



Academy of
Managed Care
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Practice Advisory on Factors to Consider in Management of Specialty Pharmaceuticals

Providing affordable and equitable health care coverage can be challenging. To meet that challenge, health plans use an array of strategies that include medical and pharmacy management. One area of particular interest is that of specialty drugs. Recent trends indicate that specialty drugs are a significant driver of health care costs. This trend is exacerbated by the ever-growing number of products coming into the marketplace and expanded indications for use of existing products. There are several different ways to manage specialty drugs and many questions that should be answered when evaluating specialty drug benefits. This practice advisory identifies those questions and suggests how they may be addressed.

Background

According to Express Scripts, Inc. (ESI) trend report of 2009¹, specialty drug cost per prescription increased by 19.5%. Similar changes were seen in the Medco Trend report for 2010.²

- Specialty drugs account for approximately 14.7% of total pharmacy spending
- Multiple sclerosis drug therapies account for about 22.7% of specialty drug spending and are growing at a much faster rate than other drug categories
- Increase in the use of cost share for specialty drugs covered under the medical benefit: in 2009, 7% more in commercial plans and 16% more MA-PD plans³.
- Unit costs for specialty drugs increased by 12.1% over the previous year due to
 - a. Price inflation of specialty drugs
 - b. Significant portion of new drug approvals for high-cost specialty drugs
 - c. Dosage creep or dosage increase in certain specialty drugs
- Highest growth in spending was seen in
 - a. Drugs used for rheumatoid arthritis and other autoimmune disorders, psoriasis, multiple sclerosis, and cancer
 - b. Pulmonary arterial hypertension specialty drugs
 - c. Anticoagulation drugs
- Spending declines have been seen with drugs that treat anemia and hepatitis C

¹ Express Scripts, Inc., *2009 Drug Trend Report*, <http://www.express-scripts.com/research/studies/drugtrendreport/2009/dtrFinal.pdf> (accessed on November 3, 2010)

² Medco. *2010 Drug Trend Report*. <http://medco.mediaroom.com/index.php?s=64&cat=5> (accessed on September 28, 2010).

³ EMD Serono Specialty Digest 6th Edition, <http://specialtydigest.emdserono.com/> (accessed on December 7, 2010)

Defining Specialty Pharmaceuticals

The first step in developing a specialty drug benefit is to determine what constitutes a specialty drug. Several organizations have advanced their own descriptions, but the industry has not yet agreed upon a standard definition. For purposes of this document, we describe the common characteristics of specialty pharmaceuticals:

Specialty pharmaceuticals are:

- Generally high-cost medications that are usually prescribed for people with complex or chronic medical conditions, e.g., multiple sclerosis, hemophilia, hepatitis, and rheumatoid arthritis;
- Medications that typically exhibit one or more of the following characteristics:
 - drugs that are injected or infused, however some may be taken by mouth;
 - drugs that have unique monitoring, storage or shipment requirements; and
 - drugs that require additional education and support from a health care professional.

Once an organization defines specialty pharmaceuticals, several additional questions should be answered before creating a specialty drug benefit. These include:

- **Where should specialty drugs be included in a health care benefit structure – medical benefit or pharmacy benefit?**
- **What decisions must be made about benefit design?**
- **If a specialty drug benefit is included in the benefit coverage, should cost-saving programs be implemented?**
- **What are the benefits of insourcing vs. outsourcing of specialty pharmacies to handle drug dispensing?**
- **What special handling requirements are necessary?**
- **How will delivery and care coordination be managed?**

Answering these questions will provide a foundation for developing specialty pharmacy benefit coverage.

Where should specialty drugs be included in a health care benefit structure – medical benefit or pharmacy benefit?

Why is one drug covered under the medical benefit and another included in the pharmacy benefit? Traditionally, if a drug is taken orally or is self-injected it is typically included in the pharmacy benefit. Conversely, a drug which is infused or administered in a physician's office or outpatient clinic is typically considered part of the medical benefit.

State/federal mandates may dictate whether a drug is a medical benefit or pharmacy benefit. Examples are found in the Medicare program, where specific drugs are covered under Part B (medical benefit) and others under Part D (prescription benefit). However, the dividing line between the medical benefit and the pharmacy benefit is not always clear; drugs which were previously considered a medical benefit have been switched to the pharmacy benefit, and vice versa.

More and more, managed care organizations appear to be switching drugs once covered through the medical benefit to the pharmacy benefit. From a financial perspective, exclusion of specialty drugs from the pharmacy benefit may increase cost of care due to 1) non-compliance, 2) omission of care leading to an increase in medical spending, 3) higher drug price margin when administered at the provider's office, 4) addition of administration fee when given at the provider's office, and 5) potential for over-billing with no assurance of the quantity given.

What decisions must be made about benefit design?

One important aspect of benefit design is member affordability. These specialty drugs are many times the last line of therapy for patients. The benefit should be designed to both encourage compliance and adherence, while appropriately distributing costs between the member and the plan.

An organization must decide how to structure the member's cost sharing. A coinsurance benefit design mitigates pricing inflation for the insurer and helps to alert the member to the true cost of care. On the other hand, a copay structure simplifies the benefit and allows the member to easily budget his/her health care expense.⁴

Prior authorization should be structured in accordance with evidence-based treatment guidelines. Prior authorization criteria for specialty medications tend to focus on assuring appropriate patient selection. It may also be appropriate to use prior authorization to steer utilization to a preferred drug with similar or equivalent medical outcomes.

If a specialty drug benefit is included in the benefit coverage, should cost-saving programs be implemented?

The cost of specialty medications has been rising rapidly over the past few years due to the availability of new products and the expanded use of existing products. Because of their increasing costs, managed care organizations (MCOs) may adopt steps to help mitigate these increases. Since a mechanism for Food and Drug Administration (FDA) approval for biosimilars is currently being developed, there are no generic equivalents for the majority of specialty medications at this time. Although there is a lack of generic equivalents for most specialty products, formulary management tools can help improve results and reduce costs. For example, plans can use protocols for monitoring drugs with abuse potential, monitoring for usage outside of approved indications, prior authorization, etc.

What are the benefits of insourcing vs. outsourcing of specialty pharmacies to handle drug dispensing?

- Insourcing: The insourcing approach requires distinct staff to manage this high cost, high demand area. These pharmacists are responsible for purchasing, handling, educating health care providers and patients, and monitoring patient outcomes including drug efficacy and safety.
- Outsourcing: The outsourcing approach relies on contracting with licensed pharmacies that have developed services to meet the unique challenges of dispensing and monitoring

⁴ Academy of Managed Care Pharmacy, *Practice Advisory on Drug Coverage Parity across Medical and Pharmacy Benefits*, 2010. <http://www.amcp.org/amcp.ark?p=AA8CD7EC> (accessed November 11, 2010).

these medications. They are referred to as “specialty pharmacies.” Preferred specialty pharmacy vendors can help MCOs reduce acquisition costs, and can provide patients with the convenience of scheduled delivery, disease management programs and compliance monitoring.⁵ When outsourcing, one consideration is whether a specialty pharmacy is accredited by a quality measurement organization. Another consideration is whether to use a single specialty pharmacy or a network of specialty providers.

What special handling requirements are necessary?

Currently, the majority of specialty pharmaceuticals are available in an injectable dosage form, rather than more conventional solid tablets, capsules, inhalers or topical agents. However, increasing numbers of specialty pharmaceuticals are now available in oral dosage forms.⁶ Many specialty drugs cannot be self-administered and often require special handling, such as refrigeration or sterile conditions for mixing drugs.

Limited distribution channels used by some manufacturers for specialty pharmaceuticals can be a burden for managed care organizations. To better serve specific populations, manufacturers have depended on limited distribution channels for their product handling and distribution. These limited distribution channels are sometimes required by the FDA as part of a risk evaluation and mitigation strategy (REMS) program for drugs that require close monitoring due to potential side effects. Patients and prescribers are often confused by limited distribution channels, as the medications may not be available from the pharmacy they typically use, and may only be obtained through a specific pharmacy provider.

How will delivery and care coordination be managed?

Specialty pharmaceuticals must be managed to meet the challenging characteristics of specialty drugs, ensure that the patient receives needed medication and services in a timely fashion, and to coordinate care. Plans must determine whether to manage these challenges internally or to manage delivery and care coordination through an external specialty pharmacy. Drugs need to be shipped in tamper-evident packaging directly to the patient’s home or office, physician’s office, or other convenient location to provide better control over the treatment schedule. A specialty pharmacy may schedule the delivery, the time, location and receiver (e.g., patient, caregiver, nurse) to prevent medication wastage and therapy disruption. Arrangements should be made to ensure that pharmacies utilize quality control measures to ensure appropriate storage and packaging of the medication. Efforts should be made to package drugs with all required treatment components (e.g., syringes, sterile dressing). Drugs that are sensitive to heat, cold or other environmental conditions should be shipped in temperature-moderating containers to protect the medication during shipping. Additionally, drugs should be tracked through the shipping process.

⁵ Academy of Managed Care Pharmacy, *Concept Paper on Specialty Pharmacy*, 2006. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed November 11, 2010).

⁶ Academy of Managed Care Pharmacy, *Practice Advisory on Drug Coverage Parity across Medical and Pharmacy Benefits*.

Because therapy with specialty drugs is complex and may frequently change, patient care-coordination is vital to appropriate therapy. Teams of experts including nurses, pharmacists, patient care assistants or coordinators, and financial specialists should coordinate a patient's care. The team should utilize clinical management and care pathways tailored to the unique, specialized care of patients. In care-coordination, licensed clinicians (nurses, pharmacists, physicians) provide comprehensive clinical management services. Clinical professionals support patients with education, training and mental health support (e.g., behavioral health, case management or disease management referral). The plan of care may address education, interventions, compliance, monitoring parameters, and goals or outcomes of therapy. Benefit coordination also ensures that patient expenses are managed effectively. Integration of care activities facilitates appropriate delivery of health care services. Therapy compliance and adherence are assessed and managed during the medication-delivery scheduling. Non-adherence or non-compliance and the rationale (e.g., adverse effects, ineffectiveness, cognitive or behavioral concern) are communicated to the prescribing physician.

There are several items that should be considered when developing and implementing a specialty pharmacy benefit. It is important to evaluate and give careful attention to those issues applicable to the specific drug benefit model.