients (18.1%) initiated either ACEI or ARB therapy compared with 821 of 4,952 patients (16.6%) from the control group (P = 0.01).

CONCLUSIONS: Physicians who received educational materials and a list of members with diabetes were more likely to initiate ACEI or ARB therapy in their identified patients than control physicians. These data suggest that the intervention had a positive impact on optimizing ACEI and ARB therapy within this high-risk patient population where clinical evidence supports its use.

### IMPACT OF CLINICIAN EDUCATION, COLD CARE KITS, AND CLINICIAN PEER REVIEW ON CLINICIAN PRESCRIBING OF ANTIBIOTICS FOR THE TREATMENT OF UPPER RESPIRATORY TRACT INFECTIONS AT A STAFF-MODEL HEALTH MAINTENANCE ORGANIZATION

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**INTRODUCTION:** The impact of clinician education, cold care kits, and clinician peer review on clinician prescribing of antibiotics for upper respiratory tract infections (URIs) was determined at our staff-model health maintenance organization (HMO).

**METHODS:** Starting in October 2003, the Department of Medicine and Department of Pharmacy used clinician education, cold care kits, and clinician peer review as methods to promote appropriate utilization of antibiotics for upper respiratory infections (URIs) in 3 clinical departments: Internal Medicine, Student Medicine, and Pediatrics. First, clinicians at our staff-model HMO were educated on appropriate use of antibiotics for URIs at mandatory staff education programs in which treatment guidelines for URIs and barriers to appropriate use of antibiotics were discussed. Second, the Department of Pharmacy stocked the Internal Medicine, Student Medicine, and Pediatrics departments with cold care kits to be given to patients presenting to the clinic with URIs. Thirdly, the Department of Medicine and Department of Pharmacy developed a clinician peer review program. On a quarterly basis, the department head provided each clinician with a letter containing their specific antibiotic utilization for the treatment of URIs versus the department average. The results of the audit are being used as part of the clinician performance review, and clinicians are encouraged to seek further education on appropriate use of antibiotics as necessary.

**RESULTS:** Overall, antibiotic prescriptions for treatment of URIs from October to December 2002 compared with October to December 2004 were reduced from 33.3% to 26.5%, a 20.4% reduction in antibiotic utilization. Antibiotic utilization in Student Medicine dropped from 45% to 26.6% (41% reduction), Internal Medicine dropped from 30.2% to 24% (20.5% reduction), and Pediatrics increased from 26.8% to 28.2% (5.2% increase). From October to December 2004, our clinicians dispensed 196 cold care kits to health plan members. A total of 110 cold care kits were dispensed in Student Medicine, 55 in Internal Medicine, and 31 in Pediatrics.

**CONCLUSIONS:** A multipronged approach (clinician education, cold care kits, clinician peer review) is effective at lowering utilization of antibiotics for treatment of URIs. At our staff-model HMO, this method had the most significant impact in our Student Medicine department.

### IMPACT OF PHYSICIAN INTERVENTION ON THE MANAGEMENT OF CONGESTIVE HEART FAILURE PATIENTS

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**INTRODUCTION:** The impact of a physician intervention program targeting congestive heart failure (CHF) patients was determined through retrospective analysis of patient charts.

**METHODS:** CHF is a chronic and progressively debilitating disease and a major public concern in the United States. Despite overwhelming evidence to support their efficacy, angiotensin-converting enzyme inhibitors (ACEI) and β-adrenergic blocker use in CHF patients is often suboptimal. Chart reviews of 775 patients analyzed established a baseline of CHF management at Beaver Medical Group. Following implementation of a physician-based intervention program, a subsequent chart review of 125 of the patients was conducted to determine the impact of the intervention program on CHF outcome and outcomes.

**RESULTS:** 53 of 125 (42.4%) patients were taking a β-blocker, and 87 (69.6%) patients were taking an ACEI or angiotensin receptor blocker (ARB) at baseline. Following physician education
program, 66 of 110 (60.0%) patients and 75 of 110 (68.2%) patients were taking a β-blocker and ACEI or ARB, respectively. Medication data were not available for 15 patients. In addition, of the 125 patients, only 30 (24.0%) of the patients remained on the same β-blocker regimen and 16 (12.8%) remained on the same ACEI/ARB regimen. Almost 25% and 35% of the patients had their β-blocker and ACEI/ARB, respectively, changed to another drug within the same class during the study period.

**CONCLUSIONS:**
Physician education may result in an improvement in management of patients with CHF. Physicians change drug regimens frequently. More study is required to determine whether these prescribing changes are due to formulary issues, financial concerns of patients, clinical reasons, or other confounding variables.

### IMPROVING PATIENT HEALTH OUTCOMES USING PHARMACY CLAIMS DATA: A PHYSICIAN-TARGETED POLYPHARMACY PROGRAM

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**INTRODUCTION:**
A physician-targeted polypharmacy program was implemented within an employer population to reduce inappropriate use of pharmaceuticals; we then evaluated the program’s impact.

**METHODS:**
Members with a medication profile meeting defined criteria for polypharmacy (duplicate therapies, drug-drug or drug-disease interactions, and drugs not recommended for use in the elderly) were identified from pharmacy claims data over a 3-month review period for a 35,000+ member employer. The last prescriber of the polypharmacy agent was notified by mail of the polypharmacy incident and relevant clinical information. A second mailing was issued to those not responding to the initial report. Pharmacy claims were analyzed retrospectively 3 months following the intervention to evaluate the polypharmacy program’s impact. Members who became ineligible prior to the end of the postintervention review period were excluded from analysis. Baseline polypharmacy cases not present during the postintervention period were considered resolved.

**RESULTS:**
Among 2,924 members with 3,988 polypharmacy incidents identified at baseline, a total of 2,217 members with 2,932 polypharmacy incidents were available for evaluation. The most frequently identified polypharmacy incident was for use of drugs not recommended for the elderly (61.7%), followed by drug-disease interactions (30.1%) and drug-drug interactions (14.8%). Following the intervention, 54.8% of polypharmacy cases were resolved. Resolution was highest for the polypharmacy categories “drug-drug interactions” (61.6%) and “drug-disease interactions” (58.7%) and lowest for “duplicate therapies” (50.4%). Resolution of at least one incident, and all baseline polypharmacy incidents, occurred in 59% and 52.4%, respectively, of identified members.

**CONCLUSIONS:**
The physician-targeted polypharmacy program was effective in eliminating a majority of polypharmacy incidents identified over a 3-month period, reducing the potential for adverse complications in 1,310 of 2,217 members examined during the postintervention period. An ongoing program may help follow up on unresolved polypharmacy incidents and also ensure that all new polypharmacy cases are quickly identified and evaluated for resolution.

### ORAL DIABETIC MEDICATION ADHERENCE IS CORRELATED WITH A1C GOAL ATTAINMENT IN A MANAGED CARE DIABETES DISEASE MANAGEMENT PROGRAM

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**INTRODUCTION:**
Poor medication adherence is a significant barrier to positive clinical outcomes. The purpose of this evaluation is to determine the relationship between adherence with oral diabetic therapy and glycosylated hemoglobin (A1c) goal attainment in a diabetes disease management program.

**METHODS:**
This was a retrospective, descriptive evaluation of patients enrolled in a managed care diabetes disease management program. A dataset analysis containing demographic, enrollment, pharmacy claims, and clinical lab data was performed. Continuously enrolled patients with a documented A1c obtained at least 90 days after the initial sulfonylurea and metformin prescription index dates were included. The medication possession ratio (MPR) was calculated from the prescription claims records and correlated with the A1c value.

**RESULTS:**
Forty-two percent of patients on sulfonylurea therapy and 46% of metformin were reaching an A1c goal of <7.0, and the average MPRs were 0.76 (+0.31) and 0.69 (+0.3), respectively. The average MPR for sulfonylurea-utilizing patients reaching and not reaching the A1c goal was 0.82 (+0.29) and 0.72 (+0.31), respectively (P <0.0001, students t test). The average MPR for metformin patients reaching and not reaching the A1c goal was 0.77 (+0.3) and 0.62 (+0.3), respectively (P <0.0001, students t test). A Pearson correlation showed significant positive associations between A1c and the MPR (sulfonylureas: r = -0.295, P <0.001; and metformin: r = -0.285, P <0.001).

**CONCLUSIONS:**
This evaluation shows that oral diabetic medication adherence is a significant factor in A1c goal attainment for diabetes patients. Nonadherence to medications should be considered and evaluated when a patient is not reaching a clinical goal. Barriers to adherence should be assessed and interventions to improve adherence implemented.
OUTCOMES OF A PROTON PUMP INHIBITOR FORMULARY COMPLIANCE PROGRAM

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OBJECTIVE: The goal of the study was to determine if utilization of formulary proton pump inhibitor (PPI) agents could be increased by providing formulary and benefit design information along with formulary brand PPI mail-in rebates to targeted members with claims for non-formulary PPIs.

METHODS: A prospective cohort study was conducted. The intervention cohort Blue Cross and Blue Shield of Nebraska (BCBSNE) was compared with a nonintervention control Blue Cross and Blue Shield plan (BCBS). Formulary options for PPIs were identical for both health plans. Members met study criteria if they had continuous enrollment, 3-tier drug copay benefit, and at least one nonformulary PPI claim during the 3-month period prior to mail date November 22, 2004. The analysis period was November 29, 2004, to March 1, 2005. Inclusion criteria were met by 3,379 BCBSNE members (~400,000 lives) and 2,028 BCBS comparison group members (~320,000 lives). The BCBSNE intervention detailed the 3-tier benefit by formulary status of PPIs and copay differentials. Formulary-brand PPI mail-in rebates were included, which reimbursed the member up to $30 in first prescription rebate dollars. The primary end point measured was the incidence of generic or formulary-brand PPI claims during the analysis period. Statistical 2-sided chi-square analyses performed with SPSS version 13.0 (SPSS, Inc., Chicago, IL).

RESULTS: There were 946 (28%) BCBSNE members and 473 (23%) BCBS control members excluded because they had no PPI claims during the follow-up period. In the 3 months after the letter, 265 of 2,433 (11%) intervention group members had a claim for a generic or formulary PPI agent claim, P < 0.001. In the intervention group, 130 of 265 (49%) of claims were for a generic PPI. Of the intervention group members, 232 (86%) maintained generic or preferred-brand formulary agents throughout the follow-up period, \( P = 0.028 \).

CONCLUSION: Targeted formulary education regarding formulary PPI agents and brand-formulary mail-in rebate incentives directed toward members utilizing nonpreferred PPI agents were associated with a statistically significant switch to formulary agents.

PATTERNS OF ANTIDEPRESSANT USE AND COST IMPLICATIONS OF PRODUCT SWITCHING

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INTRODUCTION: The study examines patterns of antidepressant use, including drug switching and related resource utilization.

METHODS: Using retrospective claims of managed care enrollees using a national database (PharMetrics), the study follows newly diagnosed depression patients (aged 18+ years) with newly prescribed anti-depressants. We identified the proportion of switches from commonly prescribed selective serotonin reuptake inhibitors (SSRIs: fluoxetine, citalopram, sertraline, and paroxetine) to serotonin and norepinephrine reuptake inhibitors (SNRIs: venlafaxine), and vice versa. We then aggregated health care costs for a 1-year period following diagnosis for various switcher groups. Multivariate regression analyses determined predictors of switching and factors influencing overall and depression-related costs while controlling for confounding factors.

RESULTS: Of the 48,950 patients included in the study population, 89% were treated with SSRIs and 11% with SNRIs. Between 12% to 15% of patients switched antidepressants. Of the SSRI switchers, 29% switched to an SNRI. Increased likelihood of switching was associated with female gender, Medicaid coverage, prior anxiolytic use, treatment by a psychiatrist or psychologist, and paroxetine as the index medication. Compared with SSRI nonswitchers, costs for SSRI switchers were 36% higher for all causes and 58% higher for depression-related causes. In contrast, compared with SNRI nonswitchers, costs for SNRI switchers were 27% higher for all causes and 5% higher for depression-related causes. Thus, relatively more costly patients are switching from SSRIs to SNRIs than vice versa. In addition, among SSRI patients switching to SNRI, costs increased with the number of switches. Multivariate analyses confirmed that switching was associated with higher overall and depression-related costs.

CONCLUSIONS: Switching among antidepressants is quite frequent among depression patients. Switchers incur significantly higher overall and depression-related costs, and, in general, more costly SSRI patients end up switching antidepressants.

PERSISTENCE WITH ANTIHYPERTENSIVE MONOTHERAPY IN A MANAGED CARE SETTING


INTRODUCTION: Persistence in taking frequently prescribed classes of anti-hypertensive (AHY) therapy was assessed through a longitudinal, retrospective analysis of pharmacy records.

METHODS: Pharmacy claims data (2001-2003) from the MedImpact database were used to identify patients with (1) at least 1 prescription claim from January 1, 2001, to December 31, 2003 (index date), (2) 6 months of negative medication history for AHY therapy, and (3) continuous benefit-eligibility 6 months preindex and 1-year post-index date. Patients were followed for 1 year to assess persistence and medication ownership ratio (MOR: the proportion of members with therapy at end of follow-up). Multiple variable linear regression was used to
assess differences in MOR, adjusted for age, gender, business segment, comorbidity, and concurrent cardiovascular-related medication utilization. Pair-wise comparisons were performed.

RESULTS: The study cohort consisted of 304,818 patients who initiated AHY monotherapy: 103,064 on β-blockers (BBs), 99,154 on angiotensin-converting enzyme inhibitors (ACEIs), 47,229 on calcium channel blockers (CCB), 41,651 on diuretics (D), and 13,720 on angiotensin receptor blockers (ARBs). A higher proportion of initial ARB patients (53.3%) remained persistent at 12 months past the index date compared with ACEI (49.3%), BB (42.0%), CCB (41.7%), and D (29.9%). Adjusted MORs were greatest for ARB patients (44.8%), followed by ACEI (43.8%), BB (37.3%), CCB (36.5%), and D (27.0%). All pair-wise comparisons were significant (P<0.0001), except BB versus CCB, for persistence.

CONCLUSIONS: Initiating AHY with ARBs versus other AHY classes tends to have a greater persistence and proportion of members on therapy after 1 year. These findings have important implications for managed care since optimal medication-taking behavior influences the extent of blood pressure control and the reduction of long-term cardiovascular risks. Further research is needed to assess whether clinical differences exist among AHY therapies as well as the relationships between utilization and health outcomes.

PHARMACOECONOMIC ANALYSES OF ANGIOTENSIN RECEPTOR BLOCKER THERAPY IN PATIENTS WITH MILD-TO-MODERATE HYPERTENSION

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INTRODUCTION: Seven angiotensin II receptor blockers, also known as sartans (candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, and valsartan), have been approved for the treatment of hypertension. The purpose of this study was to conduct a cost-efficacy analysis (CEA) based on clinical outcomes and costs to determine the least costly agent per treatment success from a managed care perspective.

METHODS: Efficacy data were derived from published head-to-head clinical studies or meta-analyses that evaluated angiotensin receptor blockers (ARBs) in mild-to-moderate hypertension patients. The primary efficacy outcome was diastolic blood pressure reduction in mm Hg at week 6 to 8 from baseline. Average efficacy rates were determined by calculating averages of the efficacy rates in the individual studies. Costs to treat were averaged for multiple dosing regimens. Costs included were 2005 average wholesale prices from FirstData Bank.

RESULTS: Eighteen published studies were identified, and efficacy data from these studies were used in the CEA model. Exclusions were applied for using doses or durations that differed from the primary efficacy outcome. The highest average diastolic blood pressure reduction from baseline was for losartan hydrochlorothiazide 100 mg/25mg (17.5 mm Hg), and the lowest was for valsartan 160 mg (5.3 mm Hg). The lowest average cost per diastolic blood pressure reduction was for olmesartan, at an average of $0.14, and highest for candesartan and valsartan, at an average of $0.24.

CONCLUSION: Using this simple straightforward pharmacoeconomic method, eprosartan mesylate had the lowest cost-efficacy ratio compared with other sartans in mild-to-moderate hypertensives.

PREVALENCE AND FACTORS ASSOCIATED WITH VACCINATION RATES AMONG U.S. ADULTS AT HIGH RISK OF VACCINE-PREVENTABLE HEPATITIS

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INTRODUCTION: This study sought to estimate the prevalence of adults at high risk of vaccine-preventable hepatitis (hepatitis A virus [HAV] and hepatitis B virus [HBV]) in the United States and their vaccination rates. Secondly, the study investigated the association between vaccination rates and demographic (age, gender, location of birth, and race) and social economic (annual household income, education level, and marital status) characteristics.

METHODS: Four years (1999-2002) of publicly available National Health and Nutrition Examination Survey data were utilized. Survey participants aged 20 to 59 years were selected. Survey participants were considered at high risk of vaccine-preventable hepatitis if they belonged to a “risk population group” where their situation and/or behavior placed them at a higher risk of contracting hepatitis, as identified by the Centers for Disease Control and Prevention. All prevalence estimates were weighted to represent the total U.S. population, using 4-year interview and examination weights. Logistic regression was utilized to identify demographic and social economic factors associated with vaccination rates.

RESULTS: The study included 6,237 survey participants who represent 153,919,438 adults aged 20 to 59 years in the United States. Of those adults, 12,347,634 (8.0%) were at high risk of HAV, 18,849,536 (12.3%) were at high risk of HBV, and 2,141,907 (1.4%) were at high risk of both HAV and HBV. The vaccination rates among these high-risk groups were 13%, 23.6%, and 13.4%, respectively. The most prevalent risk groups were persons with sexually transmitted diseases and persons using illegal drugs. Within the higher-risk population, single males between the ages of 20 and 29 years were significantly (P<0.05) less likely to be vaccinated than their counterparts.

CONCLUSION: Among persons identified at high risk of vaccine-preventable hepatitis (HAV, HBV, or both), only a small proportion
of this population had evidence of hepatitis vaccination (13%, 23.6%, and 13.4%, respectively).

### REAL-WORLD DOSSING BEHAVIORS FOR SELF-ADMINISTERED ANTITUMOR NECROSIS FACTORS

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**OBJECTIVE:** To assess real-world dosing patterns for self-administered anti-tumor necrosis factors (TNF).

**METHODS:** Retrospective analyses of National Data Corporation’s database were conducted. Patients with a pharmacy claim for etanercept (25 mg, 50 mg) or adalimumab (40 mg) for various therapeutic areas, including inflammatory, gastroenterology, and dermatology, from November 2004 through January 2005 were analyzed. Prescription claims were stratified into 3 cohorts: new, continuing, or switched. Patients in the new prescription cohort were those without a claim 3 months preceding the study period. Patients in the continuing prescription cohort were those with a claim 3 months preceding the study period. Patients in the switched prescription cohort were defined as those switched from 25 mg to 50 mg etanercept. Average dose per patient and percentage deviation from reference dosing were calculated for etanercept (25 mg, 50 mg) and adalimumab for each cohort and therapeutic area.

**RESULTS:** For both drugs, patients in the new cohort had greater dose deviations and higher average doses than those in the continuing cohort across all therapeutic areas. Among patients in the new cohort, both agents had doses well above the reference dose. Dermatology patients utilized the highest average dose for both drugs. The average dose was 94% higher than the once-weekly reference dose among patients receiving the etanercept 50 mg formulation. Etanercept patients in the 25 mg continuing cohort received doses that were slightly below the twice-weekly reference dose, and those in the 50 mg continuing cohort received doses that were 25% above the once-weekly reference dose. In the adalimumab continuing cohort, doses were 10% above the 40 mg every-other-week reference dose. Specifically, for gastroenterology, adalimumab had the highest average dose, at 66% above the reference dose.

**CONCLUSION:** Overall, in the cohorts examined through a retrospective review of claims data, this study illustrates that doses well above reference doses are commonly prescribed for the self-administered anti-TNFs.

### RESOURCE USE AND ANEMIA TREATMENT COSTS AMONG CANCER PATIENTS TREATED WITH EPOETIN ALFA OR DARBEPOETIN ALFA

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**INTRODUCTION:** This study examines resource use and treatment costs in cancer patients receiving epoetin alfa (EPO) or darbepoetin alfa (DARB) in a managed care setting.

**METHODS:** A retrospective analysis was conducted using medical claims from a large U.S. health plan from January 1, 2002, through December 31, 2003. Cancer patients aged 18 years and older with at least 2 doses of EPO or DARB were eligible for inclusion. Patients with renal failure or who were switched between erythropoietic agents were excluded. Treatment episode was defined as the period from first EPO/DARB claim to last claim (with no gaps in treatment greater than 30 days) with a 3-month maximum duration of treatment. Resource use and treatment costs were examined for each group.

**RESULTS:** 4,753 EPO and 1,601 DARB patients met inclusion criteria. Patient age was similar between groups with a higher proportion of men in the EPO group compared with the DARB group (EPO 34%, DARB 29%, P < .001). Treatment duration (approximately 8 weeks) and proportion of patients transfused were similar. While the number of hemoglobin determinations and cancer-related outpatient visits overall were similar, the number of anemia-related outpatient visits were lower in the DARB group (EPO 6.92 vs. DARB 4.89, P < .001). Mean anemia-related costs (per patient per episode) were significantly lower for the EPO group than for the DARB group, respectively ($3,943 vs. $5,723, P < .001).

**CONCLUSIONS:** In this managed care population, mean anemia-related costs were 45% higher for the DARB group than for the EPO group. A similar number of cancer-related office visits and hemoglobin determinations were observed between groups despite less-frequent DARB dosing, suggesting that factors other than frequency of erythropoietic agent administration determine resource utilization in this population.

### SYNCHRONICITY: A STUDY TO EVALUATE THE EFFECTIVENESS OF DARBEPOETIN ALFA AT 300 MCG EVERY 3 WEEKS ON CLINICAL OUTCOMES IN CANCER PATIENTS WITH ANEMIA DUE TO CHEMOTHERAPY

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**OBJECTIVE:** To assess the effectiveness of darbepoetin alfa administered at 300 mcg every 3 weeks (Q3W) in achieving and maintaining hemoglobin (Hb) levels recommended by current evidence-based guidelines.
**METHODS:** This interim analysis of a multicenter, open-label, 16-week study of patients with chemotherapy-induced anemia (CIA) includes 1,225 patients who received at least 1 dose of darbepoetin alfa. Study end points included the proportion of patients who achieved and maintained Hb levels within the range recommended by current evidence-based guidelines (11 to 13 g/dL), the proportion of patients who required red blood cell (RBC) transfusions, and patient-reported changes in symptoms of fatigue measured using the Functional Assessment of Cancer Therapy-Fatigue (FACT-F) scale.

**RESULTS:** Seventy-nine percent of patients achieved the target Hb range, of which 72% maintained Hb levels within the range of 11 to 13 g/dL, consistent with current evidence-based guidelines. The mean (95% confidence interval) change in Hb from baseline to the end of the treatment period was 1.5 g/dL (1.3, 1.6) (last-value-carried-forward approach). Darbepoetin alfa reduced the proportion of patients who required RBC transfusions from 11% in the first month to 4% in the last month of the study. Increases in Hb levels from the start to the end of the study period were associated with clinically significant improvements in FACT-F.

**CONCLUSIONS:** Darbepoetin alfa administered at 300 mcg Q3W is well tolerated by cancer patients with CIA. Most patients achieved and maintained Hb levels within the range recommended by the current evidence-based guidelines, required fewer RBC transfusions, and demonstrated improvements in symptoms of fatigue. Administering darbepoetin alfa Q3W may simplify the treatment of CIA in the oncology practice by synchronizing darbepoetin alfa therapy with chemotherapy, thereby reducing disruption to the life of patients and their caregivers.

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**TOPIRAMATE IN THE PROPHYLAXIS OF MIGRAINE: IMPACT ON RESOURCE UTILIZATION**


**OBJECTIVE:** To evaluate the effect of topiramate (TPM) prophylaxis on acute medication use and medical resource utilization among patients diagnosed with migraine.

**METHODS:** The Pharmetrics Patient-Centric Database was used to obtain pharmacy and medical claims data. The first TPM claim between January 1, 1999, and September 30, 2004, was considered the index date. Tripotan use was standardized to triptan equivalents (TE) based on the maximum daily dose allowed. Analysis included patients continuously enrolled for at least 6 months preindex and postindex date, with ≥6 TEs (but ≤180 TEs) during 6 months preindex date and ≥3 claims for TPM prescription. Patients with use of other U.S. Food and Drug Administration-approved prophylaxis therapy in the postperiod were excluded. Migraine-related inpatient and outpatient resource use were compared between the preperiod and postperiod. Statistical tests were conducted using McNemar’s tests for categorical variables and Wilcoxon tests for continuous variables. The most common TPM-associated adverse events observed in pivotal trials included paresthesia, cognitive impairment, fatigue, anorexia, and nausea.

**RESULTS:** The study included 1,749 TPM prophylaxis patients. The mean ± SD age was 43 ± 10 years, and 90% were female. The mean ± SD number of TPM claims per patient in the 6-month postperiod was 5.5 ± 1.8. Changes in preacute versus postacute medication and resource use were as follows: 15% decrease in triptan prescriptions (P < .0001); 7% decrease in other abortive medications (P < .0001); 8% decrease in outpatient services (P = .045), which included a 45% decrease in emergency room services (P < .0001) and a 50% decrease in procedures such as computed tomography scan and magnetic resonance imaging (P = .0003); and 52% decrease in hospital admissions (P = .001).

**CONCLUSION:** This is the first study to examine the impact of TPM prophylaxis on the resource use of migraineurs in a real-world setting. In this setting, use of TPM was associated with significantly lower acute medications and health care resource use. Future studies should examine the longer-term impact of TPM prophylaxis.

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**TOPIRAMATE IN THE PROPHYLAXIS OF MIGRAINE: PATIENT PROFILES FROM A PAYER DATABASE**


**OBJECTIVE:** To describe the demographic and pharmacy/medical utilization profile of patients diagnosed with migraine who received topiramate (TPM) prophylaxis.

**METHODS:** The Pharmetrics Patient-Centric Database was used to obtain pharmacy and medical claims data from January 1, 1999, to September 30, 2004. Migraine patients were required to have continuous enrollment 6 months prior to and after an index TPM prescription. In the 6 months immediately preceding the TPM index prescription, patients had to have ≥1 triptan prescription with a minimum of 6 and a maximum of 180 triptan equivalents (TEs). Patients with claims for other U.S. Food and Drug Administration (FDA)-approved prophylaxis therapy in the postperiod were excluded. Demographics, comorbidities, prescriber specialty, and migraine-related inpatient and outpatient resource use were assessed using descriptive statistics.

**RESULTS:** The study included 1,749 TPM prophylaxis patients. Mean ± SD age was 43 ± 10 years, with 83% of patients aged between 25 and 54 years. Ninety percent were female and 81% were commercially insured. Neurology providers initiated 54% of TPM prescriptions. The most common comorbidities were...
depression and psychosis (16%), allergy (11%), gastrointestinal disorders (8%), and anxiety (6%). Mean ± SD Charlson Comorbidity score was 0.20 ± 0.6. Prior to receiving TPM, 78% had a prescription for FDA- and non–FDA-approved prophylaxis therapy and 72% used abortive prescription medications in addition to triptans. The mean ± SD number of TEs per person was 23.2 ± 19.4. Six months prior to receiving TPM, these migraineurs had a mean ± SD of 0.64 ± 3.32 emergency room visits, 2.12 ± 2.99 physician office visits, 0.08 ± 1.72 procedures, and 0.41 ± 1.72 lab tests, cumulating to 4.20 ± 8.03 migraine-related outpatient services. Additionally, they had 4 hospitalizations and 18 days hospitalized per 100 migraineurs.

CONCLUSION: In the 6 months prior to TPM initiation, migraineurs showed patterns of extensive acute and prophylactic pharmacy resources as well as health services utilization. This is the first study to examine the TPM patient profile from a claims perspective. Future studies should examine the impact of TPM prophylaxis in reducing migraine-related resource consumption.


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OBJECTIVE: To characterize the elderly type 2 diabetes (T2DM) population in the United States, we evaluated patient characteristics, treatment rates, and glycemic control in a U.S.-representative, weighted sample of T2DM patients aged ≥65 years.

METHODS: The National Health and Nutrition Examination Survey 2001-2002 (n = 11,039) was used to identify persons with T2DM aged ≥65 years, defined by physician diagnosis at >30 years or current or past use of insulin and/or oral agents. Body mass index was used to classify patients as normal weight (<25 BMI), overweight (25-29 BMI), or obese (>30 BMI). Data were analyzed using SAS and SUDAAN statistical software.

RESULTS: Age-adjusted prevalence was 14.22% (SE = 0.86), estimating that 4.3 million elderly persons in the United States have been diagnosed with T2DM. Of these, 56.9% were aged 65 to 74 years, 34.3% 75 to 84 years, and 8.8% ≥85 years. Sixty percent were female, and 80% were non-Hispanic white, 9% non-Hispanic black, and 9% Hispanic. Approximately 40% were overweight and 46% obese. Mean glycosylated hemoglobin (A1c) for elderly T2DM patients was 6.99%; 42.3% had A1c >7%. Had A1c >7%. Almost half (46%) of elderly T2DM patients were obese. This study highlights a significant unmet need for more aggressive treatment of elderly T2DM patients to achieve American Diabetes Association-recommended A1c goal.

■■ TREATMENT SATISFACTION AND PATIENT FUNCTIONING WITH OXYBUTYNIN OR TOLTERODINE IN PATIENTS WITH OVERACTIVE BLADDER

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OBJECTIVE: To compare satisfaction and patient functioning with immediate-release (IR) and extended-release (ER) formulations of oxybutynin or tolterodine in patients with overactive bladder (OAB).

METHODS: Cross-sectional data were obtained from the Consumer Health Sciences 2004 National Health and Wellness Survey; a nationally representative sample of a noninstitutionalized U.S. civilian population. Patients were currently taking either IR or ER oxybutynin (n = 162) or IR or ER tolterodine (n = 277) to treat OAB. Patient satisfaction with treatment (PST) was measured using a 5-point scale (1 = not at all satisfied to 5 = extremely satisfied). Satisfaction rates were computed as the percentage of patients reporting a 4 or 5 on the PST scale. Patient functioning was assessed using the mental and physical component summary scores of the 8-item Short-Form Health Survey and the activity impairment score of the Work Productivity and Activity Impairment Questionnaire. A P value <0.05 in a 2-tailed test was considered significant.

RESULTS: The mean age of patients was 58 years, and 84% were female. More patients reported that they were satisfied with oxybutynin (66%; 107 of 162) versus tolterodine (48%; 132 of 277; P <0.001), with an adjusted odds ratio of 1.98 (95% CI, 1.31, 3.00; P <0.001). Those satisfied with their studied OAB medication reported statistically significantly better patient functioning compared with those who were dissatisfied.

CONCLUSIONS: In this study, significantly more patients were satisfied with oxybutynin versus tolterodine. Satisfaction with OAB therapy and patient functioning are important factors to consider in the selection of OAB medication by health care professionals and payers.

■■ TREATMENT WITH ETANERCEPT IMPROVES PATIENT-REPORTED OUTCOMES IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS

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OBJECTIVE: To evaluate the effect of etanercept therapy on patient-reported outcomes in patients with moderate-to-severe psoriasis.
METHODS: A 12-week, double-blind, multicenter clinical trial was conducted in the United States and Canada to confirm the efficacy and safety of etanercept 50 mg twice weekly in patients with psoriasis. Patients with stable moderate-to-severe psoriasis were randomized to receive subcutaneous etanercept 50 mg twice weekly or placebo. Patient-reported outcomes included the Dermatology Life Quality Index (DLQI), a disease-targeted health-related quality-of-life questionnaire. The DLQI has 10 questions that cover 6 life areas (symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment satisfaction). Lower scores indicate better health status; a 0 score means that a patient is “not at all” bothered by psoriasis in the 6 life areas. Patients who received at least one dose of study drug and provided baseline DLQI assessments (N = 308 for etanercept; N = 304 for placebo) were included.

RESULTS: Relative to patients on placebo, patients on etanercept achieved statistically significantly greater percentage improvements in DLQI total score by week 1 (P < 0.05). At week 12, the mean percentage improvement in DLQI was 69.1% for patients receiving etanercept compared with 22% for patients on placebo (P < 0.0001). Furthermore, at week 12, the improvements in each of the 6 DLQI life areas for patients receiving etanercept were statistically significantly superior to those for patients receiving placebo (P < 0.001). At week 12, significantly more patients on etanercept achieved a 0 score on the DLQI (28% on 50 mg twice weekly and 3% on placebo; P < 0.0001).

CONCLUSIONS: Treatment with etanercept improves patient-reported outcomes in patients with moderate-to-severe psoriasis. Combined with clinical efficacy, these results support the benefit of etanercept in patients with moderate-to-severe psoriasis.

UTILIZATION OF CHOLINESTERASE INHIBITORS IN THE TREATMENT OF ALZHEIMER’S DISEASE


INTRODUCTION: This study compared use of cholinesterase inhibitors by patients diagnosed with Alzheimer’s disease on time-to-effective-dose, persistence, discontinuation, switching, days on therapy, and medication possession ratio.

METHODS: Data were from MarketScan’s Medicare Claims Database from 2001 through 2003 (n = 3,177). Inclusion criteria were (1) age 65 years or older, (2) at least 1 claim with an International Classification of Diseases, Ninth Revision (ICD-9) code for Alzheimer’s disease (331.0), (3) at least 1 cholinesterase inhibitor prescription preceded by a 6-month period without any such prescription, and (4) at least 18 months of continuous enrollment. A 30-day gap between prescription end date and fill date indicated discontinuation. Cohorts were defined by their starting medication (index therapy) and were similar in most patient characteristics. Logistic regression models tested for cohort differences in discontinuation and switching, controlling for demographics, region of the country, type of insurer, and Charlson index.

RESULTS: Fewer patients started on galantamine (73%) and rivastigmine (79%) reached an effective dose than those started on donepezil (99%, P <.0001). Donepezil patients had higher rates of medication persistence starting at month 5 compared with rivastigmine, and at month 7 compared with galantamine (P <.05). Switching rates were higher for rivastigmine (odds ratio [OR] =1.57, P <.0001) than donepezil patients but were not different for galantamine patients. Similarly, discontinuation rates were higher for rivastigmine (OR =1.22, P <.05) than donepezil patients but were not different for galantamine patients. Donepezil patients spent more days on index therapy than galantamine (215 days) or rivastigmine (206 days) patients. Cohorts did not differ in medication possession ratio.

CONCLUSIONS: Choice of initial therapy affects medication adherence in a cognitively impaired Medicare population. Patients initiated on donepezil were more likely to reach an effective dose, persist on therapy, and have more days on the initial therapy than patients started on other cholinesterase inhibitors.