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Blurring Lines of Medical and Pharmacy Management: The New Role of Specialty Pharmaceuticals

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This activity is jointly sponsored by Postgraduate Institute for Medicine and Impact Education, LLC

Statement of Need

Specialty drug costs are projected to account for one fourth of all health plan pharmacy costs by the end of 2008. The difficulties of managing specialty products and injectables are increasing due to concerns over the high cost of therapies, distribution and reimbursement issues, and variations in care delivery methods. This is compounded by evolving technologies of new products that are causing an increase in the overall usage of specialty products. New generations of vaccines are being used not only for the prevention of disease, but also for treatment.

Managed care pharmacy is in a chasm, as the new role of specialty pharmaceuticals is beginning to include responsibilities for pharmacy administration and, in some cases, care management. Health plans are experimenting with a variety of strategies to address the challenges and issues brought by the management of specialty pharmaceuticals. These strategies include outsource management, developing in-house expertise, cost shifting to patients, pharmacy versus medical benefits management, direct contracting, and various utilization management techniques. While these marketplace changes are occurring, there is a concern that clinical outcomes may suffer if unnecessary burdens are placed on patient access and overall quality of care.

Through discussions from various perspectives, this activity will examine the current and future implications for the management of specialty pharmaceuticals on care delivery, reimbursement, and patient outcomes. Methods will be examined to guide managed care pharmacists along a pathway for the successful management of specialty pharmaceuticals.

Physician Continuing Medical Education

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The ***faculty*** reported that there is no mention of off-label (unapproved) use of prescription drugs and the following financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this CME activity:

Name of Faculty or Presenter	Reported Financial Relationship
Robert C. McDonald, MD, MBA	No financial interest/relationships with financial interests relating to the topic of this activity
Sean D. Sullivan, PhD	No financial interest/relationships with financial interests relating to the topic of this activity
Mesfin Tegenu, MS, RPh	No financial interest/relationships with financial interests relating to the topic of this activity
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Learning Objectives

After completing this activity, the participant should be better able to:

1. Discuss current health plan issues and obstacles related to the management of specialty pharmaceuticals.
2. Outline emerging strategies and case study examples for the medical and pharmacy benefit management of specialty pharmaceuticals.
3. Explain the link between appropriate specialty pharmaceutical utilization and the economics of pharmacy administration.
4. Summarize the impact of specialty pharmaceuticals on clinical, humanistic, and economic outcomes within the managed health care setting.

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The Promise of Specialty Pharmaceuticals: Are They Worth the Price?

Sean D. Sullivan, PhD

ABSTRACT

BACKGROUND: Specialty pharmaceuticals have evolved beyond their status as niche drugs designed to treat rare conditions and are now poised to become the standard of care in a wide variety of common chronic illnesses. Due in part to the cost of these therapies, payers are increasingly demanding evidence of their value. Determining the value of these medications is hampered by a lack of robust pharmacoeconomic data.

OBJECTIVE: To outline emerging strategies and case study examples for the medical and pharmacy benefits management of specialty pharmaceuticals.

SUMMARY: The promise of specialty pharmaceuticals: increased life expectancy, improved quality of life, enhanced workplace productivity, decreased burden of disease, and reduced health care spending—comes at a significant cost. These agents require special handling, administration, patient education, clinical support, and risk mitigation. Additionally, specialty drugs require distribution systems that ensure appropriate patient selection and data collection. With the specialty pharmaceutical pipeline overflowing with new medicines and an aging population increasingly relying on these novel treatments to treat common diseases, the challenge of managing the costs associated with these agents can be daunting. Aided by sophisticated pharmacoeconomic models to assess value, the cost impacts of these specialty drugs can be appropriately controlled.

CONCLUSION: Current evidence suggests that when used in targeted patient populations, specialty pharmaceuticals may represent a good health care value.

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Introduction

Specialty pharmaceuticals hold great promise for people living with an increasing number of chronic diseases. Accompanied by advances in genetic-based diagnostic techniques, specialty drugs also hold the potential to redefine the way illnesses are treated. As the combined use of these novel technologies are incorporated into routine clinical practice, pharmaceutical care will become more personalized. In the near future, physicians will prescribe drugs and select dosages that are tailored for each patient. The first steps toward personalized health care are visible today. Drug therapies designed for patients with specific genetic variations are already available (e.g., trastuzumab for HER2/neu expressing breast cancer), as are coordinated care programs for groups of patients with similar needs (e.g., those offered by manufacturers of specialty products). As the ability to practice personalized medicine evolves, it offers the potential for improving long-term outcomes and reducing cost of care across the spectrum of diseases.

The promise of specialty pharmaceuticals, however, is not without cost. Historically, specialty pharmaceuticals were developed for rare conditions affecting only a limited number of patients (e.g., Gaucher's disease). Because of their uniqueness, these agents often require special handling, administration, patient education, and clinical support—all factors that add to their cost. Despite being more expensive than traditional agents, they were viewed as a good value because they provided therapeutic options to patients afflicted with various cancers, hemophilia, and primary immune diseases who had few (if any) other choices. Consequently, their expense did not preclude their usage. Now, as use of specialty drugs rises faster than that of traditional therapies,[1] payers must scrutinize the costs associated with these agents, and payers are increasingly demanding evidence of their value.[2]

Growth of Specialty Pharmaceuticals

Specialty drugs have emerged as effective tools in treating a wide variety of illnesses. Expenditures on these agents are projected to increase from approximately $54 billion today to more than $99 billion in 2010.[1] It is estimated that specialty pharmaceuticals currently account for approximately 24% of total drug expenditures, but spending on these agents is rising about twice as fast as that for conventional drugs; a trend that is expected to continue for the next 20 years.[1] By 2030, it is anticipated that specialty pharmaceuticals will account for up to 44% of a plan's total drug expenditures.[1] A major factor in this growth is the large number of approved and soon-to-be approved specialty medicines. Since 1990, the number of approved specialty products has more than doubled every 5 years.[1] Today, nearly 200 specialty medicines have been approved by the U.S. Food and Drug Administration

(FDA), and nearly 1,000 more are in development.[1] Today, growth in the specialty sector is driven by several chronic conditions, including cancer, rheumatoid arthritis (RA), and multiple sclerosis (MS).[3]

Unique Features of Specialty Pharmaceuticals

Specialty pharmaceuticals have several unique features that differentiate them from conventional drugs. These agents are typically administered by injection or infusion; processes that are more complicated and expensive than simply taking an oral dosage form. Because of their novel means of administration, specialty drugs historically have been reimbursed under the private payer's medical benefit or Medicare Part B rather than the pharmaceutical budget. Also, handling requirements for specialty drugs also are more complicated with many requiring refrigeration, special mixing or compounding, or concurrent lab work. Specialty pharmaceuticals are "high touch therapies," meaning that many patients require close monitoring and support during, and possibly for several hours following, administration. There is also a need for more intensive patient education and careful coordination of care between prescribers, payers, patients, pharmacy providers, and the administration site.

Because some specialty drugs are associated with an increased risk of clinically important or unusual and potentially harmful adverse effects, these agents can require increased safety surveillance. For products known to have the highest risk, the FDA mandates the implementation of a risk minimization action plan (RiskMAP), which is a strategic risk assessment program designed to minimize known risks of a product while preserving its benefits.[4] A RiskMAP targets 1 or more safety-related health outcomes and uses 1 or more tools to reduce risk and related complications. It is an iterative process of assessing a product's benefit-risk balance, developing and implementing tools to minimize its risks while preserving its benefits, evaluating tool effectiveness, and reassessing the benefit-risk balance and making adjustments, as appropriate, to the risk minimization tools to further improve the benefit-risk balance.[4] The FDA envisions this 4-part process to be continuous throughout the product lifecycle. In practice, the RiskMAP will require vigorous postmarketing monitoring and reporting of safety data by prescribers of specialty agents and by the distribution systems supplying them to patients, including specialty pharmacies.

Most specialty products will not need formal RiskMAPs, as routine risk minimization measures, such as appropriate labeling, are sufficient to ensure the safe and effective use of a drug or biologic product.[4] The decision to implement a RiskMAP is made on a case-by-case basis and can be somewhat subjective. Data collected during clinical development, postmarketing surveillance, and Phase IV studies are used to inform a RiskMAP decision. In addition, an understanding of the nature and rate of known risks versus known benefits, the preventability of adverse events, and the probability of benefit in the product's target population is required. As information about a product develops through its lifecycle, new data could direct a sponsor to properly determine if a RiskMAP is necessary where one was previously considered unnecessary.

The FDA provides a list of risk minimization tools, such as targeted education and outreach, reminder systems, and performance-linked systems, to achieve the objectives spelled out in the RiskMAP.[4] However, the Agency provides minimal guidance on the processes by which these tools should be implemented. Currently, specialty pharmacies and other organizations involved in the distribution of specialty drugs are critically positioned to provide patient education and outreach, reminders, and collect data on performance. Thus, it is reasonable for payers to consider using the specialty distribution system to implement and manage FDA-mandated risk management programs. As a result, the RiskMAP program has the potential to increase the size of the specialty drug category, as medications not typically considered as specialty drugs will be classified as "specialty" because of risk mitigation requirements.

Categories of Specialty Pharmaceuticals

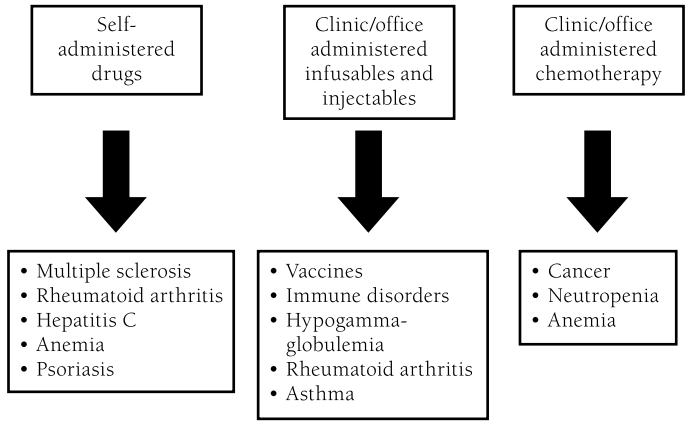
Specialty drugs are typically placed in 1 of 3 general categories: (1) self-administered therapies, such as those for RA, psoriasis, and MS; (2) products injected or infused in a clinic or office setting, including vaccines and treatments for various immune disorders, asthma, or hypogammaglobulemia; and (3) office/clinic administered chemotherapeutic agents (Figure 1). At first glance, it may appear that vaccines should not be categorized as specialty products because these agents are traditionally derived from viral or bacterial cultures and are available at relatively low cost. However, specialty vaccines are emerging as potential agents for the primary prevention of chronic disease. For example, a vaccine for the prevention of human papillomavirus was licensed for use by the FDA in 2006, and a second vaccine is expected on the market soon.[5] Likewise, a vaccine to prevent shingles in people aged ≥60 years was recently approved.[6] In addition, immunizations are currently under development for Alzheimer's disease, MS, human immunodeficiency virus, various forms of cancer, and other conditions.[7] These emerging vaccines will share several features more in common with today's specialty agents than with traditional vaccines, including the processes used to develop and manufacture the vaccine and product price.

Coordinating Access and Distribution

Because of their complexity, specialty pharmaceuticals flow through a variety of distribution channels. These channels vary widely according to the specialty product's administration requirements, the payer's benefit design, and the provider's service availability. In addition, manufacturers may control the distribution of specialty products through selected distributors due to limited production capacity and special handling requirements.

Channel selection not only affects the efficiency by which a drug is delivered to a patient, but can also impact the outcomes experienced by patients. Channel selection may also have ethical consequences. Payers must determine if the health plans are in the best position to coordinate access and delivery of specialty products. If plans are not capable of doing so, specialty pharmacy services might be considered. Given what we know about the conflict of interest inherent in provider-centric payment mechanisms, such as "buy-and-bill," another important consideration is if prescribers are capable of selecting the most appropriate treatments without undue bias. Finally, it must be determined if high copayments or coinsurance limit access to appropriate specialty therapy and, therefore, compromise clinical and safety outcomes.[8]

FIGURE General Categories of Specialty Pharmaceuticals



Assessing the Value of Specialty Pharmaceuticals

If targeted to patients most likely to benefit, specialty pharmaceuticals offer an attractive value proposition. These agents have the potential to decrease or reverse the progression of chronic illness and may also mitigate the adverse consequences of chronic disease. Specialty agents also have the potential to increase life expectancy, improve quality of life, enhance workplace productivity, minimize the burden of disease, reduce health care spending, and limit the overall cost of disease. If all of these benefits are true, the question becomes, are these agents worth their price?

Payers are likely willing to reimburse for specialty medications if they represent good value for the money. Payers want to know if costly specialty products are safer and more effective than drugs currently being used, and if they will prevent (or at least mitigate) higher medical costs today and in the future. Unfortunately, the ability to answer these questions is hampered by a lack of consensus treatment guidelines, robust long-term clinical data, and definitive and unbiased economic evaluations. Payers must make utilization, coverage, and reimbursement decisions with little or no information about the actual value of these agents.

Today, U.S. managed care plans and other payers are using evidence-based processes to evaluate clinical and economic data on new pharmaceuticals objectively, an approach supported by the AMCP *Format for Formulary Submissions*.[9] These formulary submissions guidelines suggest health plans request an evidence dossier from the drug manufacturer containing detailed information, not only on the drug's effectiveness and safety for indications approved by the FDA, but also on off-label indications and on the drug's economic value relative to alternative therapies.

Efforts to determine the value of a specialty drug are hampered by a lack of clinical and economic data upon which to base the decision. Some of the most important clinical benefits of a drug cannot be measured in clinical trials because they are not observable for years or even decades—a period of time that far exceeds the limits of most clinical trials. Additionally, trials that analyze the clinical effectiveness of new drugs rarely contain economic information. Because calculating the financial impact of specialty drugs is a critical step in the drug review process, payers should demand more than theoretical projections to support the proposed value of these agents. To fill this gap and to meet global payer requirements, sophisticated disease-based pharmacoeconomic models have been developed. These models do more than simply project the fiscal impact of a new product on the pharmacy budget. A well-designed model indicates the extent to which drug costs may be offset by reductions in other medical costs, evaluates the cost-effectiveness of the new treatment, and in some cases, helps identify target subpopulations where the drug will have a greater benefit and/or a smaller number needed to treat (improving incremental cost-effectiveness ratios in such patients).

Case studies provide a useful tool to describe the steps taken by payers to determine the overall value of specialty products. Two are outlined below.

The first case involves a full formulary evaluation of a newly introduced glycemic control product (exenatide). The assessment included an economic evaluation using a validated diabetes outcomes pharmacoeconomic model developed by the Center for Outcomes Research.[10,11] The model evaluated the new therapy by determining its impact on total health care spending and created scenarios that allowed the health plan staff and the formulary committee to ascertain the clinical and economic effects of different reimbursement strategies. The model allowed for projections of the therapeutic intervention on long-term endpoints, such as myocardial infarction and hospitalizations and identified subpopulations of patients where the drug could have a greater benefit. Combined with the available clinical data provided by the manufacturer, the model outputs provided the health plan

sufficient information to support adding the drug to the formulary.[12] As evidenced from this example, the combination of model outputs and clinical data provide a robust process for assessing the value of new agents.

The second case involves the process followed by the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom (UK) to determine the cost-effectiveness of using omalizumab in patients who had severe persistent allergic asthma and remained symptomatic despite treatment with a combination of high-dose inhaled corticosteroids (ICS) and long-acting beta agonists (LABA).[13] The desired outcome was to determine the value of adding omalizumab to standard therapy. To do this, a model was developed using clinical data from 2 well-designed clinical trials (Innovate and ETOPA) and economic data from Sweden, Canada, and the Netherlands (all countries with a single-payer health care system). On the basis of the analysis, the NICE decision was that omalizumab would be recommended as add-on therapy to standard (ICS+LABA) care. More specifically, the model allowed the payer (UK NHS) to define concisely the characteristics of patients who where eligible for the drug and subsequent reimbursement. In addition, the model output provided precise criteria that described when the drug should be initiated and when it should be discontinued.[13]

Summary

Specialty drugs represent the future of pharmaceutical management of disease. These medications offer the possibility of hope for patients, providers, and payers because many specialty drugs are more effective than traditional agents. The effective management of specialty pharmaceuticals is linked closely to a distribution system designed to assure appropriate patient selection, risk mitigation, and data collection. Costs associated with these agents are projected to have a significant impact on the health care system and play a large role in determining coverage and reimbursement. Today, payers are more interested in formal and rigorous assessments of the value of these agents.

DISCLOSURES

Sean D. Sullivan discloses that there was no relationship or financial interest related to the topic of this activity. Sullivan was responsible for the entire study concept and design of this article. He performed all the data collection, data interpretation, writing, and revision of this article.

REFERENCES

1. Express Scripts Drug Trend Report 2007. Available at: www.express-scripts.com/ourcompany/news/industryreports/drugtrendreport/2006/dtrFinal.pdf. Accessed January 12, 2008.

2. Sweet BT, Wilson MD, Waugh WJ, Hess AD, Spooner JJ. Building the outcomes-based formulary. *Dis Manage Health Outcomes*. 2002;10:473-77.

3. Medco Health. Drug Trend Report 2007. Available at: http://medco.mediaroom.com/file.php/129/2007+DRUG+TREND+REPORT.pdf. Accessed March 25, 2008.

4. U.S. Food and Drug Administration. Guidance for industry: development and use of risk minimization action plans. U.S. Department of Health and Human Services, Washington, DC. March 2005. Available at: www.fda.gov/cder/Guidance/6358fnl.htm. Accessed March 27, 2008.

5. National Cancer Institute. Human Papillomavirus (HPV) Vaccines: Questions and Answers. Available at: www.cancer.gov/cancertopics/factsheet/risk/HPV-vaccine. Accessed March 27, 2008.

6. U.S. Food and Drug Administration. Center for Biologics Evaluation and Research. Zostavax questions and answers. Available at: www.fda.gov/Cber/products/zosmer052506qa.htm. Accessed April 4, 2008.

7. Plotkin SA. Vaccines: past, present, and future. *Nat Med*. 2005;10:S5-S11.

8. Goldman DP, Joyce GF, Lawless G, Crown WH, Willey V. Benefit design and specialty drug use. *Health Aff.* (Millwood). 2006;25:1319-31.

9. The AMCP *Format for Formulary Submissions* Version 2.1. *J Manag Care Pharm*. 2005;11(5 suppl b):S1-S26. Available at: www.amcp.org/data/jmcp/formatsupp.pdf. Accessed December 12, 2007.

10. Palmer AJ, Roze S, Valentine WJ, et al. The CORE diabetes model: projecting long term clinical outcomes, costs and cost-effectiveness of interventions in diabetes mellitus (types 1 and 2) to support clinical and reimbursement decision making. *Curr Med Res Opin*. 2004;20(suppl 1):S5-S26.

11. Palmer AJ, Roze S, Valentine WJ, et al. Validation of the CORE diabetes model against epidemiological and clinical studies. *Curr Med Res Opin*. 2004;20(suppl 1):S27-S40.

12. Watkins JB, Minshall ME, Sullivan SD. Application of economic analyses in U.S. managed care formulary decisions: A private payer's experience. *J Manag Care Pharm*. 2006;12(9):726-35. Available at: www.amcp.org/data/jmcp/726-735.pdf.

13. National Institute for Health and Clinical Excellence. Omalizumab for severe persistent allergic asthma. November 2007. Available at: www.nice.org.uk/nicemedia/pdf/TA133Guidance.pdf. Accessed December 17, 2007.

Managing the Intersection of Medical and Pharmacy Benefits

Robert C. McDonald, MD, MBA

ABSTRACT

BACKGROUND: Because of the unique features of specialty pharmaceuticals and insurance plans, specialty pharmaceutical products can be paid through the pharmacy benefit or the medical benefit. While most pharmacists are very comfortable with the conventions of reimbursement in the pharmacy benefit, they are less familiar with the processes for payment in the medical benefit.

OBJECTIVE: To review the 2 parallel processes for payment of specialty pharmaceuticals, the pharmacy benefit and the medical benefit, and to compare and contrast these 2 processes.

SUMMARY: The medical benefit and pharmacy benefit processes for payment of specialty pharmaceuticals use different claim forms, product coding systems, pricing conventions, and contracts. Even though the services delivered can be identical, the financial aspects of paying for these services are quite different.

CONCLUSION: Pharmacists who are interested in entering the specialty pharmacy arena, either as a provider or manager of providers, need to understand the payment processes for specialty pharmaceuticals through both the pharmacy and medical benefits.

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Specialty pharmaceuticals may be viewed from a number of different perspectives: the patients who are prescribed specialty pharmaceuticals, the organizations regulating specialty pharmaceuticals (the U.S. Food and Drug Administration [FDA]), the pharmaceutical companies developing specialty pharmaceuticals, and the payers who pay for specialty pharmaceuticals. This review will focus on describing the payer perspective in some detail. In particular, payers have specific and unique processes of payment for specialty pharmaceuticals through the pharmacy benefit and the medical benefit. While descriptions of pharmaceutical payment methods are relatively uncommon in pharmacy literature, examples of such publications exist.[1] Literature comparing the expenditures of specific classes of specialty pharmaceuticals, such as multiple sclerosis medications, has also been previously reviewed.[2] After describing and comparing these 2 pathways, we will discuss some of the novel tactics that payers are using to manage specialty pharmaceuticals.

Literature addressing the high-level differences between the claims reimbursement processes for specialty pharmaceutical services in the pharmacy benefit versus the medical benefit is less common. The operational standards of these 2 approaches have been documented by managed care organizations, but the processes for submitting a claim in the medical benefit is less thoroughly understood by pharmacy professionals. It is challenging enough to operate a successful pharmacy submitting claims solely through the pharmacy benefit. However, when pharmacists decide to distribute specialty pharmaceuticals, they need to appreciate that the option of submitting claims through the medical benefit is available and is a tactic being used by their competitors.

Pharmacy Benefits/Medical Benefits

During the last 80 years in the United States, health insurance has been an evolving and typically expanding business.[3] Foundational programs in the insurance industry, such as Blue Cross Blue Shield, and employer prepaid programs, such as Kaiser Permanente, started by focusing on providing a predetermined number of hospital days to employees in return for a regular payroll deduction.[4] Growing from these origins as prepaid hospitalization plans, prepayment of outpatient services, such as physicians' services, were added in the decades that followed. In the 1970s and 1980s, coverage for pharmacy services was added to health plan offerings as the scope of health plan offerings continued to grow.

Pharmaceuticals are a relative newcomer to the covered benefits of health plans and occupy a rather unique position. A quick review of the benefits of 1 of the largest health insurance programs in the country, the Federal Employees Health Benefit Plan, identified the following benefit categories:[5]

- Services provided by a hospital or other facility and ambulance services
- Medical services and supplies provided by physicians and other health care professionals
- Surgical and anesthesia services provided by physicians and other health care professionals
- Emergency services/accidents
- Mental health and substance abuse benefits
- Prescription drug benefits
- Dental benefits

Hospitals began interacting with health plans and government health programs in the mid-20th century. As a result, their contracts today can include 50 or more years of history. Pharmacies, on the other hand, have a different type of contract than hospitals. For instance, patients have different copayment or coinsurance obligations at pharmacies compared with hospital care. While it may not be intuitive, the multiple parallel benefits based primarily on site of service or provider type leads to the situation such that a dose of hemophilia factor, for example, may be paid for in completely different ways. Payment differences can exist based on whether the treatment is used as part of an inpatient hospital stay, an outpatient hospital service, as part of a service received at a physician's office, or a service received from a pharmacy.

Traditionally, pharmacists have focused on managing successful pharmacies using the pharmacy benefit as the only source of reimbursement. Because pharmacies are able to contract with health plans as medical benefit providers (in a pharmacy capacity, in a supplier capacity, or in a durable medical equipment provider capacity), the opportunity exists for pharmacies to have simultaneous contracts in the pharmacy and the medical benefit. This tactic is usually not important in the retail pharmacy setting, but can be very significant for a specialty pharmacy. Specialty pharmacies have commonly pursued both payment processes as a business practice; with the area of specialty pharmacy growing at a rapid rate, the importance of this issue is increasing.

Magnitude of the Specialty Pharmacy Issue for Health Plans

How health plans manage pharmaceuticals and specialty pharmaceuticals, in particular, has been a rapidly changing issue. This issue has evolved as pharmaceuticals have become a large and rapidly growing portion of the total health care expenditures; specialty pharmaceuticals has become the most rapidly growing portion of pharmacy expenditures.[5] One of the specific challenges in calculating the exact expenditure on specialty pharmaceuticals is that their expenditures are split between the pharmacy benefit and the medical benefit. When only the specialty pharmaceuticals that are adjudicated through the pharmacy benefit are accounted for, these products make up 9.2% of the pharmacy benefit drug expenditure.[5] When total U.S. pharmaceutical sales data are used to calculate sales of specialty pharmaceuticals, these products comprise about 20% of total pharmaceutical expenditures.[6] This difference exists because half of the specialty pharmaceuticals in the United States are not paid for in the pharmacy benefit, but rather are reimbursed through the outpatient or inpatient medical benefit.

It is important to note that total health care expenditures in the United States for 2005 were approximately $1.988 trillion dollars, with 32% of the costs attributable to hospital care, 21% to physician/clinical services, and 10% to sales of retail prescription drugs.[6] Within the pharmaceutical category, the specialty pharmaceutical category is growing even more rapidly than the pharmaceutical category as a whole. When compared with 2005 expenses, the expenses for specialty pharmaceuticals in 2006 were up 20.9%; this compares with a 5.9% trend for non-specialty pharmaceuticals.[6] Specialty pharmaceuticals are getting attention as their own class of drugs because they comprise about 2% of total health care expenditures, and their costs are growing at 4 times the rate of non-specialty pharmaceuticals.

There are many ways to define specialty pharmaceuticals. Some use the term "biotechnology products," which typically refers to peptide products developed with recombinant technology. While that was a very appropriate definition of specialty pharmaceuticals in the 1990s, there are several non-peptide injectable products that fall into the category of specialty pharmaceuticals (e.g., treprostinil sodium), and there are now oral specialty pharmaceuticals for rare diseases (e.g., bosentan and imatinib). Still other specialty pharmaceuticals require special handling because of perishability (e.g., biologics, vaccines, etc.) or radioactivity (e.g., tositumomab and ibritumomab tiuxetan). Therefore, the criteria of what constitutes a specialty pharmaceutical is continuing to evolve and expand in scope; all estimates are that this trend will continue drawing added health plan focus and resources.[5,6] The details of how the underlying benefit structures have evolved over the past few decades is critical to understand.

Parallel (Not Overlapping) Benefits

Health plans' obligations to their members are structured as benefit language. Pharmacists typically understand the language of the pharmacy benefit. Fewer pharmacists understand how the current state of most benefit language results in a situation of overlapping pharmacy and medical benefits for specialty pharmaceuticals. Each chapter of an insurance contract lists categories of health care services that are covered by the health plan, and how each of those categories will be paid. Each of these sections describes a specific benefit; each benefit is defined, for the most part, by the location of where the service is delivered (e.g., hospital inpatient) or the provider type (e.g., physician). Pharmacies have a place in this hierarchy in 2 ways. First and foremost, they are providers in the pharmacy benefit, usually defined as the retail or mail-order setting provision of pharmacy services involving a drug card. Second, the pharmacy is an acceptable provider type under the medical benefit. In a sense, the pharmacy as a provider under the medical benefit is similar to a durable medical

equipment provider or supplier that ships medical equipment to patients, typically at their homes. Therefore, there are 2 possible benefits and 2 possible contracts that a pharmacy could choose to pursue. This really is not a situation of blurring of the benefits, but rather that there are 2 parallel benefits, either of which can make business sense for the pharmacy. To enter the specialty pharmacy space effectively, a pharmacist is going to have to understand both processes and both sides of this issue.

These parallel benefits require additional analysis. As seen in Table 1, there are 2 parallel processes for the 2 different benefits that require the pharmacy to have contracts with different entities. The pharmacy benefit contracts are with the pharmacy benefits managers (PBMs), while the medical benefit contracts are directly with the health plans. If we use the metaphor of this process as being bilingual, this is the step at which it becomes bilingual. PBMs and health plans have industry standard terms and processes, and these terms may not have the same definition in the 2 different worlds. The health plan may have different certification requirements or other requirements than a PBM and vice versa. For instance, a PBM may have 1 definition of a pharmacy, and the health plan may have a different definition. Also, the claims payment systems are different for the pharmacy and medical benefits; the pharmacy benefit uses the National Council for Prescription Drug Programs (NCPDP) claim standard, while the medical benefit uses the Centers for Medicare & Medicaid Services (CMS) 1500 claim form, formerly known as a Health Care Finance Administration (HCFA) 1500.

Another difference is the coding language: National Drug Codes (NDC) is used on the pharmacy benefit and Healthcare Common Procedure Coding System (HCPCS) is used on the medical benefit. The example of the home blood glucose meter can clarify the magnitude of the difference in philosophy of these 2 systems. There are hundreds of varieties of home blood glucose meters with each brand and model having a unique NDC code and price in the pharmacy claims payment system. In the medical claim system, these meters are represented by just 1 code (E0607), and typically they are reimbursed a single price. Also, standard pricing files used in the 2 benefits can be different. In the pharmacy benefit, it is common for PBMs to receive weekly or monthly updates of national standard pricing files that populate the claims payment engine. Adjusting prices in the medical benefit is a much less dynamic process with prices only updated annually in many cases. There are many other differences between these claims payment processes, including locations for submission, time to payment, etc.

A final difference is in the process of being harmonized: the provider ID numbers are used by the 2 systems. The provider numbers have been different between the 2 systems for decades, with pharmacy systems using National Association of Board of Pharmacy (NABP) numbers, and the medical systems typically using either a proprietary system or Tax Identification Number (TIN). As part of the Health Insurance Portability and Accountability Act (HIPAA), medical payers have had to migrate to the National Provider Identification (NPI) number, and pharmacy claims payment systems are currently finishing their migration to this system. Many pharmacies find it daunting enough to manage the activities of the pharmacy benefit world without extending into the medical benefit world with its very different processes.

TABLE Detailed Comparison of Elements of Process for Pharmacy Claim Payment in Pharmacy and Medical Benefits

Benefit Type	Pharmacy	Medical
Unique provider contracts	Yes, with PBM	Yes, with health plan
Provider type	Pharmacy	Pharmacy, supplier, home health care
Unique claim type	NCPDP	CMS 1500
Coding language	NDC	HCPCS
Pricing source	MediSpan Redbook FirstDataBank	Medicare or contract
Provider number	NABP, transitioning to NPI	NPI

CMS = Centers for Medicare & Medicaid Services; HCPCS = Healthcare Common Procedure Coding System; NABP = National Association of Boards of Pharmacy; NCPDP = National Council for Prescription Drug Programs; NDC = National Drug Code; NPI = National Provider Identifier; PBM = pharmacy benefits manager.

The Evolution of Specialty Pharmacy: For Better and For Worse

With the proliferation of specialty pharmaceuticals in the market and the number of differences between the ways that they can be paid on the different benefits, inefficiencies in payment practices have crept into the system.

For example, recombinant erythropoietin can be administered in a myriad of ways: as part of a hospitalization, as part of a stay in the hospital outpatient chemotherapy infusion clinic, as part of a doctor office visit for chemotherapy infusion, in the setting of a dialysis facility, or self-administered by a patient who receives the product on a pharmacy benefit. The payment rules for each of these categories are governed by different contracts and different benefit-driven payment terms. Each category of provider typically has its own contract type; it is not uncommon for 1 provider entity to have multiple contracts with a single health plan, each with a unique identity, provider type, and terms. The advent of the NPI system should make it easier for health plans to identify all the contractual relationships with a single provider. In addition, there are different sets of rules that apply to the different types of providers. Providers can set up an environment of varied contracts because it gives them multiple claims systems upon which to submit claims and to determine payment. One of the

most common combinations is for a provider to be a pharmacist at the same time that they are a medical supplier.

Health plans have created an interesting situation as they have tried to move services out of the hospital and into the home-care setting over the last 2 decades. In many cases, plans have created lower copayments to patients when services were provided in the outpatient rather than the inpatient setting.[7] Then, to create an incentive for moving the hospital outpatient services to the home-care setting, some plans have created incentives for patients to receive care in their homes. A home-care service may include the shipping of a specialty pharmaceutical (e.g., growth hormone) to someone at home. The patient copayment may be much lower for this home-care service, but as a general trend in the last 10 years, health plans have been increasing the copayments for pharmaceuticals as a cost-management technique.[7] In this scenario, patients may now have a financial disincentive against receiving these specialty pharmaceuticals from the pharmacy benefit.

This dynamic can lead to some challenges for pharmacists within health plans. Some specialty pharmacy providers know exactly what they get paid in the medical and pharmacy benefit. When a pharmacist within a health plan starts bringing the issue of these differences in payment amounts to the staff that manages the medical benefit, it can be a very challenging conversation. As explained previously, the 2 groups are managing different processes, holding different contracts, and paying at different rates. It takes a lot of analysis and mutual learning before a solution comes into focus. The following specific examples of tactics that health plans can use to address this arbitrage (the practice of paying 2 different amounts for the same item) are presented to better understand this phenomenon.

Health Plan Tactics Regarding Specialty Pharmacy

Despite the constraints of these core process differences between the medical and pharmacy claims payment systems in processing specialty pharmacy payments, health plans are making some significant inroads into managing specialty pharmacy services more effectively.

Tactic 1: Contain a Pharmacy Benefits Management Company. It is relatively common today for health plans to operate a full-service PBM as a free-standing, internal company. This gives the health plan a greater number of pharmacists within the organization to build and manage a network and execute the clinical programs of a full-service PBM. It also gives greater transparency to these arbitrage issues between the claims payment systems. Many of the largest health plans in the country, WellPoint, Aetna, CIGNA, and Humana, have an internal division that serves as their PBM. This gives the organization a critical mass when dealing with issues such as these. This type of organization can support an internal Pharmacy and Therapeutics Committee process and can align itself with the clinical programs and contracting activities on both the medical and pharmacy benefit.

Tactic 2: Build a Specific Specialty Pharmacy Benefit. The current health plan benefit language has been built upon several decades of history but fails to adequately address the issues of specialty pharmacy. Some health plans have created a new benefit type to address specialty pharmacy services that focuses less on site of service and more on the products being distributed. Once the services in the specialty pharmacy benefit are defined, the contracting for these services can be implemented, typically with a narrowing of the network. One of the definitions that has been used in this approach in the past is a "self-injectable pharmaceutical" benefit. By decreasing the number of sources from which patients can obtain these products, health plans are addressing the pricing arbitrage between the many possible procurement pathways.

Tactic 3: Contain a Specialty Pharmacy. Carrying the "build or buy" dilemma to its logical conclusion, several of the larger health plans have taken the step of building specialty pharmacies in house. WellPoint has PrecisionRx Specialty Solutions, Aetna operates Aetna Specialty Management, and Cigna operates Tel-Drug Specialty Pharmacy. A consortium of Blue Cross Blue Shield plans own Prime Therapeutics as a joint venture, and this company in turn owns and manages a specialty pharmacy. The number of lives that the health plans have needed before pursuing this kind of strategy is typically ≥9 million members: WellPoint has approximately 35 million members; Aetna, 12 million; CIGNA, 9 million; and the partners of the Prime Therapeutics joint venture, collectively approximately 16 million.

Conclusions

Managing the specialty pharmacy benefits successfully is a complex undertaking. Managing specialty pharmacy in the fullest sense of the term requires a familiarity with both the medical and pharmacy benefits, as well as contracts in both benefits. A number of historical factors, such as health plan benefits, provider types, contracts that are specific to provider type, different coding systems, and different pricing files, all contribute to the difference in payments for the same services (i.e., arbitrage) between the medical and pharmacy benefits.

There are several tactics that health plans are currently implementing to manage specialty pharmacy service more effectively, from building a PBM in-house to creating a unique specialty pharmacy benefits to building a specialty pharmacy in-house.

These tactics are designed to bring about greater transparency and scrutiny of specialty pharmacy services and, directly or indirectly, to have these services provided by the most cost-efficient providers. Specialty pharmacy services are being provided by ever-tighter networks, and often a business unit of the health plan and/or a business unit of the health plan's PBM are competitors to the independent specialty pharmacy. The opportunities for contracting with health plans and PBMs may become more complex in the future. Also, with the growth and consolidation of specialty pharmacies, these organizations themselves are now

large companies that are typically a division within an even larger company.

While the current size and rapid growth-rate of the specialty pharmacy sector suggests that there is tremendous opportunity for pharmacies to enter this space, the tactics undertaken by health plans to manage this area more closely suggest that the opportunity is, in fact, smaller than it appears. For those interested in entering into this space or interested in managing specialty pharmacy services more effectively from the health plan standpoint, there are many operational issues that need to be in alignment. Among those many operational issues, whether or not a pharmacy contracts on the medical benefit is actually a rather small issue. However, failing to consider whether a pharmacy contracts to a specialty pharmacy or to a health plan ignores a substantial amount of the specialty pharmacy opportunity and revenue that make up this dynamic and rapidly growing marketplace.

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REFERENCES

1. AMCP Task Force on Drug Payment Methodologies. AMCP guide to pharmaceutical payment methods. *J Manag Care Pharm*. 2007;13(8):S1-S40. Available at: www.amcp.org/data/jmcp/JMCPSUPPC_OCT07.pdf.

2. Kunze AM, Gunderson BW, Gleason PP, Heaton AH, Johnson SV. Utilization, cost trends, and member cost-share for self-injectable multiple sclerosis drugs—pharmacy and medical benefit spending from 2004 through 2007. *J Manag Care Pharm*. 2007;13(9):799-806. Available at: www.amcp.org/data/jmcp/JMCPMaga_N-D%2007_799-806.pdf.

3. Starr P. *The Social Transformation of American Medicine*. New York: Basic Books; 1982.

4. Blue Cross and Blue Shield Association. Blues History. Available at: www.bcbs.com/news/press/facts/blues-history.html. Accessed December 30, 2007.

5. Express Scripts. 2006 Drug Trend Report. Available at: www.express-scripts.com/ourcompany/news/industryreports/drugtrendreport/2006/. Accessed December 30, 2007.

6. Centers for Medicare and Medicaid Services. 2005 National Care Expenditures Data. Available at: www.cms.hhs.gov/nationalhealthexpend-data/01_overview.asp. Accessed December 30, 2007.

7. Fendrick AM, Chernew ME. Value-based insurance design: aligning incentives to bridge the divide between quality improvement and cost containment. *Am J Manag Care*. 2006;12:SP5-SP10.

Benefit Design Innovations to Manage Specialty Pharmaceuticals

Debbie Stern, RPh

ABSTRACT

BACKGROUND: Spending on specialty pharmaceuticals is rising faster than that for traditional drugs. In 2006, specialty drugs were the largest category driving drug costs and utilization trends. Even with effective management, expenditures on these agents are projected to increase exponentially in the coming years.

OBJECTIVE: To review benefit design strategies used by payers to control costs and manage utilization of specialty pharmaceuticals.

SUMMARY: The rapid growth in specialty pharmaceutical expenditures reflects the introduction of new agents, broader indications, and wider use in more common disease states. The true growth of the specialty pharmaceutical segment is obscured because many of these agents are reimbursed through the medical benefit, which often lacks the transparency necessary to accurately determine true cost and utilization trends. To date, efforts to control spending on biologics have been fragmented with most payers employing techniques for cost and utilization containment similar to those used for traditional pharmaceuticals. To ensure greater cost and utilization control, a benefit design that simultaneously provides optimal cost management, appropriate utilization, improved clinical management, enhanced clinical outcomes, and heightened patient safety should be established.

CONCLUSION: Current management techniques for specialty pharmaceuticals often represent a stop-gap approach for controlling rising drug costs. Creation of a specialty pharmacy benefit can optimize cost and utilization management.

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Introduction

There are more than 250 specialty products currently on the market[1] and nearly 350 agents in late-stage trials.[2] In 2006, Medco reported that spending on traditional pharmaceuticals increased by 2.8%, whereas spending on specialty pharmaceuticals increased more than 16%.[3] Similar trends were reported by Express Scripts, which noted that spending on specialty medications rose nearly 21% compared with only 6% for traditional drugs.[4] Although eye opening, these reports only capture trends within the pharmacy, but not the medical benefit, where by some estimates, up to 60% of the drug spend is on specialty products.[3] Consequently, trends published by even the largest pharmacy benefits managers (PBMs) only partially identify the true growth of spending on specialty products.

The growth in the specialty trend is dominated by higher costs for existing specialty agents, the introduction of new drugs to treat conditions where few treatment alternatives exist, new indications for existing products, and earlier and/or increased use of specialty products. Currently, the oncology therapeutic area—including oral and infused oncology drugs—accounts for more than half of the estimated $40 billion spent each year on specialty products with spending on products to treat multiple sclerosis (MS), Hepatitis C, growth hormone deficiency, pulmonary arterial hypertension, asthma, and rheumatoid arthritis (RA) responsible for the balance.[3] Several factors are expected to continue to put upward pressure on oral oncology specialty spending, including a rich pipeline containing more than 100 products (4 of which arrived in the market within the past year), a high degree of off-label use, and treatment regimens costing up to $10,000 per month.[5] In addition, in many cases, cancers are often considered chronic conditions that can be medically managed over the long term. Thus, treatment cycles are longer as many of the newer more targeted agents are better tolerated and often used for prolonged maintenance treatment as monotherapy or in combination with specialty products.

Traditional Pharmacy Benefits Management Techniques

Predictably, the increased spending on specialty drugs has challenged payers to devise cost and utilization control strategies that simultaneously minimize costs and ensure appropriate utilization. Historically, payers have responded to the economic pressures of traditional drugs through the use of generic substitution, creation of formularies, maximization of manufacturer's rebates, therapeutic substitutions, quantity restrictions, and implementation of patient cost-sharing through the use of tiered copays and coinsurance. Similarly, utilization has been aggressively managed using prior authorization, step edits, and educating patients, providers, and purchasers.

With few exceptions, payers have attempted to adapt their existing drug benefit models rather than create entirely new

benefits for specialty products. Currently, it appears that 2 features of the traditional benefit are at least partially effective when applied to specialty drugs: cost sharing and aggressive network management. However, other traditional control mechanisms are not quite applicable. For example, generic forms of specialty drugs are not available, and the number of "me-too" products is minimal, thus ruling out the economic benefits of robust market competition, such as cost savings from generic and therapeutic substitution, creation of formularies, and rebate maximization. As a result, payers are looking at new benefit strategies.

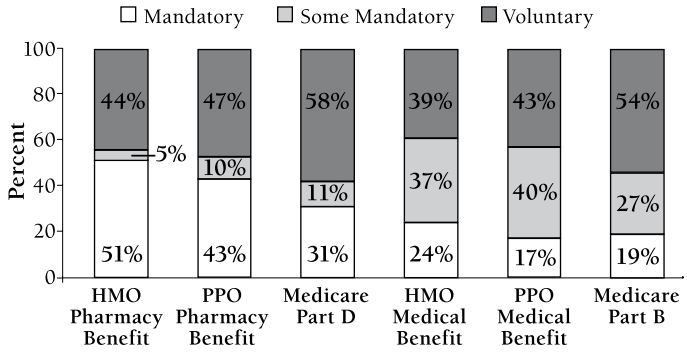
Recommended Payer Specialty Benefit Strategies

Cost Perspective

Although specialty drug benefit plans vary from payer to payer, they all share the primary goals of optimizing costs, equalizing benefits, improving clinical management, and ensuring appropriate use. Outside of negotiating a favorable acquisition cost and rebate, perhaps the most important step toward optimizing costs is limiting the number of distribution channels by mandating the use of a specific specialty pharmacy or network of specialty pharmacies. Approximately 50% of plans have closed their pharmacy networks and mandated the use of a single specialty distribution channel for drugs covered under the pharmacy benefit, and even fewer plans limit the distribution channel for drugs covered under the medical benefit (Figure 1).[6] The remaining plans allow access to both the specialty and retail pharmacy networks, as well as permit physicians to buy-and-bill. Because use of a preferred specialty pharmacy provider can result in significant cost savings, plans are often looking for ways to gradually increase control over the specialty network. Many plans identify the specialty categories that represent the greatest target for cost savings and mandates that all products in these categories be obtained through a preferred provider. Frequently, the first category subjected to a mandate is self-administered injectables. However, whether due to physician pushback, regulatory issues, lack of resources to implement and enforce a mandate, or a combination of factors, the prevalence of closed networks is significantly lower within the medical benefit and other settings where utilization is difficult to manage (e.g., Medicare and Preferred Provider Organizations).[6]

In addition to the mandated use of specialty pharmacy providers, other cost optimization strategies involve increased patient cost-sharing. Examples of cost-sharing strategies include establishing a flat copay for all drugs, implementing tiered copays for preferred and non-preferred agents, and requiring coinsurance, with or without a maximum dollar amount out-of-pocket (OOP). While patients tend to remain compliant to therapy despite paying higher overall OOP costs, further data are necessary to determine if these measures limit access to the appropriate specialty therapies.[7]

FIGURE 1 Voluntary Versus Mandatory Use of a Specialty Pharmacy Provider by Line of Business and Benefit



HMO=health maintenance organization; PPO=preferred provider organization.

Benefit Perspective

As mentioned, the design of the pharmacy benefit varies between plans, but the purpose of the benefit is consistent—it defines the terms and limits of the drug coverage provider by the third-party payer. More specifically, the drug benefit identifies the drugs and drug categories covered by the payer, the patient's share of the drug cost, the location where the drug can be prescribed, dispensed, and/or administered, and the quantity of the drug that will be covered. The benefit also spells out if the drug is subject to step edits, prior authorization, or other utilization controls.

Unlike traditional pharmaceuticals that are reimbursed under the pharmacy benefit, many office-administered specialty agents are covered as part of the medical budget. From a benefit design perspective, there appears to be a trend, albeit a slow one, to move all specialty drugs from the medical benefit into the pharmacy benefit. Generally, the applicable benefit is determined by the location in which the drug is administered. For example, infused medications (e.g., treatments for cancer and immune disorders) are more likely to be billed under the medical benefit, whereas self-administered therapies (e.g., treatments for MS and hepatitis C) are more commonly billed through the pharmacy benefit. However, because significant differences exist between the medical and pharmacy benefit design in terms of reimbursement rates, billing systems, patient cost-share, and clinical and utilization management techniques, integration of specialty agents into the pharmacy benefit raises complex cost, access, and administrative issues.

Differences between the design of the medical and pharmacy benefits may also lead to a misalignment of financial incentives among physicians, specialty pharmacy providers, and patients. Under the medical benefit, physicians can create a profitable revenue stream by controlling the selection of specialty drugs,

specialty pharmacy providers can gain from the most profitable reimbursement schedules, and patients are attracted to the drug with the lowest copay. The inherent risk underlying all these conflicting incentives is that neither the health care providers nor patients are making sound clinical decisions unbiased by a financial motive. Thus, the onus is on the managed care industry to minimize the financial bias and implement a system that ensures the right drug is provided to the right patient at the right time.

From a payer's perspective, the ideal specialty benefit would be a single plan that encourages clinically sound and cost-effective utilization. Although desirable, creating a unified specialty benefit would require a significant commitment to change on the part of multiple stakeholders within the organization (i.e., contracting, customer service, pharmacy department, medical management, legal, etc.) and would have implications across the entire enterprise. The reward for establishing a unified specialty benefit, however, could potentially be substantial. A single benefit would enhance data collection across the organization, allow the use of uniform coding (i.e., less worry about Healthcare Common Procedure Coding System [HCPCS] J-codes and National Drug Codes [NDC]), improve decision making around cost sharing, utilization and clinical management, improve contracting leverage, and allow for the implementation of well-established processes and controls.

Although attractive in many ways, arguments can also be made against the creation of a specialty benefit. There is the potential that a tightly controlled specialty benefit will negatively impact member and provider contracting as patients face increased OOP expenses with rising copays and cost sharing, while restrictions on buy-and-bill and mandates to use mandated specialty distribution methodologies, can alienate physicians. Additionally, employer groups that carve out pharmacy management to a PBM lack an internal pharmacy benefit in which to capture specialty prescriptions.

Clinical and Utilization Management

Patients using specialty drugs often require a significant amount of education on the disease itself, self-injection techniques, side-effect management, and product handling and storage. Specialty pharmaceutical patients must also understand the importance of compliance with their prescribed treatment regimen. Many payers lack the capacity to provide the educational and clinical support programs necessary to maximize clinical outcomes and minimize the risk to patient safety, and often outsource these services to a specialty pharmacy provider.

Developing Clinical Guidelines

Payers are increasingly developing evidence-based clinical guidelines to ensure appropriate utilization, prevent waste and misuse of products (e.g., hemophilia, infertility, growth hormone), improve clinical outcomes of treatment, improve adherence to the prescribed regimen, and to ensure patient safety. Historically, health plans have developed clinical guidelines with little attention paid toward equalizing the multiple competing interests involved in selecting a proposed treatment strategy. To equilibrate this bias, a growing number of payers now mandate the involvement of members of the pharmacy and therapeutics or technology assessment committees in the guideline development process.

Use of Prior Authorization

In the absence of robust cost-effectiveness data on most specialty products, payers have implemented prior authorization (PA) requirements to ensure that physicians follow evidence-based practice guidelines and to ensure appropriate use of therapy. In addition to regulating utilization, a PA review every 6 months can be helpful to determine if a patient is experiencing an appropriate response to treatment based on achieving certain predetermined outcomes. PA also provides a system for tracking duration of therapy and for monitoring off-label or experimental usage. However, some patients fail to respond to therapy despite evidence-based treatment. In these cases, the challenge becomes identifying the appropriate next step. Should utilization of the drug continue to be authorized even if the predetermined outcomes are not achieved? Despite the lack of evidence of their overall efficacy, in many cases, plans ultimately pay for specialty agents because they represent the only therapeutic option for some diseases.

Step Edits and Preferred Products

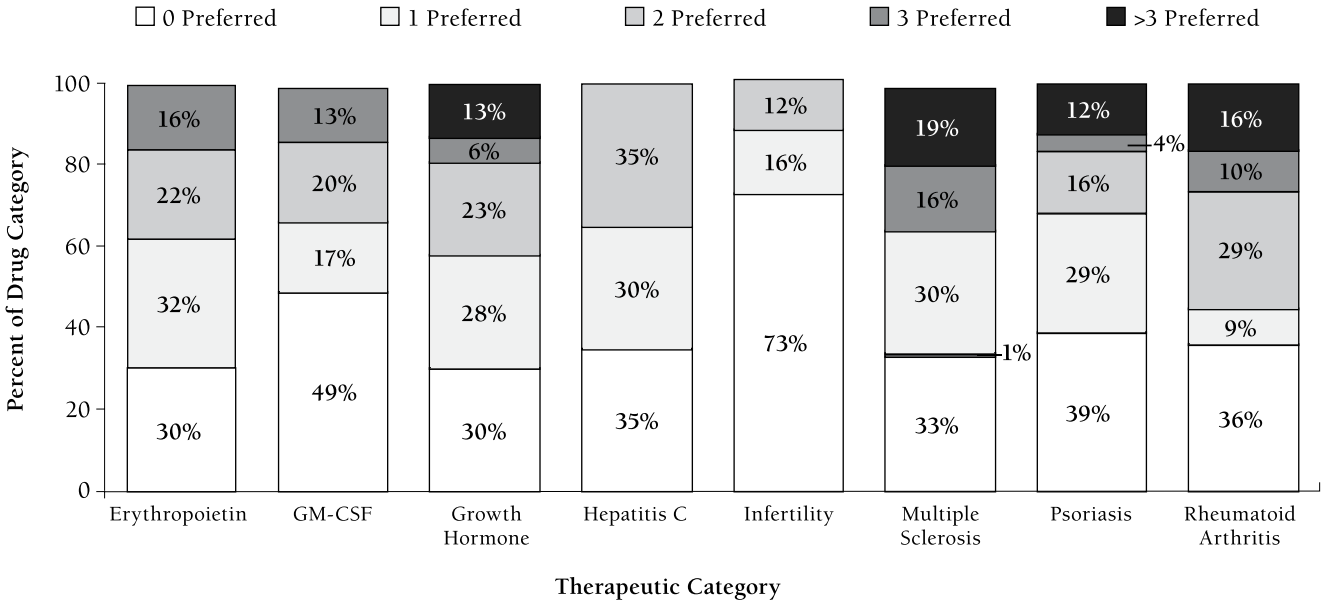
Many payers are beginning to implement step edits to drive utilization to preferred drugs or to ensure the use of appropriate agents prior to initiating therapy with an injectable specialty product. According to a recent survey, 86% of plans designated 1 or more preferred specialty drugs, and 61% did so in 5 or more therapeutic categories.[6] This trend, which is growing in popularity, is currently most common for therapeutics classes containing multiple agents, such as those used to treat MS, RA, hepatitis C, anemia, and growth hormone deficiency (Figure 2).

Because few specialty drugs are considered to be bio-equivalent despite belonging to the same therapeutic class, care needs to be exercised when selecting a preferred agent, as well as when determining access to alternative therapy. In several drug classes, the individual drugs within the drug class may have different indications. For example, a potential conflict can arise if infliximab has been selected as the preferred tumor necrosis factor (TNF) inhibitor, but a patient requires TNF inhibitor therapy for a condition not included in the infliximab label.

Looking to the Future

In the next 5 years, it is anticipated that specialty drugs will account for approximately 25% to 30% of total pharmacy costs.[4] An analysis of future strategies for managing specialty pharmaceuticals indicates a trend toward requiring patients to pay more cost share via increasing the level of annual OOP maximums is very likely.[8] Similarly, more payers will migrate specialty

FIGURE 2 Numbers of Preferred Specialty Products by Therapeutic Category



pharmaceutical coverage to the pharmacy benefit or possibly create a separate benefit for specialty pharmacy.

Specialty Vaccines

Paralleling the growth of specialty pharmaceuticals is the emergence of several novel vaccines that can potentially be effective for the prevention of chronic disease. From a distribution standpoint, vaccines are typically office-administered agents covered under the medical benefit. However, due to their high cost and targeted therapeutic indications, they may also be considered specialty drugs. Payer strategies may drive the coverage of these agents to the pharmacy benefit, to maximize the cost and utilization management. Where these agents ultimately fall remains to be seen.

Generic Biologics

If available, generic biologics would introduce a degree of competition in the specialty market not currently present. However, the term "generic biologic" is actually somewhat misleading, as no 2 biologically engineered specialty products are truly equivalent. Terms such as 'biogeneric,' 'biosimilars,' and 'follow-on biologic' have been used in the United Sates and Europe, but currently there is no widely accepted definition of what actually constitutes a generic biologic. Introduction of generic biologics is also complicated by the current regulatory process, which lacks a pathway for generic biologic approval. In addition, the U.S. Food and Drug Administration (FDA) has no standard for proving generic versions of a specialty product are equivalent to the original branded agent. Congress will need to designate an approval pathway for these agents.

Pharmacogenomics and Personalized Medicine

There is growing interest in the use of genomics and proteinomics to guide diagnosis and treatment of disease. In fact, molecular diagnostics represents a $5 billion market growing at an annual rate of 25%.[9] Pharmacogenomic processes use molecular analysis to test for individual variations in genes, gene expression, proteins, and metabolites. The results of these tests can be used to guide treatment using drugs specifically designed to target the molecular mechanisms of the disease, but can also introduce several moral and ethical dilemmas for patients, employers, and health plans. Recently, a genetic test to evaluate a patient's suitability for warfarin treatment was introduced.[10] This next wave of the biotechnology revolution promises the ability to achieve optimum treatment outcomes or even alter an individual's predisposition for a disease, but not without a cost. To avoid being overwhelmed in the coming years, payers are encouraged to apply what they have learned regarding utilization management, benefit management, and cost containment of specialty agents and proactively apply it to pharmacogenomic products.

Summary

The combined impact of the exponential growth in the number of specialty pharmaceuticals, approval of new indications for existing products, earlier and/or increased use of specialty products, and the aging of the population guarantees that the costs associated with increased use of these agents will continue to rise in the years to come. Currently, many payers reimburse for these agents through both the medical and pharmacy benefit. However, to effectively manage cost and utilization, payers must implement a comprehensive specialty benefit design that guarantees that the right drugs are used by the right patients at the right time. Cost containment tactics inherent to a specialty benefit include assessing a uniform patient cost-share and mandated use of closed distribution networks by physicians. Utilization management tools include following evidence-based treatment guidelines and use of prior authorization to verify achievement of treatment endpoints. With the impending arrival of novel products, such as specialty vaccines, and the continued advances in the field of pharmacogenomics, it is imperative that payers begin to proactively plan their future specialty benefit designs.

DISCLOSURES

Debbie Stern, RPh, discloses that there was no relationship or financial interest related to the topic of this activity. Stern was responsible for the entire study concept and design of this article. She performed all the data collection, data interpretation, writing, and revision of this article.

REFERENCES

1. BIO (Biotechnology Industry Organization). Approved Biotechnology Drugs. Available at: www.bio.org/speeches/pubs/er/approveddrugs. Accessed July 10, 2007.

2. Butcher L. Newly final CMS policy may help plans when evidence for coverage is lacking. *Biotechnol Healthcare*. 2006;3:41-45.

3. Medco Drug Trend Report 2007. Available at: www.drugtrend.com. Accessed October 12, 2007.

4. Express Scripts Drug Trend Report 2007. Available at: www.express-scripts.com/ourcompany/news/industryreports/drugtrendreport/2006/dtrFinal.pdf. Accessed January 12, 2008.

5. PhRMA. Medicines in Development. Available at: www.phrma.org/medicines_in_development/. Accessed March 27, 2008.

6. EMD Serono Injectables Digest 3rd Edition, 2007. Available at: www.emdserono.com. Accessed September 28, 2007.

7. Goldman DP, Joyce GF, Lawless G, Crown WH, Willey V. Benefit design and specialty drug use. *Health Aff.* (Millwood). 2006;25:1319-31.

8. Silverman E. Copayments: Too much, yet not enough? *Biotechnol Healthcare*. 2006;2:21-26.

9. Wyllie MG. Diagnostic potential unmasked. *BJU Int*. 2004;93:627-28.

10. U.S. Food and Drug Administration. FDA News. FDA Clears Genetic Lab Test for Warfarin Sensitivity. Available at: www.fda.gov/bbs/topics/NEWS/2007/NEW01701.html. Accessed March 27, 2008.

Health Plan Approach to Operationalizing a Specialty Drug Management Program

Mesfin Tegenu, MS, RPh

ABSTRACT

BACKGROUND: Expenditures related to specialty drugs consume a significant percentage of available health care resources.

OBJECTIVE: Explain the process of transitioning the management of specialty drugs from medical services to pharmacy services in 2 managed care plans and provide insight into the issues encountered and solutions implemented based on 6 years of experience using traditional and innovative pharmacy utilization management tools to insure appropriate specialty drug use and reimbursement.

SUMMARY: The level of involvement in a specialty management program varies from managing only products dispensed by the retail, mail, and specialty pharmacy vendor to encompassing a broad list of specialty drugs distributed through a variety of channels. Efficient administrative, operational, and clinical processes are critical to the success of the program. Additionally, an accurate and timely claims processing procedure is also essential for success as is the ability to mine data and effectively report on the use of specialty products. A clinically sound, cost-effective, and patient-friendly program requires input from health plan members, pharmacy service leaders, and physician providers, and must overcome challenges associated with disrupting current relationships and removing competing incentives.

CONCLUSION: A well-constructed and properly funded specialty drug management program results in clinical and financial benefits for the plan.

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Introduction

During the last 10 years, the use of specialty pharmaceutical products has increased significantly. While use of many of these products continues to be confined primarily to physician office settings, infusion clinics, or hospitals, the number of self-injectable and oral drugs categorized as specialty drugs is growing rapidly.[1] Additionally, the use of specialty products is no longer limited to rare or life threatening medical conditions. As a result of their growing number and increasing use, expenditures related to specialty drugs now consume a significant percentage of available health care resources.[1]

Because specialty drugs have been traditionally administered in an office or clinic setting, they were typically not covered or managed as part of the pharmacy benefit, but instead handled as part of the medical benefit. Similar to many other plans, our experience at Keystone Mercy and AmeriHealth Mercy Health plans suggests that utilization and cost management of these products was not subject to oversight by the pharmacy service department or pharmacy benefit manager. As a result, use of specialty drugs was relatively unrestricted and unmanaged, with many being administered at the discretion of the prescribing physician. Often times, these products were being utilized for unapproved uses or in situations unsupported by clinical research.

In early 2002, the senior management at the 2 health plans was charged with identifying new cost-containment opportunities. It was quickly proposed that the knowledge and expertise of the pharmacy department could be brought to bear on the acquisition, distribution, and appropriate use of specialty drug products, specifically those administered by physicians. As a result, while specialty drugs would continue to be covered under the medical benefit, the utilization and cost management of these drugs would become the responsibility of the pharmacy service area. The following is an overview of the knowledge gained from the process of transitioning management of specialty drugs from the medical benefit to the pharmacy benefit and the 6 years of experience using traditional and innovative pharmacy utilization management tools to insure appropriate use and reimbursement.

Definition of Specialty Drug

As discussions unfolded with current and potential clients of the health plans' Pharmacy Benefits Management (PBM) division, it became apparent that the definition of a specialty drug varied from client to client. For example, some clients categorized drugs as specialty if they were used to treat a specific disease state or condition, such as cancer or hemophilia. Others defined a product as specialty based on the method of administration (e.g., injectable or infusion), while still others used the location of administration (e.g., home, infusion center, physician's office, hospital, etc.) as the defining feature. There were also definitions based

TABLE 1 Challenges Confronted When Medical Claims Data Is Used to Manage the Utilization of Specialty Drugs

• Claims data for drug use archived in multiple, segregated data systems operated by different process areas (e.g., pharmacy, PBM, medical)
• Lack of real-time access to claims data ◦ Data only available 30 to 90 days after date-of-administration
• Lack of usable claims data to identify provider and member utilization patterns for capitated physicians and physician groups
• Prevalent use of non-specific Healthcare Common Procedure Coding (e.g., J, S, and Q codes) to identify drug usage
• Extremely limited capability to conduct prospective, concurrent, and/or retrospective drug utilization review for specialty drug products administered and billed by physicians
• Inability to prevent duplicative payments of drugs via HCFA 1500 forms and PBM claims processing system

HCFA = Health Care Financing Administration; PBM = pharmacy benefits management.

on cost tiers where agents costing more than a certain amount (e.g., >$500, $1000, $1500, etc.) were defined as specialty.

Coverage Concerns

Once a product was determined by the plan to fall into the specialty drug category, the issue of coverage became the focus of discussion. The health plan had to decide if the drug in question was going to be covered as part of the member's benefit package, and if so, if it was going to be covered as part of the medical benefit or pharmacy benefit. Additionally, considerations as to who should be allowed to prescribe the drug, when, or for what condition(s) the drug should be prescribed, and specific objective requirements that must be met prior to the drug being approved for use had to be determined.

This process of identifying steps to manage the use of specialty drugs can be complicated, because these agents have historically been developed and approved for diseases and conditions that were previously untreatable or for which few satisfactory therapeutic alternatives were available. Specialty products are often the only treatments approved by the U.S. Food and Drug Administration for a given disease or condition. This reality, combined with a lack of comparative clinical trials, limited long-term outcome and economic data, and a cost factor that can be 10 to 50 times greater than existing treatment options, complicates coverage determination. Non-pharmacoeconomic factors also make coverage discussions difficult. For example, coverage of certain medications is frequently mandated by state or federal laws or insurance regulations. Direct to consumer advertising campaigns and other marketing techniques that highlight the potential benefits of the product often encourage providers, members, and advocacy groups to pressure a health plan to cover a new treatment with little regard to clinical outcomes or cost-effectiveness. Once the client and the plan have categorized the specialty drug and determined coverage limitations, the existing medical or pharmacy processes are typically employed to manage utilization and distribution of the agent.

Need for a Specialty Drug Management Program

A number of issues became apparent as our pharmacy services department began to investigate the tools and/or resources that would be necessary to initiate a successful transition of specialty drug management from the medical benefit to the pharmacy benefit. The most important of these was the necessity to gain access to timely, accurate, and actionable data detailing: (1) the identity of the providers prescribing and administering specialty drugs in their office, (2) the identity of members receiving physician-administered drugs, (3) the disease or condition the drug was being used for, (4) the strength, dosage form, and brand of specialty drug being used, (5) the amount the plan was being billed by the physician for the drug, and (6) the amount the plan was paying for the drug.

We quickly realized that incompatibilities between the medical and pharmacy information management systems made it extremely difficult to acquire data describing the use of specialty products (Table 1). In reality, the 2 systems were never designed to be cross-compatible. However, when the available medical claims data was subjected to more intense scrutiny, several trends became apparent. Among these was the fact that few, if any, financial limitations were placed on specialty drug claims submitted through the medical claims department. It also became apparent that specialty drug claims were being reviewed by staff with only a limited understanding of standard pharmacy, clinical, administrative, and reimbursement practices. As a result, oversight of hospital and outpatient surgery claims for specialty drugs carved out of Diagnosis-Related Group (DRG)-type agreements and for specialty drugs distributed through home infusion and home health care settings was limited at best.

Prerequisites for Success

As the result of experience gained during this process, our organization identified several prerequisites necessary to establish a successful specialty drug management program (Table 2). Although resolution of these issues increases the potential success of a medical benefit to pharmacy benefit transition, the degree of success depends on the ability of each health plan to reconcile the conflicting provider, patient, and distributor incentives inherent in the existing system.

Program Scope

Once the health plan decides to target specialty drugs as an opportunity to improve clinical and financial outcomes for the organization, decisions must be made regarding the level of involvement and amount of financial, human, and technology resources dedicated to implement the program. Our experience identified 5 potential targets for specialty management, including:

(1) self-injectable and oral products, (2) office administered injectable products, (3) hospital administered products, (4) products administered in outpatient hospital and short-term stay settings, and (5) products administered via home infusion and home health care providers. The final scope of the specialty management program will vary among plans and will be greatly influenced by the quantity of resources available to fund and operate the program.

Self-injectable and oral products are typically the first and easiest group of specialty drugs to target for more aggressive management. Self-injectables and oral agents can usually be managed without dramatically changing the organizational business model or requiring large capital or staffing allocations. However, once beyond self-injectables and oral agents, management of specialty products becomes increasingly difficult. In our experience, each level of control also requires a unique set of operational, administrative, and clinical processes.

We identified a number of capabilities that must be present for any plan considering in-sourcing specialty product management. A partial list of the capabilities required for those plans interested in taking full responsibility for implementing specialty drug cost and utilization controls includes: (1) a dedicated provider and member call center, (2) claims management and processing oversight, (3) specialty drug network management, (4) rebate contracting, (5) pharmacists and technicians trained in specialty drug prior authorization protocols, and (6) clinical pharmacy specialists in specialty drug utilization management. For organizations that currently have similar responsibility and operational capacity for traditional pharmacy product management, incorporating specialty products under the existing umbrella can be a relatively easy extension of existing services. However, for those considering this as a stand-alone program, it is important to create the necessary infrastructure prior to implementation.

Unfortunately, it is very difficult to assess the human resource needs of a specialty drug management plan using algorithms associated with traditional pharmacy products and services. The resources necessary to manage specialty products are very plan specific—they depend on the number of drugs and disease types that are included in the program and the number of members within the plan requiring specialty management services. For example, the management of palivizumab, when used for the prevention of respiratory syncytial virus (RSV) in premature infants, is labor intensive and complicated by the fact that this is a seasonal program that lasts from 5 to 7 months of each year or longer if the patient resides in a region (e.g., Hawaii) that has an extended RSV season. Programs that deal with hemophilia and hepatitis C are typically labor intensive early in the case management process, but require less time on a case-by-case basis over the long term.

Program Strategy

Regardless of the level of involvement the health plan ultimately chooses, our experience led us to develop a 3-phase approach to managing all specialty products. Phase 1 of the approach involved reducing net cost of all drug product and services to the health plan. Phase 2 encompassed implementation of basic drug utilization management programs, and Phase 3 included the development and use of a specialty drug utilization management program. While these phases can be implemented in parallel, we found that when performed sequentially, there were fewer problems with implementation and a lower number of provider-related issues.

TABLE 2 Prerequisites for a Successful Specialty Drug Management Program

• Health plan has identified management of specialty drugs as an opportunity to reduce overall health care costs
• The health plan has defined the scope of the specialty drug management program
• Appropriate internal and external resources have been identified and allocated to assist with the management of specialty products
• Coverage, contribution, reimbursement, distribution, and utilization management strategies for specialty drugs have been agreed to by pharmacy, medical, and management leadership
• Operational mechanism to process claims, track costs, and utilization of specialty drugs are in place
• Product and service cost issues have been identified and addressed
• Appropriate disease states, member populations, and drug products have been identified and targeted for management programs

Phase 1 requires that the plan closely examine how all drug products are purchased, distributed, and reimbursed. For health plans that are looking to simply control the costs and use of products currently managed under the pharmacy benefit, reviewing pharmacy purchase agreement for these products becomes critical. The plan should aggressively negotiate acquisition costs and rebates to achieve the best price available in the market for all products whether distributed by retail, mail, or specialty pharmacy networks. Also, the use of vendors who specialize in the distribution of specialty products often results in deeper discounts for those products for plans, particularly when compared with vendors who historically have focused on traditional drugs. Our experience leads us to recommend that contracts for specialty products should be drug specific; plans should avoid having a universal discount rate for all drugs covered under a single agreement. While typical retail reimbursement rates of Average Wholesale Price (AWP) minus 15% are acceptable for some injectable products, other products are more appropriately reimbursed in the AWP-20% range, while some brands of specialty injectable products should receive discounts up to AWP-40%.

A common problem associated with certain specialty drug vendor agreements (e.g., hemophilia factor products) is the bundling of nursing costs or other services into the price of the drug product. These contracts often make it difficult to determine if product pricing is appropriate. Equally important, the ability to properly segregate costs and assign them to the correct internal cost center becomes extremely complicated when nursing and

other clinical support services are bundled into the contract. To avoid these issues, we feel it is better to segregate drug product and medical/nursing services whenever possible to determine the appropriateness of the contract pricing.

The decision to expand the scope of specialty management beyond self-injectables to injectables administered in the physician office, infusion center, and home health care settings requires a different set of contracting and reimbursement strategies. In our experience, the most common type of physician reimbursement program currently in use is 'buy-and-bill.' In a buy-and-bill scheme, the physician procures the drug from a wholesaler, manufacturer, or broker. Following administration of the drug, the physician bills the health plan and/or member directly for the drug product and all drug-related professional services for reimbursement at a level frequently specified in the overall provider agreement. Our experience is that the reimbursement rates are very favorable to the physician and are often not representative of the pricing available through traditional pharmacy or specialty pharmacy vendors. It is critical that provider services contracts are reviewed and, whenever possible, modified to contain terms that are similar or identical to the reimbursement terms in the contracts with the most aggressive rate available in the retail, mail, or specialty drug vendor agreements.

In the past, it has been extremely difficult to determine the appropriate pricing of products billed by physicians due to their use of non-specific Health Care Procedure Codes (HCPC). The ability to require and use National Drug Code (NDC) level information when contracting, and reimbursing for drugs is a significant benefit. Having NDC level data, in addition to other physician and patient information, provides a more comprehensive view of physician-prescribing patterns and overall drug utilization.

Another reimbursement option is called product replacement. In a product replacement program, the physician does not bill the health plan for any drugs administered in the office, but requests a replacement item from the health plan when a drug is used for a plan member. The health plan then instructs a vendor to send a replacement product to the physician's office. The replacement cost for the drug is at the contracted rate and is often much less than the amount typically billed by the physician. This approach can be either mandatory or voluntary, however, physicians are often reluctant to sign up for this type of program without some form of incentive because participation typically means a significant reduction in profit resulting from the in-office administration and billing of specialty injectable products.

In our case, we allow buy-and-bill when the provider reimbursement contract for those products contains the same terms as those negotiated with the specialty drug replacement vendor. Additionally, we recommend the availability of a replacement drug program for those physicians who decide to use that particular process. Replacement programs offer physicians the additional advantage of reducing the time, space, and personnel requirements needed for inventory management. In many cases, the office simply requests the product from the plan immediately prior to the patient visit, thus avoiding the carrying costs associated with the more expensive specialty products.

Another issue to be aware of when contracting for specialty drug products is how to determine or negotiate contract rates. More specifically, what pricing algorithm and/or formula should be used to determine an appropriate price. AWP or Wholesale Acquisition Cost (WAC) are the most common methods of contracting with traditional pharmacy vendors. The introduction of average sales price (ASP) pricing by Centers for Medicare & Medicaid Services (CMS) for physician reimbursement of drugs used for Medicare enrollees has added another dimension to the discussion of appropriate pricing for specialty drug products.[2] Whichever baseline pricing is used, it is important to monitor pricing and modify service agreements when necessary to insure the health plan is appropriately reimbursing pharmacy and physician providers.

Phase 2 involves the development and implementation of basic drug utilization management programs. These often include point-of-service edits that screen for quantity, age, and gender, as well as prior authorization protocols that rely on objective criteria to determine if a drug is being used appropriately. The prior authorization criteria can be created internally, purchased separately from a third party, or received as a value-added component of a larger package purchased from a specialty pharmacy vendor. When appropriate, reauthorization or postauthorization review of a particular treatment is undertaken to determine effectiveness, or lack thereof, for a prescribed treatment. These basic utilization management programs and principles are the first step in helping to insure the appropriate use of specialty drug products.

Phase 3 includes the introduction of specialized pharmacy case and disease management programs. While resource intensive, these programs have been extremely cost-effective in terms of return on investment, at least from the health plan's point of view. These programs target specific diseases, conditions, or individual members that are identified based on the total cost of providing necessary care and pharmaceutical treatment. Initially, the health plans targeted medical conditions that affected a clearly identifiable group of patients who consumed a significant amount of health care resources (e.g., hemophilia, hepatitis, multiple sclerosis, end stage renal disease) for the Phase 3 specialty drug management programs.

For example, 1 of the first Phase 3 programs initiated by our pharmacy service area was for the management of hemophilia. The health plan was spending in excess of $10 million annually on the 45 plan members identified as having the condition. The program combined the skills of a clinical pharmacist and nurse case manager to individually manage the drug therapy of these members. Use of prophylaxis factor, hospitalization from bleeding events, and the members' environment at home and school were all monitored. Shipments of drug products were also monitored and adjusted based on actual use of product as opposed to the

standing orders for medication on record. Automatic shipment of product was discontinued, and a policy requiring all shipments to obtain authorization from the pharmacist or nurse case manager was implemented. These interventions, in concert with an aggressively renegotiated acquisition price, saved the health plan several million dollars in hospital and drug costs.

Early in the process, our plan decided to use specialty product vendors to take advantage of their expertise in the distribution of these products. We also determined that utilization management for all specialty drugs would be done by either the health plan itself or a third-party vendor that did not profit from the distribution of the drugs. While it cannot be said that all vendors would let a profit motive influence clinical judgment or decision making, this competing incentive must be considered when determining who should be given responsibility for making clinical decisions involving specialty drugs. This concern can be mitigated if the clinical criteria used to determine approval of a particular drug is provided by the health plan and not the vendor providing the product. In this case, use of a third-party vendor responsible for monitoring adherence to the prior authorization criteria would be a logical approach to reducing the chance of clinical bias.

Post-Implementation Issues

In the plan's specialty drug program, which was limited to self-injectable and oral medications, opposition to the transition to a single or exclusive network was typically limited to physicians voicing concern about the possible disruption of relationships with current vendors or distributors. Patients have also opposed the plan and voiced their displeasure about having their preferred pharmacist or pharmacy vendor eliminated from a newly constructed specialty network. When the specialty program was expanded to include office-administered drug products, the degree of dissatisfaction often depended on the substitute distribution and reimbursement processes that were implemented. The primary complaint from physicians previously allowed to buy-and-bill was predictably related to lower reimbursement rates, and the impact of this process lowered income stream to the profitability of their practice. The replacement programs also generated complaints from providers about having to front the cost of the drug to the health plan and the requirement that the physician must maintain a plan-mandated inventory, including stocking many ancillary specialty drug-related items in their offices.

Providers have also voiced concern about the additional administrative process involved with requesting replacement drug. The plan's specialty management utilization program also requires approval from the plan before the physician can even administer the drug. This has created problems, particularly when the physician requests replacement for a drug that was not authorized and, upon review, was not eligible for approval. In these cases, physicians have voiced their dissatisfaction about losing money from products that they administered, but are subsequently unable to get reimbursement.

While complaints regarding revenue and profit are certainly expected, the more consistent complaints are rooted in the requirement that providers and patients adapt to limits on the drugs that were previously unmanaged. Probably the most vocal in this regard are specialist physicians, many of whom are of the opinion that they should be exempt from any and all utilization management programs, including those established for specialty drugs. It is important for the plan to anticipate this form of resistance and devise strategies to work with their providers to resolve these issues in a mutually acceptable manner. It is our experience that plans unwilling to find workable solutions with their specialist providers will run into difficulties implementing an aggressive utilization management program.

Summary

While our experience is limited to 2 health plans, we strongly believe that a thoughtful, well-constructed, and properly funded specialty drug management program can have a positive clinical and financial impact on the plan. The level of involvement in a specialty management program can vary from touching only those products that are dispensed by the retail, mail, and specialty pharmacy vendor to encompassing a broad list of specialty drugs distributed by a variety of health care providers and vendors. Critical to the success of these programs are efficient administrative, operational, and clinical processes. The ability to duplicate an accurate and timely claims processing procedure for specialty drugs that is similar to that currently available for traditional oral drug products is essential for success. The ability to mine data and effectively report on the use of specialty products is also paramount. A clinically sound, patient-friendly, and cost-effective program involves input from health plan members, pharmacy service leaders, and physician providers.

To realize the maximum benefits of a specialty drug management program, the plan must be willing to acknowledge and overcome challenges associated with implementing a system that disrupts current relationships and removes many attractive financial incentives. Additionally, a dedicated and knowledgeable staff that understands the detailed workings of a specialty drug program and the needs of those impacted is critical. However, once the programs are in place and working, the results are well worth the effort.

DISCLOSURES

Mesfin Tegenu, MS, RPh, discloses that there was no relationship or financial interest related to the topic of this activity. Tegenu was responsible for the entire study concept and design of this article. He performed all the data collection, data interpretation, writing, and revision of this article.

REFERENCES

1. Medco Health. Drug Trend Report 2007. Available at: http://medco.mediaroom.com/file.php/129/2007+DRUG+TREND+REPORT.pdf. Accessed March 25, 2008.

2. Centers for Medicare & Medicaid Services. Medicare Part B Drug Average Sales Price. Available at: www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/. Accessed March 25, 2008.

Blurring Lines of Medical and Pharmacy Management: The New Role of Specialty Pharmaceuticals

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There are no fees for participating in and receiving credit for this activity. During the period from April 1, 2008, through May 1, 2009, participants must (1) read the entire supplement; (2) complete the posttest, credit application, and evaluation form; and (3) either send the completed forms to Postgraduate Institute for Medicine by FAX at 303.790.4876 or complete the activity online at www.amcp.org (CE/CME Center) where you will access the posttest, credit application, and evaluation form.

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Blurring Lines of Medical and Pharmacy Management: The New Role of Specialty Pharmaceuticals

1. Specialty pharmaceuticals account for approximately what percentage of the total pharmaceutical expenditure?
   a. 5%
   b. 10%
   c. 20%
   d. 25%

2. The medical and pharmacy benefits are defined, for the most part, by the location where a service is provided and _____
   a. The type of provider administering the service
   b. The complexity of the service
   c. The cost of the service
   d. The duration of the service

3. Which of the following is *not* a common tactic being employed by health plans to manage specialty pharmacy services more effectively?
   a. Containing a pharmacy benefits management (PBM) company
   b. Building a specific specialty pharmacy benefit
   c. Containing a specialty pharmacy
   d. Discontinuing coverage of high-cost specialty pharmaceuticals

4. Approximately _____ of plans have closed their pharmacy networks and mandated the use of a single specialty distribution channel for drugs covered under the pharmacy benefit.
   a. 10%
   b. 20%
   c. 25%
   d. 50%

5. Examples of cost-sharing strategies include all of the following *except*:
   a. Implementing a prior authorization program
   b. Establishing a flat copay for all drugs
   c. Implementing tiered copays for preferred and non-preferred agents
   d. Requiring coinsurance

6. From a benefit design perspective, there is a modest trend to…
   a. move all specialty drugs from the pharmacy benefit into the medical benefit.
   b. move all specialty drugs from the medical benefit into the pharmacy benefit.
   c. eliminate the pharmacy benefit for specialty drugs.
   d. maintain the current structure.

7. Expenditures on specialty pharmaceutical agents are projected to increase from approximately $54 billion today to more than _____ in 2010.
   a. $69 billion
   b. $79 billion
   c. $99 billion
   d. $109 billion

8. Growth in the specialty pharmaceutical segment is driven by several chronic conditions, including cancer, rheumatoid arthritis, and
   a. Multiple sclerosis
   b. Diabetes
   c. Asthma
   d. Cardiovascular disease

9. Which of the following is *not* one of the three general categories of specialty pharmaceuticals?
   a. Self-administered therapies
   b. Chemotherapy support agents
   c. Products injected or infused in a clinic or office setting
   d. Office/clinic-administered chemotherapeutic agents

10. Specialty drugs may be defined as such by health plans based on all of the following, *except*:
    a. Targeted disease state or condition
    b. Method of administration
    c. Site of administration
    d. Manufacturer

11. Which of the following is the first and easiest group of specialty drugs to target for more aggressive management?
    a. Office-administered injectable products
    b. Hospital-administered products
    c. Self-Injectable and oral products
    d. Products administered via home infusion and home health care providers

12. Although contracting with traditional pharmacy vendors is typically based on methods, such as average wholesale price (AWP), pricing for specialty products may require the use of physician reimbursement methods such as:
    a. Wholesale acquisition cost (WAC)
    b. Average manufacturer's price (AMP)
    c. Retail acquisition cost (RAC)
    d. Average selling price (ASP)

POSTTEST ANSWERS, CREDIT APPLICATION, AND EVALUATION FORM

Blurring Lines of Medical and Pharmacy Management: The New Role of Specialty Pharmaceuticals

To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few minutes to complete this evaluation form. ***You must complete this evaluation form to receive acknowledgment for completing this activity.***

Please answer the following questions by circling the appropriate rating:

1 = Strongly Disagree	2 = Disagree	3 = Neutral	4 = Agree	5 = Strongly Agree

EXTENT TO WHICH PROGRAM ACTIVITIES MET THE IDENTIFIED OBJECTIVES

Upon completion of this activity, participants should be better able to:

1. Discuss current health plan issues and obstacles related to the management of specialty pharmaceuticals	1	2	3	4	5
2. Outline emerging strategies and case study examples for the medical and pharmacy benefit management of specialty pharmaceuticals	1	2	3	4	5
3. Explain the link between appropriate specialty pharmaceutical utilization and the economics of pharmacy administration	1	2	3	4	5
4. Summarize the impact of specialty pharmaceuticals on clinical, humanistic, and economic outcomes within the managed health care setting	1	2	3	4	5

OVERALL EFFECTIVENESS OF THE ACTIVITY

6. Was timely and will influence how I practice	1	2	3	4	5
7. Enhanced my current knowledge base	1	2	3	4	5
8. Addressed my most pressing questions	1	2	3	4	5
9. Provided new ideas or information I expect to use	1	2	3	4	5
10. Addressed competencies identified by my specialty	1	2	3	4	5
11. Avoided commercial bias or influence	1	2	3	4	5

IMPACT OF THE ACTIVITY

Name one thing you intend to change in your practice as a result of completing this activity:

Please list any topics you would like to see addressed in future educational activities:

Additional comments about this activity:

POSTTEST ANSWERS, CREDIT APPLICATION, AND EVALUATION FORM

Blurring Lines of Medical and Pharmacy Management: The New Role of Specialty Pharmaceuticals

FOLLOW-UP

As part of our ongoing continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey:

❑ Yes, I would be interested in participating in a follow-up survey

❑ No, I'm not interested in participating in a follow-up survey

Continuing Education for this program is processed through AMCP.org Online Learning Center site at www.amcp.org (CE/CME Center). You can also take the test by faxing this posttest and evaluation form to Postgraduate Institute for Medicine (PIM) at 303.790.4876. It is recommended that participants keep a copy of their completed materials until they receive their certificate. For questions, please call PIM at 303.799.1930 or e-mail information@pimed.com. Please reference *Project ID: 4892-ES-17*. Please be sure to submit your posttest and evaluation form on or before May 1, 2009. After this date, the activity will no longer be designated for credit. A CME certificate will be mailed within 4-6 weeks.

In order to receive CE credit for this program immediately, you must complete the following forms online:

1) Posttest form for this program, "Blurring Lines of Medical and Pharmacy Management: The New Role of Specialty Pharmaceuticals (Journal Supplement)," on the AMCP.org Online Learning Center site. To receive CE credit, you must receive a score of at least 70%. You will have 2 opportunities to pass the posttest.

2) Program Evaluation Form: Upon successful completion of this activity online, you will automatically receive your CE statement. Your CE credits will be automatically archived and tracked for you on the AMCP.org Online Learning Center site. All information is kept confidential.

Note: There is a $10 processing fee for nonmembers. (See payment instructions on site.)

POSTTEST ANSWER KEY

1	2	3	4	5	6	7	8	9	10	11	12

REQUEST FOR CREDIT

Name *(please print)* _____ Degree _____

Organization _____ Specialty _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____ E-mail _____

Signature _____ Date Completed _____

FOR PHYSICIANS ONLY

I certify my actual time spent to complete this educational activity to be: _____

❑ I participated in the entire activity and claim 1.5 CME or 1.4 ACPE credits.

❑ I participated in only part of the activity and claim _____ credits.

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