BY DENISE MYSHKO

The Fourth Tier
Tighter Control of Specialty Drugs

SPECIALTY DRUGS AND BIOLOGICS ARE COMING UNDER THE SAME SCRUTINY AS OTHER PRESCRIPTION DRUGS.

Managed care organizations are tackling the rising costs and expanding use of specialty products. Specialty drugs, injectable biologics, and other higher-cost drugs that require close supervision and monitoring are the fastest-growing segment of the overall pharmaceutical space.

The average annual increase in drug cost expenditures reported in 2007 was 6.9%, according to the Pharmacy Benefit Management Institute's (PBMI) 2007 Prescription Drug Benefit Cost and Plan Design Report released in October 2007.

Experts say specialty drug costs as a whole are rising faster than nonspecialty drugs. For example, at Prime Therapeutics, a pharmacy benefit manager, specialty drugs accounted for 13.8% of clients' drug spending in 2006. The most dramatic increase in specialty drugs was in the oncology market.

At Express Scripts, spending on high-cost biotech drugs increased 21% in 2006. This increase excludes spending for biotech drugs within the medical benefit, such as those administered in physicians' offices or other therapies that traditionally fall into the medical benefit. The company estimates overall biotech drug costs will reach $99 billion by 2010, accounting for 26% of total drug spending.

"In 2006, specialty drugs accounted for about 20% of the market, or $54 billion of a total market of about $275 billion," says Tony Lanzone, VP, trade and distribution practice, at Campbell Alliance. "In 2010, the specialty market is expected to be just under a $100 billion. Furthermore, the specialty market is anticipated to double in a couple of years, while the nonspecialty spend in 2010 is projected to be $284 billion."

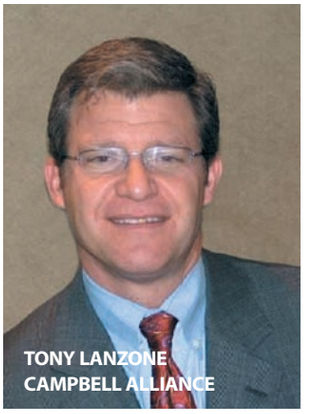
Certain drug classes, such as arthritis, oncology, and multiple sclerosis, are growing tremendously in terms of utilization, says Michael Jacobs, national clinical practice leader at Buck Consultants. (See related box on page 72.)

Specialty drugs generally encompass a category that contains genetically engineered, injectable therapies with costs greatly exceeding those of most traditional therapies, and address a number of complicated conditions, including osteoporosis, arthritis, multiple sclerosis, and cancer.

The Centers for Medicare & Medicaid Services now informally defines specialty drugs as those regularly costing $500 or more for a 30-day supply.

These are higher-cost products for a number of reasons, Mr. Lanzone says.

"These drugs require special handling and special instructions in terms of administration," he says. "The therapeutic categories that are driving specialty pharmacy growth include: multiple sclerosis, cancer, blood cell deficiency, growth hormone products, and inflammatory conditions such as rheumatoid arthritis."



TONY LANZONE
CAMPBELL ALLIANCE

By strategically partnering with selected specialty pharmacy providers, pharma and biotech companies are able to address their objectives and strategies in a much more focused fashion.

MICHAEL GOODMAN
AVOS LIFE SCIENCES

In recent years, injectable and office-administered biologic drugs are being put on formularies.

According to The Segal Company, the 2008 projected trend for specialty drugs is 19.5%, almost 10 percentage points above aggregate retail trend. This is significant because specialty pharmaceuticals account for 17.1% of the total drug trend. The high cost and trend-driving impact of these drugs will continue to be felt in the coming years as research and new drug approvals continue.

SPECIALTY NETWORKS

PBMs and managed care organizations are trying to control specialty drug usage by bringing high-cost injectables that were formerly covered under the medical benefit — especially those that are self-administered — under the pharmacy benefit, says Michael Goodman, VP of research products at AVOS Life Sciences.

"This gives managed care organizations a powerful lever for controlling drug utilization," Mr. Goodman says. "And if there are alternatives, the MCOs are obviously going to channel some patients to cheaper alternatives."

A Pharmacy Benefit Management Institute report states that 30% to 60% of specialty drugs are included under the pharmacy program. The report also found that 75% of employers offer a specialty pharmacy benefit. Slightly more than half — 51.5% of employers — require specialty drugs reimbursed under the drug benefit to be dispensed by the pharmacy benefit manager's designated pharmacy.

"There is greater insight and transparency of drug utilization for products covered under the pharmacy benefit based on current system functionality and data availability," Mr. Lanzone says. "This transparency allows payers to provide greater oversight of utilization for products covered on the pharmacy benefit versus if the products were bundled in the medical benefit. This is a trend worth watching based on the information from the health plan decision makers with whom we've spoken."

Mr. Jacobs says other companies are using

specialty distribution networks as a way to control costs.

"They are trying to switch as many drugs as they can out of the retail network and into their own specialty distribution channels," he says. "They're trying to switch drugs from a mail service, which has deep discounts, into specialty distribution, which has fewer deep discounts. And they're selling it under the guise that they are going to help manage utilization."

The largest of the PBMs — Medco Health Solutions, Express Scripts, and CVS Caremark — all have their own specialty networks.

Medco, for example, has made efforts over the last few years to address the specialty pharmacy market. In 2005, Medco completed its acquisition of Accredo Health, a company that provides pharmacy and related services for the treatment of patients with certain costly, chronic diseases. In 2007, Medco added to the company's specialty services when it acquired PolyMedica, a provider of diabetes care and treatments.

More recently, in January 2008, Medco received URAC's Drug Therapy Management (DTM) Accreditation for its clinical management program, which provides patients with access to specialist pharmacists trained in specific chronic and complex conditions. Medco completed the rollout of the Medco Therapeutic Resource Centers last year, culminating three years of development and the process of training specialist pharmacists in specific chronic and complex conditions.

Mr. Jacobs says using a specialty distribution network can be positive for the PBM.

"PBMs collect all the data so they bill the drug under the NDC," he says. "There is a guaranteed price that is paid up front. By having the data go through the pharmacy benefit manager, there is a very clear idea of what specialty product was given, what dose, what size. And there is a hard figure on price plus a discount. On the physician side, a company doesn't know any of that information, which then can't be managed or tracked. The data are put into reports and the information is shared with the employer or the managed care organization; the PBM can then either negotiate for better pricing or rebates from the manufacturer."

THE TOP SIX SPECIALTY CATEGORIES

1. Inflammatory Conditions
2. Multiple Sclerosis
3. Cancer
4. Blood Cell Deficiency
5. Growth Deficiency
6. Hepatitis C

IS IT ALL BAD NEWS?

An April 2007 report from Express Scripts predicted that specialty drug utilization was going to slow in the next couple of years because of lower than historical growth in a few therapeutic categories.

In the inflammatory conditions class, market expansion beyond the treatment of rheumatoid arthritis (RA) has leveled off — leading to a slowdown in the explosive growth since 1998. That deceleration is expected to continue even as new products are approved.

Slower growth also is expected in the blood cell deficiencies category because several recent clinical studies have reported safety issues with the use of erythropoietin (EPO). Toward the end of the decade, utilization growth will be fueled

by new products that are expected to be approved in 2008 and 2009 for multiple sclerosis and hepatitis C, as well as combination cancer therapies.

Cost-per-prescription growth will be dampened slightly by less expensive growth hormone products approved in 2007 and by true generic anticoagulants that should enter the market within the next few years. Additional downward pressure may be exerted by new oral medications for conditions such as MS, currently treated only by injectables.

Experts say pharmaceutical manufacturers will encounter greater cost pressure and demand for outcomes data in their negotiations with managed care organizations, and specialists will gain prescribing control.

Rebates and price discounts, industry analysts say, will not be as effective in securing preferred formulary placement for novel-acting biological agents as they are for conventional primary-care drugs, where utilization volume is so much greater and can translate into significant savings for the plan.

A key lever in negotiating preferred formulary placement for specialty products will be the quality of the data behind the product and the clinical guidelines governing its use, particularly as therapeutic categories fill up with more treatment options.

"Companies that want to succeed in the specialty market have to understand the needs of the specialist and form equity relationships with key opinion leader specialists early on, during discovery," Mr. Goodman says. "This is a very complex and rich relationship, unlike anything in the primary care world."

Mr. Lanzone suggests that pharmaceutical companies need to systematically evaluate partnership opportunities and requirements with specialty pharmacy companies.

"A best practice is for pharma or biotech companies to clearly define their objectives and strategies for each brand and then partner with the type of specialty pharmacy provider that is best able to deliver the services required to optimally position their product to physicians and patients," Mr. Lanzone says. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

2007 TO 2010 FORECAST FOR SELECTED SPECIALTY THERAPY CLASSES

2006 RANK	THERAPY CLASS	TREND 2007	2008	2009	2010	COMMENTS
1	Inflammatory Conditions	21.9%	21.9%	21.9%	21.9%	New products such as Cimzia and new indications for existing drugs will continue to drive increases in utilization. Inflation will drive cost due to no new follow-on generics and little competition among brands.
2	Multiple Sclerosis	16.2%	16.3%	16.4%	15.4%	New oral brands, which are expected in 2008 and 2009, may increase utilization but decrease cost/Rx. Drugs currently used to treat cancer may be approved for MS — potentially reducing the use of existing MS drugs.
3	Cancer	43.8%	38.0%	38.0%	38.0%	New drugs and combination therapy will drive up utilization.
4	Blood Cell	5.0%	6.1%	7.1%	7.1%	Less growth is expected in utilization, primarily driven by recently publicized safety concerns associated with the use of EPO products for anemia.
5	Growth	5.0%	10.2%	9.2%	9.2%	Omnitrope, a less expensive follow-on protein launched in January 2007, will reduce 2007's cost/Rx. After 2007, expect slightly slower growth in utilization and a return to consistent inflationary cost/Rx increases.
6	Hepatitis C	(0.3%)	(0.3%)	12.4%	14.5%	Current medications are not effective for all patients, and no new therapies have been introduced. New products expected in 2009 and beyond are likely to increase utilization. The introduction of generic ribavirin continues to impact cost/Rx.
7	Other	24.2%	25.4%	26.5%	26.5%	Other specialty categories are expected to experience slightly higher than historical growth as new products are introduced for previously untreated or undertreated conditions. Biogenerics in some categories should help to slow overall growth in cost.
Total		21.2%	22.0%	23.5%	24.0%	

Source: Express Scripts 2006 Drug Trend Report, St. Louis. For more information, visit express-scripts.com.

Experts on this topic

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