Opportunities and Challenges of Specialty Pharmaceuticals

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As we welcome the small molecule brand patent cliff, pharmacy benefit managers and plan sponsors refocus their concern and management acumen on the growing specialty pharmacy market. Pharmaceuticals are granted “specialty” status due to high cost and unique clinical management requirements to achieve clinical outcomes and minimize often serious adverse events. One report found that a prescription cost of $1,200 justified specialty management; a pharmacy benefit management company reports that the average specialty prescription cost is almost $1,800. Over 90% of Medicare Prescription Drug Plans cover specialty drugs in a higher formulary cost-share tier and often use a $600-per-month benchmark as a specialty drug designation and management.

Specialty pharmaceuticals offer unprecedented advances in the treatment of many serious and life-threatening diseases, including cancers, rheumatoid arthritis (RA), hepatitis C, multiple sclerosis (MS), respiratory and cardiovascular diseases, human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), several orphan diseases, and many other serious conditions. However, despite the clinical potential, specialty pharmaceuticals must be stringently managed to ensure adherence, minimize potentially life-threatening adverse effects, and, of course, manage significant and expanding costs. This specialty pharmacy issue of JMCP presents experiences and innovative approaches from five organizations to achieve cost and quality objectives.

Specialty pharmacy benefit management is a primary concern of virtually all plan sponsors largely because of the associated cost trend when compared to traditional retail and mail order pharmaceuticals. Specialty pharmaceutical costs are growing at approximately 17% annually, with drugs to treat hepatitis C showing a trend of 117%, largely due to utilization (see Figure 1). Medically managed specialty drug costs are also increasing at a 15% trend rate, and total specialty costs may overtake nonspecialty drugs within five years. The annual cost of some specialty products (e.g., bevacizumab, imiglucerase, and aglycerase) exceeds $100,000, and pipeline drugs for epilepsy, lipid disorders, cancer, and other conditions promise to be as expensive. Specialty pharmacy managers must identify appropriate patient candidates, manage utilization and costs, and balance cost sharing with adherence, while minimizing safety issues to achieve desired clinical and economic outcomes.

Specialty pharmacy practices are best equipped to provide the unique clinical and cost-management requirements of specialty pharmaceuticals and do so using a variety of drug- and patient-specific programs. Over the past decade, specialty drug care management programs have shown positive outcomes in the quality of care for disease states such as hemophilia, MS, HIV, and other diseases. Specialty management strategies include custom formularies and benefit designs, clinical utilization management, provider reimbursement contracts, fraud and billing error monitoring, and distribution channel management. Formulary management of specialty products has been used by payers for many years, and nearly 10% of the cost of self-administered specialty products can be avoided with a robust formulary optimization program. However, most of the distribution-related specialty savings for self-administered drugs have been extracted due to pervasive specialty pharmacy distribution contracting. Most specialty pharmacies purchase drugs for similar prices, and incremental savings are achieved through exceptional operational efficiencies.

Specialty benefit design strategies, including member cost sharing, have existed for over a decade. As the cost of specialty drugs and the burden of member cost share increases, we must consider the negative impact upon adherence and clinical outcomes. Adherence is critical to achieve desired effectiveness and fortunately can be improved with aggressive patient management, as discussed by Aslam et al. in their article on renal transplant patients found in this issue. Managing appropriate utilization by selecting patient candidates for specific drug therapy is also important to achieve clinical and cost outcomes. Gleason et al. demonstrate in “Dalfampridine Prior Authorization Program: A Cohort Study” that clinical effectiveness may be improved through a clinical prior authorization program to use dalfampridine in patients with specific characteristics.

In another article in this issue, “Best Practices in Specialty Pharmacy Management,” Patterson shares success with implementing a management program for several medical conditions, including cancer and RA. Guidelines may also be effective in minimizing practice variation and improving clinical outcomes, as demonstrated by Hanson et al. in their article “Improvement in Safety Monitoring of Biologic Response Modifiers After the Implementation of Clinical Care Guidelines by a Specialty Pharmacy Service in an Academic Health System.” This group implemented clinical care guidelines for biological response modifiers and improved specialty drug adherence and safety.

Most health plans are not integrated delivery systems, but care management may become integrated virtually by providing community health care professionals access to patient data through integrated electronic health records. Specialty
pharmacies must also consider their organizational opportunities and limitations when implementing a management program since the future of specialty management lies in the ability to evaluate both specialty and traditional drugs concurrently across all benefits and sites of service.

The opportunities and challenges of specialty pharmaceuticals are indeed great. Our patients, and the entire health care system, depend on specialty pharmacies to develop, research, and implement effective patient- and drug-specific clinical and cost-management programs. This issue of JMCP describes innovative specialty pharmacy practices that are required to manage the threats and opportunities of the growing specialty pharmaceutical pipeline.

DISCLOSURES
Navarro and Johnson were responsible for the concept and design, data collection, data interpretation, and the writing and revision of the manuscript.

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REFERENCES

FIGURE 1 Pharmacy Spending Trends

Adapted from Express Scripts, Inc. 2011 Drug Trend Report, exhibit 8.2
*aBased on Express Scripts, Inc. 2011 Drug Trend Report.2
*bBased on Magellan Pharmacy Solutions data (no data prior to 2009).

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