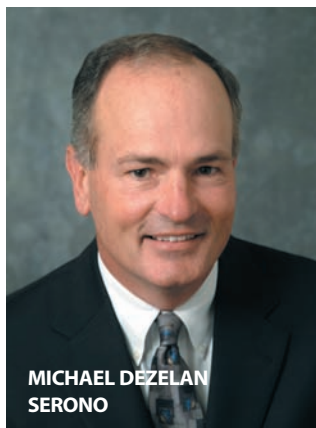


Managed Markets: **FORMULARIES**

MCOS AND PBMS ARE NOW APPLYING THEIR COST-MANAGEMENT STRATEGIES TO BIOTECH AND SPECIALTY DRUGS.



**MICHAEL DEZELAN
SEROZO**

Payers are going to want to manage specialty products from two angles: to ensure appropriate utilization and to ensure adherence and compliance so the medical spend is not impacted.

Biologics and injectable medications are coming under increased scrutiny by managed care organizations (MCOs). MCOs, pharmacy benefit management companies (PBMs), and other payers are beginning to apply cost-management strategies to high-cost biologic, injectable medications, and specialty drugs. They are using distribution networks to capitalize on lower pricing and rebates from manufacturers.

They also are implementing cost-sharing arrangements with mem-

bers. In 2005, 74% of workers with employer-sponsored coverage had a cost-sharing arrangement with three or four tiers, compared with 27% in 2000, according to the Henry J. Kaiser Family Foundation's June 2006 report.

As payers become more sophisticated in managing specialty products, they will likely implement other strategies, such as clinical guidelines and outcomes measurements.

MANAGED CARE'S HOT BUTTON

Spending in the United States for prescription drugs was \$188.5 billion in 2004, according to the Kaiser Family Foundation. By 2015, the amount spent on drugs in the United States is expected to increase 138% to \$446.2 billion.

Although prescription drug spending is a relatively small proportion of overall healthcare spending — about 16% — it has been one of the fastest growing components. The three factors driving this include more drug utilization, price increases, and changes in the types of drugs used, such as biotech and specialty medications.

Specialty and biotech products are hot buttons for managed care organizations, says Kevin Barnett, senior VP of the managed markets practice at Campbell Alliance.

Kaiser Permanente, for example, has experienced biotechnology drug cost increases of

505% over the past eight years. In September 2006, the health plan began taking steps to address these rising costs. Evidence analysis, usage measurements, and multidisciplinary planning are part of Kaiser Permanente's strategy for managing biotech drugs.

There also is an effort among payers to manage high-cost drugs that are administered by physicians, says John Carlsen, a principal in consulting services at Covance Inc.'s Market Access Services division.

"These are drugs that are administered in the office, such as IV infusion medications," he says. "Historically these drugs have been covered by the medical benefit, whereas oral and other self-administered drugs have been covered by the pharmacy benefit. In the future, there is going to be more of an effort to add a pharmacy benefit-type structure to physician-administered drugs. This could mean the use of formularies, as well as other strategies, including prior authorization and tiers."

According to the second edition of the Serozo Injectables Digest, injectables can represent between 20% and 30% of a health plan's total drug spend. The Serozo Injectables Digest is based on a survey conducted in 2005 of more than 70 key health plans.

In 2005, 10% of plans covered all injectables under the pharmacy benefit, a 5% increase from 2004, although a majority of health plans (85%) covered office-based administered injectables under the medical benefit, according to the Serozo Injectables Digest. A majority of health plans (64%) covered self-administered injectables under the pharmacy benefit.

There has been further evolution in MCO's use of formulary tiering, says Tom Koenig, senior

Specialty pharma sales in the U.S. were about **\$35 BILLION** IN 2004.

Serozo Injectables Digest

director of segment marketing at Endo Pharmaceuticals.

"Some organizations have three tiers, and some have four or five tiers," he says. "Some plans require a percentage of the cost as coinsurance

instead of requiring a flat copay. These higher tiers are clearly being applied to biologics, self-injectables, and biotech drugs."

The Serozo Injectables Digest found that tiered copayments are assessed by 64% of health plans, an increase of 17% from 2004.

The report also found plans were assessing higher copayments and coinsurance. In 2004, the highest copayment didn't exceed \$60. In 2005, a fourth-tier injectable had an average copayment of \$106; a fifth-tier product on average had a \$275 copayment.

Mr. Barnett says another trend is the rapid

PAYERS' STRATEGIES FOR MANAGING SPECIALTY PRODUCTS*

CURRENTLY USED

CLINICAL SERVICES

Proactive refill management
Adherence/persistence programs

Prior authorization
Utilization management

Patient education

CLIENT SERVICES

Business review
Pipeline information/analysis

Utilization reports

Compliance reports

Measurement of savings

WOULD USE IN FUTURE

Therapy management
Prefilled syringes to reduce waste and cost

Injectable formulary
Clinical guidelines

Clinical programs with documented outcomes

Pull-through with doctors
Performance guarantees

Electronic medical claims pre-adjudication for doctors

Measurement of outcomes

Industry benchmarks

* Note: Services that health plans typically use with their specialty pharmacy provider

Source: Serozo Injectables Digest, Serozo Inc., Rockland, Mass. For more information, visit serozousa.com.



JOHN CARLSEN
COVANCE

In the past, companies could charge a premium for new products and be confident they would be reimbursed. Today, companies might have to rethink that approach as premiums begin to erode.



TOM KOENIG
ENDO PHARMACEUTICALS

When marketing to health plans and PBMs, marketers need to keep in mind that they cover a product based on a business decision. We have to help them see how our products will help that equation.

growth of specialty pharmacy providers and distributors.

“The large PBMs and even MCOs are either establishing their own or are acquiring specialty pharmacy groups to help them manage these drugs,” he says.

Beyond this trend, he says there is a broader theme: managed care is focusing on appropriate use of specialty products.

“Most managed-care decision makers would

acknowledge the clinical utility of many of the products being discussed,” Mr. Barnett says. “They want to make sure the correct patients are getting the right drugs and are using the appropriate regimens. This is particularly important for this category of drugs.”

Of the plans surveyed for Serono Injectables Digest, the majority (78%) already either contract with one or more specialty pharmacy providers (SPPs) or are in the process of contracting with one. In 2005, 60% of health plans required members to obtain some or all of their injectables through the SPPs, compared with 47% in 2004.

For products covered under the medical benefit, 33% of the surveyed health plans required physicians in 2005 to order some or all specialty injectable products through the SPP, compared with 24% in 2004.

STRATEGIES FOR SUCCESS

Industry leaders say a winning strategy for the MCO market has to be multifaceted.

“A critical step is making sure senior management understands the importance and the evolving dynamics of managed care,” Mr. Barnett says. “Certainly, that’s foundational, but in addition, pharma and biotech companies need to make sure that the payer environment is understood across key functional areas within an organization. Senior management, brand

management, the sales-force, sales executives, and even clinical development professionals have to clearly understand the importance of payers and the realities of the evolving environment with payers. Then companies need to make the appropriate organizational adjustments to processes, strategies, and tactics.”

Mr. Barnett says for many pharma and biotech companies a significant

barrier has been the inability to establish a compelling value proposition for their products for payers.

“Most organizations have certainly not done a good job of this,” he says. “Historically, managed care and access and reimbursement were viewed by marketers and brand managers as more tactical considerations. But when the realities of today’s environment are considered — more than 80% of drug utilization in the United States is controlled by either private or public payers, according to data from the Centers for Medicare and Medicaid Services — pharmaceutical and biotechnology leaders have to better understand who those payers are and the requirements for success for interacting with them and selling to them.”

To do this, Mr. Koenig says companies have to have a commitment to outcomes-based data.

“Pharmaceutical companies have to create a message that explains the value of the drug for

all three constituents in the chain: the health plan, the employer that pays the premium, and the patient who pays a significant portion of the copay,” he says.

Managed care organizations are looking for evidenced-based or health outcomes measures to demonstrate the benefit of specialty injectables, says Michael Dezelan, senior VP of managed markets at Serono Inc.

“This process should start early in Phase II clinical trials so that companies can include the outcome endpoints in their various studies,” he says.

Mr. Dezelan says health outcomes plans can provide managed care companies with data to help patients remain compliant.

“Biotech and pharma companies can encourage compliance through support services, such as call centers and other programs,” he says. “Serono offers patient support services such as the MS LifeLines call center and nurse educators, who can provide support and information to both physicians and patients taking Rebif (interferon beta-1a). For example, nurse educators can provide in-home product and device training for patients to teach them how to inject the product properly and help them understand the importance of being compliant to treatment.” ♦

Average co-insurance for tier two drugs was **30% and 50%** for tier three in 2005.
Serono Injectables Digest

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

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