Specialty Healthcare Benefits Council
Defining Specialty Health

Enhancing the Strategy for Specialty Pharmaceuticals

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Not long ago specialty pharmaceuticals were missing from everyone's radar and vocabulary. Then, suddenly, they burst on the scene. Based on their high cost and increasing use, the reaction has mimicked that of the astronauts who said, "Houston, we have a problem!" The concern about specialty pharmaceuticals, the common strategies used to manage these important products, and how those strategies can be enhanced are the focus of this paper.

SPECIALTY PHARMACEUTICAL TRENDS

The rising cost of specialty pharmaceuticals continues to cause concern. Over the last 5 years, the cost increases for these agents have averaged 16%.[1] Express Scripts reported: "Looking at pharmacy benefits alone, 17.6% of total 2011 pharmacy costs among Express Scripts plan sponsors were for specialty medications."[2]

Although many factors are contributing to this increase, more than half of it is due to increasing unit cost. For the multiple sclerosis agents, the increased cost per year has averaged more than 20% for the past 4 years. However, the real growth in specialty drug costs is hidden, as roughly 47% of overall specialty medication costs are billed under medical benefits.

A recent *Specialty Pharmacy Times* article titled "Eight mega trends shaping the future of specialty pharmacy" cited the following trends[3]:

- **Escalated spending**—There is increased drug spending and trend within this category.[4]
- **Generic wave**—There will be more industry consolidation because of patent expiration for small molecule products.
- **Bulging pipeline**—At least 700 new drugs are in the specialty pipeline.[5]
- **Targeted therapies**—Expectation is for more targeted, tailored, and personalized medicine.
- **Healthcare reform**—Legislative and regulatory developments will continue to shape the future.
- **Emergence of biosimilars**—More than 40 biosimilar compounds are in development.[5]
- **Growth of copays**—The industry issued 86 copay cards in 2009 and 300 in 2011.
- **Adherence**—The higher the patient cost for these drugs, the poorer the adherence and the higher the cost for medical, laboratory, and facility use.

There are 2 trends not noted in the *Specialty Pharmacy Times* article. First, the literature reveals little concern about and little to no publication on the inappropriate use of these agents (surely there is some). Second, because of the complexity of billing for these agents, organizations may be leaving a significant amount of revenue on the table.

CURRENT STRATEGIES

The 2 basic approaches for controlling the use of these agents are management strategies and clinical strategies.

Management Strategies

Most payers under the pharmacy benefit have turned to traditional techniques used by pharmacy benefit management companies for managing conventional drugs, like tinkering with the benefit design, using formulary restrictions, and requiring the use of specialty pharmacies. However, specialty pharmaceuticals are not conventional agents.

Benefit Design

Specialty drugs raise complex cost, access, and administrative issues for payers, and do not fit nicely into traditional benefit design structures. Thus, there is inconsistency among payers in coverage, access, and reimbursement. Should specialty pharmaceuticals be placed

in the pharmacy or the medical benefit, and how much member cost sharing should be applied?[6] Currently, 83% of employers place drugs under the pharmacy benefit.[7] Increasing the member share of payment for specialty drugs and limiting patients to a 30-day supply have been key management strategies for controlling use.[6]

Specialty drugs fall into 2 distinct categories based on the site and method of administration: those that can be administered by either the patient or caregiver and those that require a healthcare professional to administer them in a physician's office, infusion center, outpatient hospital department, or home. Most payers include self-administered injectables in the pharmacy benefit. There is a large difference in the average monthly cost to a payer for a self-administered injectable compared with the cost for other prescription drugs. For example, self-administered injectables often cost more than $1500 a month, compared with an average of $18 a month for generic drugs and an average of $88 a month for brand name drugs.[8]

Formulary Design, Restrictions, and Management

Two formulary strategies work better than others—listing preferred agents and strict prior approval. About 83% of employers use prior approval for these agents under the pharmacy benefit, but only 37% use prior approval under the medical benefit.[6] A moderately effective approach is using step therapy—starting with the most cost-effective and safest drug therapy before progressing to other more costly or risky therapies. Other strategies include restricting quantities, dose, and duration of therapy.

Using Specialty Pharmacies

Many health plans require some specialty drugs to be channeled through specialty pharmacy providers. About 72% of employers use a formulary and contracted specialty pharmacy network.[7] The most common services provided by specialty pharmacies include direct distribution of drugs to patients and physicians, coordination of reimbursement and eligibility, all-day access to a healthcare professional, and appropriate drug use.

THE REAL PROBLEM

To solve a complex problem, wise proponents seek agreement on the problem before discussing possible solutions.[9(p51)] From reading the medical literature and listening to the media, one would think the problem is high cost. That is part of the problem, as is a continuing march toward developing more of these agents. However, the other part of the equation is that many patients need these agents and benefit from them. Therefore, the real problem is how to strike a balance between patient access to these agents and controlling inappropriate use.

One study found that "Increased cost sharing for specialty drugs will not reduce their use, but will transfer a greater share of their costs to patients."[10] Therefore, "Care management should focus on making sure that patients who will most likely benefit receive them. Once such patients are identified, it makes little economic sense to limit coverage."[10] However, for many payers, few care management activities have been used, especially if specialty pharmaceuticals are covered under the medical benefit.[8] For example, while most specialty pharmacies offer some therapy management service for specific disease categories, fewer than one-third (30%) of payers report using these programs.[11] It appears that the patient-centered approaches that health plans reportedly seek to improve adherence and limit unwarranted use can reap benefits in the form of improved patient outcomes. However, methods to identify inappropriate use and waste are seldom being used.[11] Perhaps this is because the incentives are nonexistent or misaligned.

ADDING CLINICAL STRATEGIES

Major clinical strategies for controlling the use of specialty pharmaceuticals include patient-centered management by pharmacists, use of clinical guidelines, performing medication use evaluations (MUEs), and integrating the entire medication use of specialty pharmaceuticals into a single organization structure.

Patient-Centered Management by Pharmacists

URAC (an independent, nonprofit accreditation agency formerly known as the Utilization Review Accreditation Commission) standards for specialty pharmacy accreditation cover a broad range of services, but patient-centered management is the most important standard to fulfill.[11] The URAC standards include several medication management requirements that say there should be:

- Strategies and interventions to optimize appropriate therapeutic outcomes for patients through improved medication use based on available information.
- Support for patient advocacy and empowerment to self-administer drugs.
- Initial assessment of appropriate and/or inappropriate drugs.
- Education concerning side effects, drug interactions, food/drug interactions, and safe

disposal and other safety precautions such as handling, as well as coordinated development of a care/service plan.
- Monitoring and promotion of medication adherence.
- Effort to minimize the incidence of adverse events.
- Effort to optimize therapeutic outcomes by promoting continuity of care during all patient care transitions and facilitation of collaboration among all the patient's healthcare providers.
- Self-management and effective use of available clinical and educational resources related to individual patients' medications.
- Counseling and education related to medication.
- Proper use.
- Timely administration or intake.
- Monitoring for side effects and contraindications.
- Safety precautions.
- Reconciliation, such as for multiple medications.
- Proper storage and disposal.
- Concurrent use review of over-the-counter medications if provided by the patient.

Clinical Guidelines

Clinical guidelines for using specialty drugs are not readily available. A literature search using the search terms "guidelines," "specialty drugs," "specialty pharmacy," and "specialty pharmaceuticals" came up empty. Apart from the drug labeling, there is little guidance on appropriate use. Then there is the issue of which specialty drugs to monitor—the ones used most often or the most expensive ones? The answer is neither. The specialty drugs to monitor should be the ones most often used inappropriately. However, since guidelines seem to be nonexistent, prudent clinical pharmacists are left with the URAC standards and general monitoring criteria such as the following:

- Is the drug indicated?
- Is step therapy appropriate?
- Is there a less expensive agent that will achieve the same outcome?
- Is the dose appropriate?
- Is the duration appropriate?
- Are there any interactions or adverse effects?
- Is the drug working?
- Is the patient adherent?

Adherence with specialty pharmaceuticals is inversely proportional to the copay. "While 20% coinsurance on a drug costing $30,000 a year may work actuarially, patient nonadherence leads to increased medical, laboratory and facility costs with the potential for poor clinical outcomes."[12]

Medication Use Evaluations

Pharmacists seeking improvement in the use of specialty pharmaceuticals should identify instances of inappropriate use. An effective tool for identifying inappropriate use is the MUE. The supportive drugs (eg, hematopoietics, immunosuppressants) are the best candidates for better management by pharmacists.

Guidelines on prospective, concurrent, and retrospective MUEs are available.[13,14] When there is a significant difference between appropriate and actual use, pharmacists are advised to discuss therapeutic changes with physicians by focusing on safety and efficacy, rather than cost.

Integrating Specialty Pharmaceutical Distribution Into the Medication Use Decision Process

In a few large academic medical centers where a significant volume of specialty pharmaceuticals are used, specialty pharmacies have been established as part of the pharmacy department. Clinical pharmacist specialists, working closely with the physicians who typically prescribe specialty pharmaceuticals, assist in developing clinical guidelines and monitor patients for achievement of therapeutic outcomes, minimization of adverse events, and treatment adherence.

Clinical pharmacists also coordinate access to medications by working with the in-house specialty pharmacy, patient benefits representatives, and financial counselors. Many large transplant, cancer, and arthritis centers are also qualified as disproportionate share hospital facilities, making them eligible for participation in the federal 340B drug discount program. Since the 340B program was specifically established to help disproportionate share hospital facilities to expand access to uninsured and underinsured patients through the substantial (often exceeding 50%) discounts on drug purchases, specialty pharmacies in such medical centers can make a significant contribution to the organization's financial success. Some large academic medical centers have seen a more than $6 million positive impact on their bottom line, which in turn can be used to support the expanding population of "low pay or no pay" patients.

CASE STUDIES

Those with an interest in managing specialty pharmaceuticals should read about 2 approaches undertaken by 2 different organizations: the University of Michigan and Kaiser Permanente. The University of Michigan shares its

approach in a comprehensive document, outlining how it has shaped benefits, managed cost, and monitored the use of specialty pharmaceuticals.[15] Kaiser leverages its integrated healthcare delivery system to deploy management tools for costly therapies: evidence analysis, use measurements, and multidisciplinary planning.[16] They say that evidence-based medicine and realizing value provided by new therapies depend on data capture and outcomes measurement.

LEAKING REVENUE

The billing for specialty pharmaceuticals is complex. Seldom does any one individual in medical billing understand the entire process. Drugs billed under the pharmacy benefit are adjudicated with a unique 11-digit National Drug Code (NDC).[8] The NDC for a new drug is available at the time the drug receives Food and Drug Administration approval and before it enters the market. Drugs billed under the medical claims system are typically adjudicated with a Healthcare Common Procedure Coding System J code.

J codes at best identify only the chemical name of the drug, not the specific product manufacturer, strength, or package size. Therefore, a single J code can be used to represent several NDC numbers for multiple drug products. Determining the cost of the product is further complicated by the lack of reliable values in the quantity field on medical claims for J codes. A J code specific to a drug is assigned anywhere from 6 to 18 months after a drug enters the market.[8]

Lack of a uniform and consistent coding system for drugs across pharmacy and medical benefits results either in overpayment (a potential fraud, waste, and abuse issue) or much underpayment to providers, and inaccurate accounting of spending on specialty pharmacy drugs. Without proper audits and procedures, many institutions are probably leaving large amounts of money on the table.

TRENDS

A recent survey of more than 300 employers who provide prescription drug plans indicated increasing concern about the cost. "Five years ago, 57% of the respondents said their prevailing philosophy for a pharmacy benefit was 'providing the broadest coverage.' But now that number has fallen to 14%, while 78% now support 'balancing cost with care,' up from 41% five years ago."[17] Meanwhile, Medco recently announced a program to curb spending on specialty drugs that focuses on reducing the waste on managing specialty drugs that fall within the medical benefit versus the pharmacy benefit.[18]

SUMMARY

For specialty pharmaceuticals, most payers under the pharmacy benefit have turned to traditional techniques used by pharmacy benefit management companies for managing conventional drugs. For example, many have modified benefit design, used formulary restrictions, and added the use of specialty pharmacies. However, specialty pharmaceuticals are not conventional agents, and these strategies need enhancement.

Implementing major clinical strategies for controlling the use of specialty pharmaceuticals like patient-centered pharmacist management, use of clinical guidelines, and performing MUEs will help. However, the literature is devoid of MUE criteria, MUE results, and clinical guidelines showing where specialty pharmaceuticals are inappropriately used. Therefore, clinical pharmacists seeking to help promote the appropriate use of these agents will need to follow general medication monitoring procedures with an eye on URAC standards.

Billing specialty pharmaceuticals is complex. No individual working in medical billing can know everything there is to know about billing these expensive agents properly end-to-end. Therefore, there is opportunity to improve revenue capture with these agents.

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