Implications of Real-World Data and Pharmacoeconomics for Managed Care

By Lilly Ostrovsky

The following summaries represent a sample of the many real-world, evidence-based studies presented at the 28th Annual Meeting of the Academy of Managed Care Pharmacy (AMCP), April 19-22, 2016, in San Francisco, CA. These studies highlight some of the main trends in the current US healthcare with important implications for payers, employers, drug manufacturers, providers, patients, and other healthcare stakeholders.

Manufacturers' Copay Cards Improve Access to Biologic Drugs

The high out-of-pocket costs of biologic drugs discourage many patients from using them, resulting in reduced adherence to therapy and poorer health outcomes. To help offset the cost of biologic drugs, manufacturers offer copay cards to patients. In 1988, Massachusetts enacted a ban on copay cards, and in July 2012, this ban was lifted. The results of a new retrospective review presented at the AMCP meeting demonstrated that the uptake of biologics significantly improved after this ban was lifted, especially among lower-income patients.

Using medical and pharmacy claims data of patients with autoimmune disorders, Patrick William Sullivan, PhD, Regis University School of Pharmacy, Denver, CO, and colleagues evaluated the impact of drug manufacturers' copay cards on the uptake of biologics, which was defined as having at least 2 prescription fills for an indicated biologic. The study included 667 patients from Massachusetts with 5116 patients in 8 other states (representing the control states) before and after the copay ban was lifted.

The use of copay cards among patients with autoimmune conditions in Massachusetts increased by an average of 20.7% annually after the ban was lifted: this change was even more pronounced among lower-income patients, with an average annual growth of 26.6% in the use of copay cards.

After adjusting for all the covariates, the uptake of biologics increased 6% among patients in Massachusetts in the long-term (11-21 months after the ban was lifted; $P = .019$). Again, these results were more marked among lower-income patients, where the drug uptake rate increased by 13.6% in the long-term ($P = .013$).

These data suggest that the availability of copay cards expands access to biologic drugs, and helps reduce patients' out-of-pocket costs, both of which may increase adherence to therapy and improve patient outcomes.

Source: Sullivan PW, Skup M, Mittal M, et al. The impact of pharmaceutical manufacturer copay cards on patient access to biologics.

Payers Weigh In on Presidential Candidates' Strategies to Lower Drug Costs

Controlling escalating drug prices has become an important issue in the 2016 presidential elections, namely, ensuring that high-cost drugs are affordable to patients who need them and securing the government's role in reducing drug prices. According to a new survey presented at the AMCP meeting, payers' perceptions of the presidential candidates' tactics to lower drug prices indicate that transparency in drug pricing is paramount to containing the cost of drugs.

Using Xcenda's PayerPulse online survey, Maher Abdel-Sattar, PharmD, Xcenda, Palm Harbor, FL, and colleagues surveyed 53 pharmacy directors and medical directors from managed care organizations, integrated health delivery systems, and pharmaceutical benefit managers to evaluate their perceptions of the current drug-pricing landscape and to assess the potential impact of the presidential candidates' proposed strategies on the healthcare system.

Although 94% of payers agreed that new strategies are needed to control drug prices, only 68% were familiar with the presidential candidates' suggested strategies.

Rarity of disease state was identified as the primary driver of drug costs by 81% of survey respondents, but the majority of payers agreed that drug cost should con-

tinue to be driven by efficacy outcomes in clinical trials (87%), and by the cost of clinical development (62%), and less by the rarity of disease (28%).

Overall, 72% of payers noted that increased transparency in drug pricing was the most effective strategy for lowering drug pricing for the healthcare system as a whole, followed by lowering the biologic exclusivity period from 12 years to 7 years (64%), and prohibiting direct-to-consumer advertising (51%).

As for managed care, 58% of payers also agreed that increased pricing transparency is the most effective strategy to lower drug costs to managed care.

Of the multiple strategies that are most likely to be enacted in the next 5 years, payers see the top 5 strategies as improving pricing transparency (72%), prohibiting pay-for-delay settlements (53%), requiring higher rebates from manufacturers if a drug's price increases at a greater rate than inflation (45%), capping out-of-pocket costs at $250 monthly (42%), and lowering biologic drug exclusivity from 12 to 7 years (40%).

Source: Abdel-Sattar M, Corey L, Shields S, et al. Drug pricing in the United States: payers evaluate strategies proposed by presidential candidates to lower drug costs.

Information Gaps Exist Regarding Companion Diagnostic Tests

Companion diagnostic tests are being increasingly approved with corresponding targeted drugs. When making formulary decisions, payers need to evaluate companion diagnostic tests together with the relevant drugs. The AMCP therefore asks drug manufacturers and companion diagnostic test developers to include information about the analytic and clinical validities and the clinical utility of companion diagnostic tests in drug dossiers. A study presented at the AMCP meeting shows that the quality and quantity of information provided on companion diagnostic tests are often insufficient and vary between companion diagnostic test manufacturers and drug manufacturers.

Using a standardized questionnaire, Aashish Surti, PharmD Candidate, Genentech, San Francisco, CA, and colleagues made 10 calls to companion diagnostic test manufacturers and 11 calls to drug manufacturers to assess potential gaps between test information provided by manufacturers and payers' expectations about this information. Pharmacy and Therapeutics Committee members from a major medical institution completed a survey to gauge their expectations for information regarding the tests.

According to the survey results, payers expect drug manufacturers and companion diagnostic test developers to provide information about the analytic and clinical validities, clinical utility, and cost of the tests, and preferred that this information be based on primary medical literature. However, when asked for information on companion diagnostic tests, 60% of the requests to test manufacturers resulted in an e-mailed response that included the test's package insert, and only 23% of requests resulted in medical letters with variable amounts of the desired information. The majority of responses from drug manufacturers resulted in a referral to the companion diagnostic test's manufacturer or to the US Food and Drug Administration (FDA)'s website.

These findings suggest that payers may encounter difficulties in obtaining information on companion diagnostic tests from the manufacturers. Because information on these tests is crucial for formulary decision-making, inability to acquire this information may hinder payers from appropriately evaluating drugs that should be used in conjunction with a companion diagnostic test to make educated formulary decisions.

Source: Surti A, Surofchy D, Tam I. Industry diagnostic test information provision versus expectations.

Hospitalization and Mortality Associated with Heart Failure

Heart failure is a major cause of morbidity and mortality in older adults in the United States, and although the current literature focuses on hospital admission and mortality within the 30-day postdischarge window, expanding this period may help identify additional factors linked to hospital admission and/or mortality in patients with heart failure. This is precisely what Engels Obi, PhD, Novartis Pharmaceuticals, East Hanover, NJ, and colleagues reported in their study presented at the AMCP meeting.

Using data from the Medicare Current Beneficiary Survey, which includes 16,000 beneficiaries linked to Medicare medical and pharmacy claims, Dr Obi and colleagues conducted a retrospective observational study of 645 patients aged >65 years who had ≥2 physician or outpatient claims for heart failure between 2005 and 2010. The team examined the associations between sociodemographic factors (eg, age, sex, race, education) and clinical factors (eg, assistance with activities of daily living, number of physician encounters in 12 months after the first physician or outpatient claim, comorbidity burden, and self-reported health status) with 1-year, all-cause hospital admissions and 1-year all-cause mortality.

Overall, 65% of patients were admitted to a hospital and 28% of patients died within 1 year of their first physician or outpatient heart failure claim. Female sex and comorbidity were associated with an increased incidence of 1-year, all-cause hospital admission and mortality, whereas older age was associated with a lower incidence of all-cause admission. In addition, an additional year of age, living in a long-term care facility, higher comorbidity burden, and more assistance for daily living activities were linked to higher risks for 1-year mortality.

These findings have important implications for payers and for providers, because they help to identify older patients with heart failure who have unmet needs, and underline potential areas of focus to reduce heart failure admissions and mortality.

Source: Obi E, MacEwan JP, Turner S, et al. Predictors of admission and mortality among patients with heart failure.

Impact of High Costs, Limited Access to Rheumatologists on Patients with RA

Disease-modifying antirheumatic drugs (DMARDs) are the cornerstone of treatment for rheumatoid arthritis (RA), but not all patients with RA have access to DMARDs; regional variations in patients' out-of-pocket costs and access to a rheumatologist may be responsible for this gap in quality care.

Arijit Ganguli, PhD, MBA, AbbVie, North Chicago, IL, and colleagues used medical and pharmacy claims filed across the United States between 2008 and 2014 to assess how patient out-of-pocket costs and access to a rheumatologist are associated with DMARD use among patients with RA. Area Health Resources Files were used to measure the average socioeconomic status within each metropolitan statistical area.

Approximately 65% of patients with RA used a DMARD in the average metropolitan area, and patients who visited a rheumatologist annually were more likely to receive a DMARD; 57% of patients visited a rheumatologist annually, and of these patients, 72% received a DMARD compared with 53% of patients who received a DMARD but did not visit a rheumatologist.

A key finding was that patient out-of-pocket expenses made up nearly 10% of all outpatient prescription drug costs. Overall, pharmacy costs comprised a significant proportion of patients' healthcare costs, and the metropolitan areas with the highest healthcare costs were associated with 6.6% less DMARD use than areas with the lowest costs.

These data indicate that although the quality of care for patients with RA varies by region, the majority of metropolitan areas are not considered high in quality care for RA, based on DMARD use. "Efforts to incentivize better quality of care hold promise in terms of unlocking value for patients, but for some diseases this approach may result in higher costs," concluded Dr Ganguli and colleagues.

Source: Ganguli A, Shafrin J, Shim JJ, et al. Increased out-of-pocket cost and limited access to specialists are associated with lower quality of care for patients with rheumatoid arthritis.

Natalizumab Reduces Relapses, Costs in Multiple Sclerosis

Clinical trials have demonstrated that natalizumab reduces relapses in patients with relapsing-remitting multiple sclerosis, and real-world data show that natalizumab reduced multiple sclerosis–related inpatient costs. However, the impact of natalizumab on the overall relapse-related costs for patients with multiple sclerosis in real-world settings has not been defined. A new analysis using pharmacy and medical claims data from a regional managed care organization was presented at the AMCP meeting, showing that natalizumab reduced disease relapses and relapse-related costs for patients with multiple sclerosis.

In this analysis, Brandon K. Bellows, PharmD, SelectHealth, Murray, UT, and colleagues compared the 1-year overall and disease relapse–related costs in multiple sclerosis before and after starting therapy with natalizumab in 56 patients with commercial health plans. In addition, the researchers evaluated the 1-year adherence to natalizumab, as measured by the proportion of days covered.

Overall, nearly 68% of patients receiving natalizumab had ≥80% of days covered, and the mean number of disease relapses was significantly reduced after starting natalizumab therapy compared with relapses before starting the treatment (0.27 vs 0.52, respectively; $P = .034$).

The mean multiple sclerosis relapse–related 1-year costs significantly decreased from $1787 before starting natalizumab therapy to $404 after starting the drug ($P = .006$).

Of note, approximately 33% of patients did not receive disease-modifying therapies before starting natalizumab; therefore, the total healthcare costs significantly increased after starting natalizumab.

Source: Bellows BK, Higley L, Buckley B, et al. Impact of natalizumab on multiple sclerosis relapse-related costs in a real-world setting.

Apremilast Shows More Cost-Savings Than Biologics for Patients with Psoriasis

Real-world data comparing healthcare costs among patients with psoriasis who use apremilast versus those who use a biologic are lacking. A new observational, retrospective cohort study using medical and pharmacy claims was presented at the AMCP meeting, showing that apremilast therapy is associated with lower healthcare costs than biologic therapy.

Steven R. Feldman, MD, PhD, Wake Forest University School of Medicine, Winston-Salem, NC, and colleagues defined healthcare costs as the sum of pharmacy and medical service costs, including inpatient, outpatient, and emergency department costs, and all other service costs. Apremilast was approved by the FDA on March 21, 2014, which was designated as the index date in the study.

Overall, 839 patients in the study filled at least 1 prescription of apremilast and were included in the apremilast group, and 1981 patients received biologic therapy (eg, adalimumab, infliximab) during the index period and comprised the biologic therapy group.

The patients in the apremilast group incurred a mean monthly healthcare cost of $2910 versus $4222 among patients in the biologic therapy group. In addition, the total psoriasis-related mean monthly cost, including pharmacy and outpatient costs, was $2231 in the apremilast group compared with $3661 in the biologic therapy group.

"In patients with psoriasis, apremilast offers cost-savings compared with biologics, with average savings of greater than $1000 per patient per month," concluded Dr Feldman and colleagues. The team attributed the cost-savings associated with apremilast therapy to lower psoriasis-related pharmacy and outpatient costs.

Source: Feldman SR, Kuznik A, Clancy Z. Healthcare costs in psoriasis patients newly initiated on apremilast or biologic therapies.

Pharmacist-Led Diabetes Program More Cost-Effective Than Usual Care

The Diabetes Intensive Medical Management (DIMM) clinic is a collaborative, pharmacist-endocrinologist diabetes intervention center that was established in 2009 to help patients with diabetes better manage their disease. A retrospective cohort study presented at the AMCP meeting found that this pharmacist-led diabetes program was more cost-effective than the usual care provided by primary care physicians.

Jan D. Hirsch, BSPharm, PhD, University of California San Diego, and colleagues compared the cost-effectiveness of the DIMM clinic versus that of usual care in patients aged ≥18 years with type 2 diabetes and with hemoglobin (Hb) A_{1c} of ≥8% who received treatment at the DIMM clinic or by a primary care physician for at least 6 months. Cost-effectiveness was assessed from 3 perspectives, including clinical, health system, and societal.

Clinical cost-effectiveness was evaluated using the 6-month cost per HbA_{1c} benefit; health system cost-effectiveness was evaluated using the 3-year medical avoidance and return on investment; and societal cost-effectiveness was examined using the 10-year complication risk reduction and cost per quality-adjusted life-year (QALY) gained.

The mean changes in HbA_{1c} level were –2.1 percentage points in the DIMM clinic group and –1.7 percentage points in the primary care physician group (P <.001). In addition, the cost per QALY gained in the DIMM clinic cohort decreased from –63,194 at 2 years to –23,440 at 10 years. Furthermore, the 3-year medical cost avoidance was $8793 in the DIMM clinic group compared with $3506 in the primary care physician group, and the 3-year return on investment was $15.65 in the DIMM clinic cohort.

These data indicate that care provided by the DIMM clinic was less costly and more effective than the care provided by a primary care physician. Larger controlled clinical trials will need to be conducted to confirm these preliminary results. "Assessing economic value from multiple perspectives and time frames resulted in value evidence that is meaningful to clinicians, health system administrators, and policymakers," concluded Dr Hirsch and colleagues.

Source: Hirsch JD, Bounthavong M, Arjmand A, et al. Cost effectiveness of a pharmacist-led diabetes intense medical management "tune up" clinic from three perspectives and timeframes.

Employers Incur Significant Healthcare Costs Related to Opioid Abuse

Prescription opioid abuse and misuse is an increasing epidemic in the United States, and employers bear a considerable proportion of the economic burden associated with opioid abuse, particularly among employees with injury-related workers' compensation or short-term disability, according to the results of a retrospective, observational cohort study presented at the AMCP meeting.

Using insurance claims data from MarketScan Databases, Stephen S. Johnston, MA, Truven Health Analytics, Bethesda, MD, and colleagues compared the medica-

tion use patterns and the 12-month healthcare costs and work-loss outcomes among patients with and without opioid abuse within 12 months after an injury-related workers' compensation or short-term disability event.

A total of 35,967 employees were included in the workers' compensation group, 189 of whom had a confirmed diagnosis of opioid abuse and 35,778 employees without diagnosed opioid abuse. In the short-term disability group, 386 employees were diagnosed with opioid abuse versus 71,622 employees without diagnosed opioid abuse.

Overall, the mean total days supplied for opioid prescription fills were significantly greater among employees with diagnosed opioid abuse than in employees without such a diagnosis. In both injury-related groups, <50% of employees with diagnosed opioid abuse stopped their opioid treatment (ie, ≥60-day gap in days' supply of opioid prescriptions) compared with 71% of employees without diagnosed opioid abuse.

Healthcare costs were significantly higher among employees with diagnosed opioid abuse versus employees without such a diagnosis; employees with diagnosed opioid abuse incurred >$9600 in total all-cause healthcare costs compared with employees who were not opioid abusers. Furthermore, sensitivity analyses that were conducted to correct for potential undercoding of opioid abuse in employees without diagnosed opioid abuse demonstrated that the adjusted mean total all-cause healthcare costs strictly increased from the lowest to the highest quintiles of predicted risk for diagnosed opioid abuse.

"Because of the high toll of opioid abuse, effective strategies to reduce its incidence among employees who are candidates for opioid therapy, such as those on injury-related WC [workers' compensation] or STD [short-term disability], may result in cost offsets and savings for employers," noted Mr Johnston and colleagues.

Therefore, employers may benefit from proactively addressing opioid abuse and appropriate use in their employees.

Source: Johnston SS, Alexander AH, Masters ET, et al. Healthcare cost burden of opioid abuse among employees with injury-related workers' compensation or short-term disability events: a retrospective, observational cohort study.

Specialty Pharmacy Program for Oral Oncolytics Improves Medication Adherence, Reduces Costs

The total global spending on oncology is projected to reach $130 billion by 2020. With the ongoing and future rise in oral cancer drugs, oncology is rapidly gaining a prominent place within specialty pharmacy. Low adherence to oral cancer drugs remains a challenge, which is attributed to the high cost of the drugs, the complexity of the regimens, and the associated adverse events. A new retrospective study presented at the AMCP meeting demonstrated that specialty pharmacy programs can improve medication adherence and reduce costs.

Irvin Molina, PharmD, Lead Clinical Pharmacist, Commcare Specialty Pharmacy, Plantation, FL, and colleagues retrospectively reviewed data from 3639 patients who participated in the Commcare Oncology Assist program between January 2014 and October 2015. The goals of this oncology-specific specialty pharmacy program were to improve medication adherence, provide patient education, and reduce healthcare costs.

An oncology pharmacist contacted patients via phone, texts, and e-mail before initiating oral oncolytic therapy and then every 2 weeks to assess the patient's level of medication adherence as measured by medication possession ratio (MPR) and medication tolerability or side-effect management.

Overall, medication adherence improved for the patients in this program, with an average MPR of 93.8%, and the average length of therapy for the top 7 oral cancer drugs was 8 months. The 7 top oral cancer drugs, by MPR, were erlotinib, dasatinib, enzalutamide, pazopanib, capecitabine, abiraterone, and imatinib.

Furthermore, the cost avoidance was $252,000 associated with 360 pharmacist-administered interventions that included drug information to patients, therapy recommendations, dosage clarifications, prevention of drug interactions, and side-effect management. In addition, among the 38% of patients who required copay assistance, 80% received help from the program to lower their copays significantly.

"Specialty pharmacy programs, such as Oncology Assist, have the ability to promote medication adherence, improve survival rates, and reduce costs. These programs, implemented globally, can improve overall population health and patient outcomes," concluded Dr Molina and colleagues.

Source: Molina I, Bongero D, Edillor F, et al. Impact of an Oral Oncology Program in Specialty Pharmacy.