



“Well, Isn’t *That* Special?”

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There’s no way of knowing exactly how *Saturday Night Live*’s Church Lady (a.k.a. Dana Carvey’s Enid Strict) would react to today’s emerging crisis with the rising cost and usage of specialty drugs. But, her sarcastic catchphrase probably rings true for many benefits managers. That’s because the techniques frequently used to manage the rapidly increasing cost and usage of specialty drugs are not well suited for the challenge. Benefit managers may soon be facing specialty drug costs of a magnitude not seen before, while at the same time not having the tools to manage these costs without working hardship on their employees.

What is it that makes a drug a *specialty* drug? While the definitions PBMs use differ, commonly agreed upon characteristics of specialty drugs include:

- Special delivery, storage and handling requirements
- Significant medication administration training for patients
- Much higher cost than traditional medications
- Ongoing monitoring of medication adherence, side effects, and dosage changes is required
- May be available only through limited distribution channels
- May be injectable or oral
- May be biotech

Express Scripts is projecting specialty drug costs to increase from today’s \$54B to \$100B annually by 2010. Benefits managers are attempting to deal with the rising cost and expanded usage of specialty drugs by applying such techniques as:

- Requiring prior authorization and quantity limitation policies
- Requiring step therapy policies and mandatory generic programs
- Requiring that specialty drugs be available only from their PBM’s specialty pharmacy
- Creating a separate copay or coinsurance tier (Tier 4) in the drug plan for specialty drugs
- Exploring a pay-for-performance model in which the price paid for a drug is tied to how well it works.

These management techniques have had limited impact. New tools will be needed in the face of the coming flood of more specialty drugs. Express Scripts predicts that more than 300 new specialty drugs now in the pipeline will be on the market by 2010. 60% of those drugs will be for common chronic conditions, not for rarely occurring diseases.

These techniques also aren't winning any accolades for benefit managers. The Tier 4 approach typically has a higher copay (or coinsurance percentage) than is applied in Tiers 1, 2, and 3. Imposing higher out-of-pocket costs for specialty drugs is beginning to draw a national backlash. In April, both the *New York Times* and *USA Today* published articles highly critical of shifting specialty drug costs to employees. *USA Today* said of Tier 4, "[It] comes at a high personal cost for anyone who is sick . . . Often, there are no equivalents on a lower-price tier for these expensive drugs. Quite simply, tiered systems make those who are the sickest pay the most. That's not how insurance is designed to work."

One saving grace operating in the world of conventional drugs is the fact that expensive, heavily advertised brand name drugs eventually lose their patent protection and far less expensive generic drugs take their place. That's not yet true in the specialty drug world. There is federal legislation on the way but it gives specialty drug manufacturers up to 14½ years of patent protection. No nearer-term help from Congress is expected.

Adding further complexity to all of this is that one of supposed allies of benefit managers, their PBMs, may be part of the problem. A second *New York Times* article in April pointed out: "In recent years, PBMs have built lucrative side businesses seemingly at odds with their best-price mission. A growing portion of their revenue comes from acting as exclusive or semi-exclusive distributors of expensive specialty drugs." In fact, Express Scripts, CVS Caremark, Medco, Aetna, CIGNA, United Health and Wellpoint have all signed contracts with specialty drug makers to serve as exclusive selling channels. In response, David Rickard, a CVS Caremark executive vice president said, "We saved clients \$115 million last year that would have been spent on specialty drugs."

As outlined earlier, benefits managers are using many techniques to try to manage specialty drug cost to an acceptable level. But there is every reason to believe that these techniques will not significantly curb demand or price, and cost shifting may be reaching its limit.

A legitimate role for the federal government is to take on risks that the private sector cannot. A good example of this is the federal National Flood Insurance Program, which provides flood insurance to communities located in flood plains. The private sector proved inadequate in protecting these communities. According to the Federal Insurance and Mitigation Administration, "It became clear that private insurance companies could not profitably provide such coverage at an affordable price, primarily because of the catastrophic nature of flooding and the inability to develop an actuarial rate structure which could adequately reflect the risk to which flood-prone properties are exposed."

Does this sound a little like what benefit managers may be facing with specialty drugs? Coverage becoming unaffordable for employees and some employers in the near future because of a catastrophic level of specialty drug cost? No sound way to measure the risk of your employees' specialty drug demand and cost? If so, should we begin thinking

about a national pool for specialty drugs? Put another way, would you be willing to sell your specialty drug risk for 1%, 5%, even 20% of your current drug spend?

Did You Know?

"What, if any, additional federal regulation is needed to ensure that Federal Employee Health Benefits Plan enrollees are able to access critical, life-saving or disease modifying drugs?" Sen. Barack Obama, D-Ill, writing to Office of Personnel Management (OPM) Director Linda Springer, calling on her to release more information about OPM's role in approving federal employee drug plans that included Tier 4 coinsurance requirements for specialty drugs.