

## Specialty Drug Programs Rx: Special Solutions for Employers

By Michael S. Jacobs, RPh and Robert Kalman, MS

***Major changes in the pharmaceutical marketplace in recent years have challenged employers to develop and implement new strategies for pharmacy benefit program design and administration. In particular, the unique challenges of specialty (biotech) drugs require employers to strike the right balance between providing plan participants with needed medications and managing the extremely high cost for employers and plan participants alike.***

This *InsightOut*™ looks at specialty drugs from four perspectives.

- First, it defines these drugs in pharmacological and economic terms.
- Second, it describes the typical plans and practices through which many employers provide coverage of specialty drugs.
- Third, it examines why specialty drugs present employers with administrative and financial challenges quite different from traditional prescription drug medications.
- Finally, it poses the questions employers should ask themselves as they develop new strategies to manage these expensive therapies.

### **SPECIALTY DRUGS: PHARMACOLOGICAL — AND ECONOMIC — HEAVYWEIGHTS**

Specialty/biotech drugs are developed from human proteins and DNA research, using biotechnology engineering and research techniques, such as monoclonal antibody and recombinant DNA technologies. Specialty/biotech drugs are targeted to treat disease at the cellular level. (In contrast, traditional drugs are normally developed from extracting plant chemicals and modifying the structure of chemical compounds in the human body.)

Specialty drugs offer new treatments and cures for previously untreatable and intractable conditions, such as multiple sclerosis, blood disorders (e.g., hemophilia), rheumatoid arthritis, and many forms of cancers. When these drugs successfully treat plan participants who have these conditions, they improve patients' quality of life, potentially lower employers' medical and disability plan costs, and enable employees to return to, or stay at, work.

These benefits, however, come at a hefty price. The average per-prescription cost of specialty drugs is approximately \$1,500 monthly per drug, although the monthly cost can range from about \$1,000 to more than \$20,000, depending on the drug. Typically, these patients also use an average of 12 additional different drugs per year, compared with an average of five prescription drugs per year used by non-specialty drug patients. Annual specialty drug trend for 2005 was 17 percent, compared with an average of six percent to eight percent for traditional drugs. In 2006, specialty drug trend climbed to 21 percent, compared with six percent for non-specialty drugs.

Figure 1 lists commonly prescribed specialty drugs and sales in 2006. Note the double-digit percentage increase in drug spending from 2005 to 2006 for eight of the 12 drugs shown.

In addition, these drugs can require specialized physicians, pharmacists, and nurses for patient-specific dosing (e.g., weight-based dosing), patient adherence efforts, laboratory and diagnostic monitoring, and special handling of the prescription during delivery because of temperature sensitivity and instability of the drug.

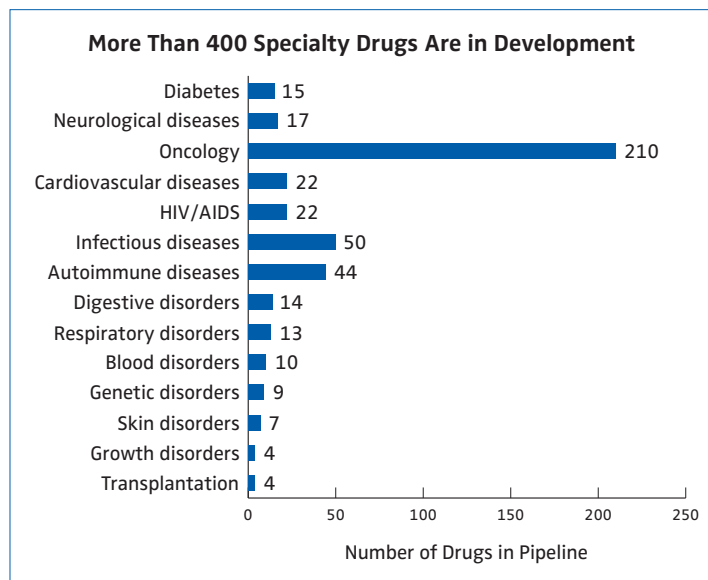
The pipeline of specialty drugs under development is robust and growing. More than 400 specialty drugs and vaccines are currently in development, with many expected to enter the U.S. marketplace in the next several years. With so many drugs in development, the annual specialty drug trend is anticipated to soon reach 25 percent or higher. As Figure 2 illustrates, many of these biotech drugs are targeted for treatment of common chronic conditions, compared to the rare diseases that these drugs originally were developed to treat.

Figure 1 |

Commonly Prescribed Specialty Drugs and Sales – 2006			
Drug	Common Use	Retail Total (\$ in millions)	Change from 2005 (%)
Enbrel	RA	1,084,243	24.1
Humira	RA	505,566	28.0
Procrit	Hematopoietic	418,431	6.3
Gleevec	Cancer	338,139	24.8
Copaxone	MS	305,828	7.0
Forteo	Osteoporosis	295,172	11.9
Avonex	MS	289,082	21.2
Thalomid	Cancer	273,921	25.7
Fuzeon	HIV/AIDS	256,183	15.8
Xeloda	Cancer	179,612	10.9
Neupogen	Hematopoietic	159,279	7.1
Betaseron	MS	157,966	3.9

RA, rheumatoid arthritis; MS, multiple sclerosis.  
 Adapted from *Drug Topics*, February 19, 2007.  
 Reprinted with permission: *Drug Benefit Trends*, Vol. 19 No. 7.

Figure 2 |



Reprinted with permission: *Drug Benefit Trends*, Vol. 19 No. 7.

As noted previously, new drug development results in a growing annual trend rate for these drugs. But other factors also contribute to this trend rate. For instance, because of the aging of the baby-boomer population and the continued absence of a regulatory mechanism for the introduction of “generic-version” specialty drugs into the U.S. marketplace, the amount spent on these products is forecasted to grow significantly in the foreseeable future. If generic versions of these medications were to be made available in the United States, the cost of older products (e.g., for the treatment of multiple sclerosis or Growth Hormone Therapy) could substantially decline. Currently, unlike the flow of new generic versions of traditional drugs, the U.S. Food and Drug Administration has not as yet been able to develop a viable mechanism for enabling generic drugs (with few exceptions) to enter the specialty marketplace because of the unique characteristics of these drugs.

## CURRENT PRACTICE OF EMPLOYERS PROVIDING SPECIALTY DRUG COVERAGE

Most employer pharmacy benefit plans have covered specialty drugs through retail network or mail order pharmacies. Typically, employee cost share for these drugs has been consistent with the fixed cost sharing of any other drug dispensed in the retail or mail order setting.

As the cost and utilization of specialty drugs increased significantly over the past five years, some employers began to realize that this approach results in a cost share of two percent or less for these drugs for the increasing number of employees who use specialty drugs. This does not compare favorably with the 20 percent or greater cost sharing for traditional prescription drugs. At the same time, the all-important patient management issues and concerns associated with specialty drugs were not effectively addressed.

Although some employers have discontinued mail service coverage (which typically provides quantities up to a 90-day supply) for specialty drugs, coverage of specialty drugs is still common in the retail setting (typically up to a 30-day supply). Many pharmacy vendors are attempting to persuade employers to allow specialty medications to be dispensed only from specialty pharmacies, most of which are currently owned and operated by the pharmacy vendors themselves.

Typically, costs for specialty drug coverage under a medical plan include an annual deductible, coinsurance, and annual out-of-pocket maximum limits for all covered services under the plan. Thus, when a patient reaches the annual out-of-pocket maximum, the plan pays the full cost of the specialty drug coverage for the remainder of the plan year. It is not uncommon that specialty drug costs under the medical plan represent 50 percent or more of the total cost of employer specialty drug costs (relative to medical plan and pharmacy benefit plans combined).

Some employers have added a fourth tier under the pharmacy benefit for specialty drugs, with separate copay and/or coinsurance levels, with maximum flat-dollar copay amounts

per specialty prescription (e.g., \$200/Rx). For example, the fourth tier may require the participant to pay 10 percent of the prescription drug cost up to a maximum dollar amount that limits the patient's out-of-pocket liability for each specialty prescription. If the discounted price of the drug is \$5,000, the patient's share would be 10 percent, or \$500 without a maximum limit. But the maximum dollar amount in this example limits the patient's cost share to \$200. This equates to approximately four percent cost sharing in this particular example. Some pharmacy vendors suggest that utilization of these expensive medications will not be affected by patient cost sharing up to \$150 per 30-day prescription.

Studies have shown that, as employee coinsurance/copays increase for traditional prescriptions drugs, these higher expenses become too high a financial hurdle for many participants, who eventually may discontinue their drug therapies. This outcome would be even more likely for patients treated with high-cost specialty drugs, particularly those in lower salary brackets. This issue needs to be considered by employers in developing a cost-sharing strategy for specialty drugs.

*More than 400 specialty drugs and vaccines are currently in development, with many expected to enter the U.S. marketplace in the next several years. With so many drugs in development, the annual specialty drug trend is anticipated to soon reach 25 percent or higher.*

## THE REVERSE PARADIGM

Employers need to develop a comprehensive strategy for managing specialty drug costs. However, in order to be effective, such a strategy may be quite different from a strategy for managing the costs of a traditional pharmacy benefit plan program.

In the traditional pharmacy benefit plan model, intense marketplace competition, and price flexibility allow plan sponsors to achieve significant savings through price negotiations with pharmacy benefit managers. The potential for savings is not as great through clinical and utilization management programs, as unit costs are much lower.

The reverse is true with specialty drug programs, hence the term, “reverse paradigm.” With specialty drug cost management, most savings *are* generated through patient care management programs that are designed to avoid expensive medical costs, such as hospitalizations and emergency department visits. Vendor price negotiations result in relatively low savings because there is not as much price flexibility (yet) for these high-cost drugs, compared to traditional prescription drugs.

*It is not uncommon that specialty drug costs under the medical plan represent 50 percent or more of the total cost of employer specialty drug costs (relative to medical plan and pharmacy benefit plans combined).*

In the world of specialty drugs, care management programs can reduce costs by:

- Ensuring only medically appropriate dispensing of specialty drugs;
- Mitigating the risk of life-threatening adverse effects; and
- Improving adherence to the drug therapy regimen to achieve maximum therapeutic benefit.

Better clinical outcomes, as mentioned earlier, mean improved quality of life, as well as lower costs, for patients and other payers. From an employer’s perspective, those lower costs manifest themselves in lower pharmacy and medical benefit costs, decreased disability costs, and improved productivity.

## SPECIALTY DRUG STRATEGY DEVELOPMENT: STRIKING A DELICATE BALANCE

Spending on specialty medication costs represents a growing proportion of employers’ drug spending as the number of specialty drugs entering the marketplace increases and shifts toward the treatment of common chronic conditions, as opposed to episodic therapies. It currently represents approximately 20 percent of total annual drug spend. Therefore, it is important for employers to develop plan designs that balance employee cost sharing and drug access with providing patient care management to ensure appropriate drug therapy and optimal outcomes that mitigate expensive inpatient medical plan costs. To be sure, there is a delicate balance between cost and access with appropriate drug therapy and patient care management.

We strongly recommend that employers achieve this balance through operations and strategies. The days of short-term, operational “fixes” alone, including employee cost shifting, are over. Multiple dynamic marketplace forces are in play that require a carefully planned strategy for specialty drugs.

Employers committed to developing a strategically based specialty drug program need to realistically address difficult financial and philosophical questions, including the following:

- Should employers continue to offer specialty drug coverage through the medical and/or pharmacy benefit plan, or offer coverage separately through a specialty pharmacy vendor?
- Should coverage for self-injectable and oral specialty drugs be covered through the specialty pharmacy vendor and infusible drugs through the medical plan?
- What are the advantages and disadvantages of this approach, relative to a complete carve-out of specialty drugs from the medical and pharmacy benefit plans to a specialty pharmacy vendor for all specialty injectable, self-injectable, and oral specialty drugs?
- Which specialty drugs will be covered and which will not, and why?
- Are employers able — or prepared — to evaluate specialty drugs on a return-on-investment (ROI) basis? This evaluation is difficult to do, principally because the effectiveness of many of these drugs on those taking them typically takes years to determine.
- Are employers able — or prepared — to evaluate specialty drugs as measured by likely incremental improvement in employees' health?
- Have employers considered how an ROI calculation might be different in industries with high employee turnover?
- How should employers most effectively communicate pharmacy benefit plan policies and changes to employees and providers?
- Should employers set annual or lifetime benefit limits for specialty drugs, or will unlimited coverage be provided? How will this be affected by the changes in the workforce that are anticipated over the next decade?

- What criteria should be used in evaluating and selecting an appropriate specialty pharmacy vendor?
- Perhaps most important, how should employers coordinate care of specialty drug patients with the employer's disease management and medical vendors?

## SUMMARY

As the number, cost, and utilization of specialty drugs continues to rise, the current approach of offering coverage for these drugs through both the medical and pharmacy benefit plans is not viable over the intermediate and long term. The unique challenges presented by specialty drugs will force employers to develop strategic specialty drug programs that will provide plan participants with affordable access to these drugs and appropriate patient management. These strategies have the potential to ensure both quality care for plan participants, with improved outcomes, and effective cost management for employer plan sponsors.

## ABOUT THE AUTHORS:

Michael Jacobs, RPh. With three decades of experience in the health care industry, Mr. Jacobs, Buck's Clinical Practice Leader, provides clients with a unique and practical perspective to manage health care benefits. He can be reached at [Michael.Jacobs@buckconsultants.com](mailto:Michael.Jacobs@buckconsultants.com) or 770.916.6018.

Robert Kalman, MS. Mr. Kalman, National Pharmacy Practice Leader at Buck Consultants, has consulted on pharmacy and related health care benefit issues for nearly 30 years. He can be reached at [Robert.Kalman@buckconsultants.com](mailto:Robert.Kalman@buckconsultants.com) or 202.776.1045.

*... there is a delicate balance between cost and access with appropriate drug therapy and patient care management.*