

Concept Series Paper on Specialty Pharmaceuticals

Introduction

Over the past several years, utilization and cost of specialty pharmacy products have been increasing at a rate substantially greater than that of other pharmaceuticals.ⁱ This paper examines the characteristics of specialty pharmaceuticals; the growth of new expertise to handle and manage these pharmaceuticals; and the needs these products create for patients, health plans and practitioners.

What are specialty pharmaceuticals and how do they differ from other medications?

Specialty pharmaceuticals are typically large, unstable, protein-based molecules, produced through a biotechnology process. They are differentiated from other more common medications that are manufactured through synthetic processes or are extracted from biological sources. Early specialty pharmacy products treated complex conditions affecting distinct disease populations, such as multiple sclerosis, cancer, pulmonary hypertension, hemophilia and hepatitis C. However, the newer products may be targeted to more common chronic diseases requiring maintenance therapy, such as rheumatoid arthritis and asthma.ⁱⁱ Health plans and other payors may vary as to the medications they classify as specialty pharmaceuticals, but the consistent link is that specialty pharmaceuticals demand more attention and management.

Not only are these pharmaceuticals complex in structure, but they may also require expertise in handling. The dosage form for most specialty pharmaceuticals is by injection rather than the more conventional solid tablets, capsules, inhalers or topical agents. Many cannot be self-administered and often require special handling, such as refrigeration or sterile conditions for mixing doses.

Due to the sometimes severe drug reactions encountered with these medications, patient education is a key component of management. Education is needed to promote appropriate utilization and to limit the impact of the severe side effects. Education regarding storage and administration is also necessary. Management of specialty pharmaceuticals also requires that high technology diagnostics or tests be conducted to determine the outcomes of treatment and to monitor for severe side effects or adverse drug reactions.

Complex pharmaceuticals that require special monitoring and handling are often very expensive, sometimes ranging from \$10,000 to over \$250,000 per patient per year.ⁱⁱⁱ In addition, payors or patients may incur other non-drug costs, such as the distribution of the drug, required special laboratory testing, and adjuncts to therapy, such as needles and syringes. While traditional medications are subject to market forces to control costs, few specialty pharmaceuticals have competing or generic alternatives, because of the unique attributes of each product, high technology production methods and/or patent protection. Some manufacturers may limit the distribution of their drugs to certain pharmacies because of limited production capability, limited target patient populations, or the need to closely monitor patients for safety. Therefore, these drugs are not always available through traditional community or mail service pharmacies.

Special Expertise Required of Pharmacists to Handle Specialty Pharmaceuticals

The unique requirements often necessary to handle and manage these medications obligate pharmacists to acquire special expertise. Since this expertise is not always available in community or mail service practices, health plans and other managed care organizations have developed alternative approaches to the delivery of specialty pharmaceuticals. These approaches are generally categorized as “insourcing” and “outsourcing.”

The insourcing approach is seen when distinct staff is hired to manage this high cost, high demand area. These pharmacists are responsible for purchasing, handling, educating physicians and patients, and monitoring patient outcomes, including safety. The outsourcing approach is represented by contracting with licensed pharmacies that have developed services to meet the unique challenges of dispensing and monitoring the use of these medications. They are referred to as “specialty pharmacies.”

Whether a managed care organization chooses to insource or outsource, both approaches have common characteristics and requirements. While each organization may customize its approach to their particular needs, they both:

- Negotiate for discounted purchase prices, either by volume buying or the use of formularies
- Employ staff with particular expertise in the administration, appropriate utilization, and patient training and monitoring necessitated by these products
- Access centralized distribution points for specialty pharmaceutical manufacturers, which may limit distribution of their products

Specialty pharmaceuticals demand unique management practices for patients, health plans and employers

Patients prescribed specialty pharmaceutical products have distinct needs. Health plans and employers who are paying for these treatments look for ways to manage this area of care. The following services are necessary to accomplish these objectives:

- medication management
- patient management
- cost management
- distribution

Medication Management

Specialty pharmaceuticals can be high cost products and they may also be used in specific patient populations. To ensure that the medications are used appropriately, payors manage utilization through the use of a prior authorization.^{iv} The authorization includes ongoing monitoring to ensure appropriate use and to reduce the incidence of adverse events. Monitoring can also include measuring disease improvement, laboratory test results, adverse effects and other clinical outcomes.

Pharmacists that handle specialty pharmaceuticals must have the capability to administer prior authorization programs to ensure appropriate use and capture the necessary data for ongoing monitoring. Because specialty pharmaceuticals are often used in cases where it is extremely important for patients to be compliant with their prescription drug therapy, monitoring of adherence is essential, Approved by AMCP Board of Directors November 2006

particularly in patients with hepatitis C, HIV or transplant recipients and candidates. Other activities commonly associated with the delivery of specialty pharmaceuticals include contacting the patient to monitor health status and/or changes in the prescription drug regimen, and assessing whether physicians should be contacted. Health plans or specialty pharmacies can either provide or coordinate instruction for patients to learn how to self-administer injectable medications.

Patient Management

Over the past few years, a number of specialty medications have been developed for self-administration, especially for maintenance treatments of chronic diseases. This trend toward outpatient self-treatment will most likely continue.

Pharmacists, who handle specialty pharmaceuticals, and particularly those in specialty pharmacies, dispense higher volumes of these medications than traditional community or mail service pharmacies. As a result, their staffs have a high level of expertise in providing medication therapy management to patients receiving these medications.^v Pharmacists often telephone patients to remind them of refill dates; to provide patient training and education; to monitor for adverse events and to ensure that other aspects of patients' treatments are fulfilled, such as the scheduling of appropriate lab tests. These pharmacists work closely with physicians and case managers to ensure medication adherence, resolve any problems and coordinate changes in therapy. Some groups also offer disease management programs for specific conditions in which specialty pharmaceuticals are used.

Cost Management

The increasing utilization and high cost of specialty pharmaceuticals require that managed care organizations and other payors employ cost management techniques. One of these techniques is volume purchasing, often through centralized distribution systems. Combining bulk purchasing economies of scale with patient management services can lead to less product waste, identification of adverse events and better achievement of therapeutic effect, potentially lowering overall health costs.

Other cost management strategies can include variations in benefit design. Considerations can include shifting coverage from the medical to the pharmacy benefit, or the reverse. Designating a higher tier copayment or higher percentage of coinsurance will impact cost sharing with the covered beneficiary. Care must be taken when designing the benefit so as not to put a patient in a position where these costly, but important products cannot be afforded. A plan can use reasonable minimums and maximums to accomplish this objective.

One of the current challenges in managing costs for specialty pharmaceuticals is the reliability of the claims data submitted. Physicians and hospitals submit claims through medical claim systems which have less product detail, are not always electronically submitted and are often difficult to retrieve and analyze.^{vi}

Distribution

Because specialty pharmaceuticals typically require special handling, such as refrigeration or freezing, they are packaged to prevent breakage, maintain a specific temperature and ensure that their potency is not diminished during the delivery process. Additionally, a patient's supply of a specialty pharmaceutical must include non-drug supplies such as syringes, needles and disposal containers provided in conjunction with the drug product.

An additional challenge to managed care organizations, government agencies and patients is the limited distribution channels used by some manufacturers for specialty pharmaceuticals. A number of these products are only appropriate for a limited number of patients, and the manufacturing costs are therefore very high. To better serve these limited populations, manufacturers have depended on limited distribution channels for their product handling and distribution. It can be confusing to members and physicians, so communication from case managers and the manufacturers is important.

Conclusion

As the trend toward expanded use of high technology drugs continues, the need for the provision of medication therapy management services, specifically for specialty products, is becoming more important to maximize the value of these products to the patients who need them. The effective use of systems to manage specialty pharmaceuticals culminates in more appropriate medication therapy, better treatment outcomes for patients and improved cost management results.

ⁱ JP Morgan Industry Update, "Specialty Pharmacy: Conduit of Growth for Biotechnology," March 14, 2003.

ⁱⁱ CuraScript, "2004 Specialty Pharmacy Management Guide & Trend Report," June 2005.

ⁱⁱⁱ Pharmaceutical Care Management Association (PCMA), "An Introduction to Specialty Pharmacy," June 2005 <http://www.pcmnet.org/research/pdf/An%2520Introduction%2520to%2520Specialty%2520Pharmacy%25202005.pdf> (accessed January 3, 2007).

^{iv} Alex Gilderman and Christine Chow, "Traditional Managed Care Strategies Can Impact Specialty Pharmacy Programs," *Managed Healthcare Executive*, July 1, 2004. <http://www.managedhealthcareexecutive.com/mhe/content/printContentPopup.jsp?id=105390> (accessed January 3, 2007).

^v PCMA, "The Frontier of Specialty Pharmacy Care: An Examination of Primary Disease States," October 2005. http://www.pcmnet.org/research/pdf/SP_diseaseStates%20FINAL100505.pdf (accessed January 3, 2007).

^{vi} Debbie Stern and Debi Reissman, "Specialty Pharmacy Cost Management Strategies of Private Health Care Payers," *Journal of Managed Care Pharmacy*, November/December 2006. <http://www.amcp.org/data/jmcp/Nov-Dec06JMCP1.pdf> (accessed January 3, 2007).