



PCMA

Specialty Pharmacy Trends
and
Management Strategies

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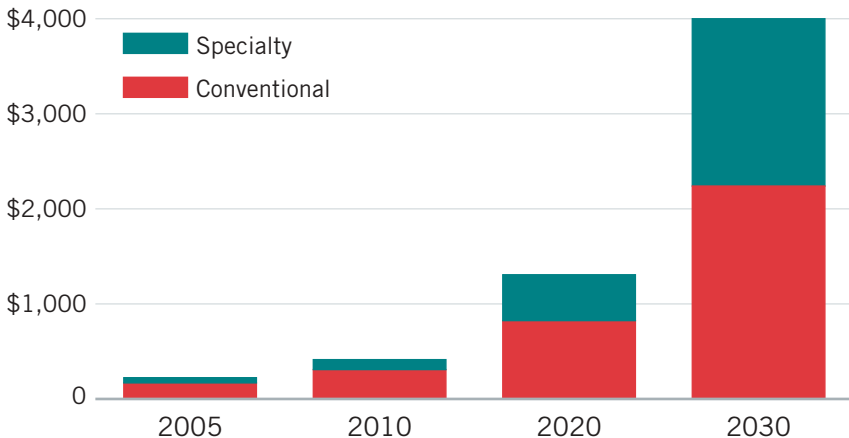
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SPECIALTY PHARMACEUTICALS HOLD GREAT PROMISE FOR people currently living with rare and chronic conditions like rheumatoid arthritis, hemophilia, and multiple sclerosis. That promise, however, is not without cost. Specialty pharmaceuticals are typically developed for limited patient populations. Due to this and other factors manufacturer prices for these high-tech medicines are often very high. Likewise, specialty pharmaceuticals often require special handling, administration, patient education, and clinical support — all factors that add to their cost.

Ensuring that patients and payers receive the maximum benefit from today's high-tech, high-cost, high-touch medicines is the job of specialty pharmacies. With the biotech pipeline bursting with new medicines and an aging population increasingly relying on biotech treatments for more and more conditions, the challenge of managing the specialty pharmacy benefit can be daunting. Even with effective management, expenditures on specialty pharmaceuticals are projected to increase exponentially in the coming decades.

EXHIBIT 1: Specialty Pharmacy Expenditures to Increase Exponentially Over 25 Years

Prescription drug expenditures (\$ Billions)



SOURCE: Stevens, D., Accredo Health, "Specialty Pharmacy to Therapy Management: The Next Generation," presented at PCMA Specialty Pharmacy Annual Meeting, October, 2005.

DRIVERS OF THE SPECIALTY PHARMACY EXPENDITURE TREND

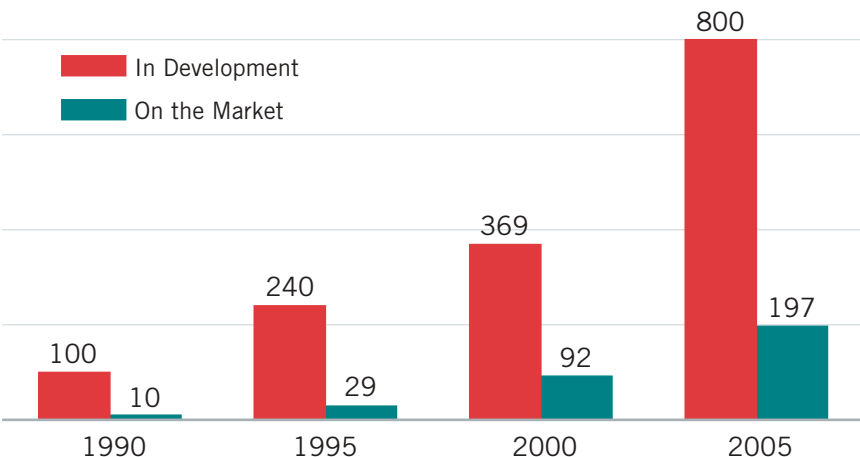
Expenditures on specialty pharmaceuticals are expected to increase from approximately \$55 billion in 2005 to \$1.7 trillion in 2030 — a more than 30-fold increase (Exhibit 1).

- In 2005, specialty pharmaceuticals accounted for approximately 24 percent of total drug expenditures. By 2020, that share will increase to about 37 percent.
- By 2030, specialty pharmaceuticals are expected to account for as much as 44 percent of a plan's total drug expenditures.

Today, expenditures on specialty pharmaceuticals are growing about twice as fast as spending on conventional drugs. A major factor in this growth is the sheer number of approved and soon-to-be approved biotech medicines (Exhibit 2). Since 1990, the number of approved biotech products has more than doubled every five years. Today, nearly 200 biotech medicines have won FDA approval and an additional 800 are in development, according to AON.

EXHIBIT 2: Increasing Number of Specialty Pharmaceuticals in Development

Number of biotech drugs



SOURCE: Lednar, W., AON, "Benefit Designs: Biotech vs. Conventional Treatments," presented at PCMA Specialty Pharmacy Annual Meeting, October, 2005.

The differences between specialty pharmaceuticals and conventional drugs help explain why expenditures are increasing so rapidly (Exhibit 3). In terms of their delivery, specialty pharmaceuticals are typically administered by injection or infusion — processes obviously more complicated and expensive than simply taking a pill. Handling requirements for specialty drugs are also more complicated, with refrigeration required in many cases. Required patient monitoring and support are more intensive than typically required with conventional therapies.

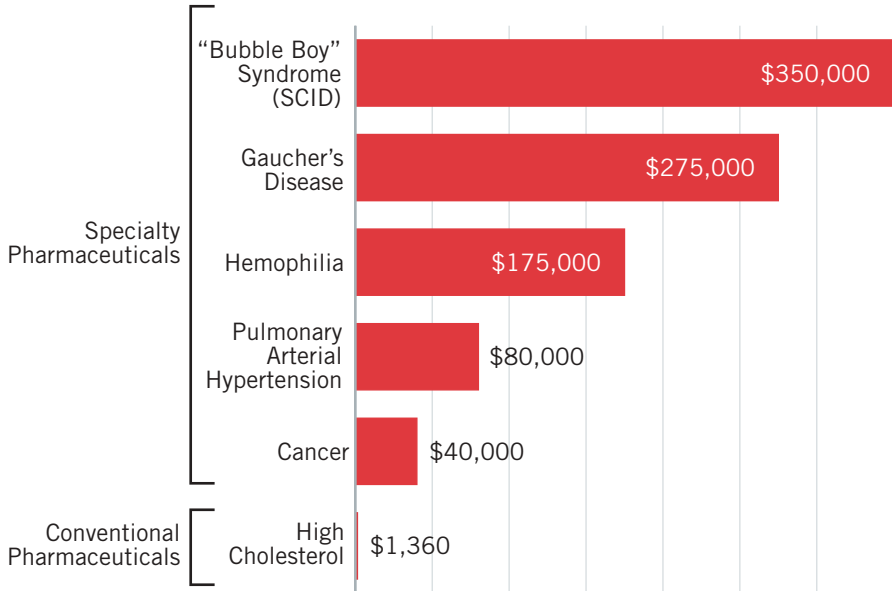
EXHIBIT 3: High-Cost, High-Touch Specialty Pharmaceuticals Differ from Conventional Pharmaceuticals

	Conventional		Specialty	
Type of Condition	Common Acute	Common Chronic	Complex Chronic	Rare Disease
Medication	<i>Augmentin</i>	<i>Lipitor</i>	<i>Avonex</i>	<i>Folan</i>
Indication	Acute Bacterial Infection	Cholesterol Reducer	Multiple Sclerosis	Pulmonary Arterial Hypertension
U.S. Patient Population	23 million scripts in 2001	Affects >50 million people	Affects about 350,000 patients	Affects less than 20,000 patients
Handling Requirements	No special requirements	No special requirements	Refrigeration training	Refrigeration/mixing/pumps/central line/training
Duration of Therapy	About 10 days per episode	Ongoing (maintenance drug)	Lifelong	Lifelong
Cost of Therapy	\$92 per episode	\$1,360 per year	\$17,000 per year	\$80,000 per year
Optimal Distribution Channel	Retail Pharmacy	Mail-service pharmacy	Specialty pharmacy	Specialty pharmacy with advanced clinical services

SOURCE: Stevens, D., Accredo Health, "Specialty Pharmacy to Therapy Management: The Next Generation," presented at PCMA Specialty Pharmacy Annual Meeting, October, 2005.

The high research, development, and manufacturing costs of specialty pharmaceuticals are typically spread over a limited patient population. As a result, the price of specialty pharmaceuticals can be multiples higher than the price of conventional drugs (Exhibit 4).

EXHIBIT 4: Annual Drug Costs for Selected Specialty Pharmaceuticals vs. Conventional Medications



SOURCE: Stevens, D., Accredo Health, "Specialty Pharmacy to Therapy Management: The Next Generation," presented at PCMA Specialty Pharmacy Annual Meeting, October, 2005.

To illustrate this difference, consider that a cholesterol lowering drug taken by 20 percent of patients on medication for that condition would have about 1.6 million prescribed patients. In contrast, a new pulmonary hypertension drug might only be used by about 1,400 prescribed patients. If research and development costs for both products are assumed to be \$868 million, the R&D break-even point for the cholesterol product is \$532 per patient, while the R&D break-even point for the pulmonary hypertension drug is \$607,142 per patient.¹

¹ Stevens, D., Accredo Health, "Specialty Pharmacy to Therapy Management: The Next Generation," presented at PCMA Specialty Pharmacy Annual Meeting, October, 2005.

Historically, specialty pharmaceuticals have targeted rare genetic conditions such as Gaucher's disease and multiple sclerosis. Today, specialty pharmaceuticals are used to treat conditions that affect about 3 percent of the general population.² As new biotech medications are approved, the use of specialty drugs for more common diseases will undoubtedly expand. Today, some 154 biotechnology medicines are in development for cancer, 43 for infectious diseases, 19 for cardiovascular disease, and 17 for HIV/AIDS.³ As biotech products for these conditions are approved, the cost implications for health-care payers will be profound. Even if these new treatments are priced significantly less than today's more narrowly focused specialty drugs, expanded utilization will greatly increase pharmaceutical expenditures.

Specialty pharmacy care is focused on ensuring that society's growing investment in high-tech treatments is well managed. Recent evidence demonstrates that in addition to saving lives and improving clinical outcomes, effectively implemented specialty pharmacy programs can also save money:

- Specialty pharmacy care for rheumatoid arthritis has helped reduce annual treatment costs from nearly \$25,000 per patient to approximately \$20,000 per patient, according to a PBM's recent analysis of nearly 30,000 specialty and retail prescription drug claims.⁴
- A study of patients with pulmonary arterial hypertension receiving specialty pharmacy care revealed that the specialty pharmacy helped save \$6,552 per patient per year in prevented physician and emergency room visits and \$43,281 per patient per year in avoided hospital admissions.⁵
- A recent analysis revealed that specialty pharmacy care resulted in Hepatitis C patients adhering to their therapy 90 percent through a specialty pharmacy compared to adherence of just 49 percent through retail pharmacy. The program accomplished this while implementing a preferred formulary that resulted in a 5 percent savings to the health plan.⁶

Clearly, widespread implementation of such effective specialty pharmacy programs will be necessary to manage the expenditure trend.

² Curascript Pharmacy, "2004 Specialty Pharmacy Management Guide & Trend Report," June, 2005.

³ PhRMA, "Biotechnology Medicines in Development," 2004.

⁴ Marks, A., Caremark, "Examination of Disease States: Rheumatoid Arthritis," presented at the PCMA Specialty Pharmacy Symposium, June 2005.

⁵ Russek, S., and Szymanski, J., Medco, "Specialty Pharmacy: Rare Disease Management," presented at the PCMA Specialty Pharmacy Symposium, June, 2005.

⁶ McDermott, R., Express Scripts/CuraScript Pharmacy, "Clinical Outcomes in Hepatitis C Management," presented at the PCMA Specialty Pharmacy Symposium, June, 2005.

CHALLENGES IN MANAGING SPECIALTY PHARMACEUTICALS

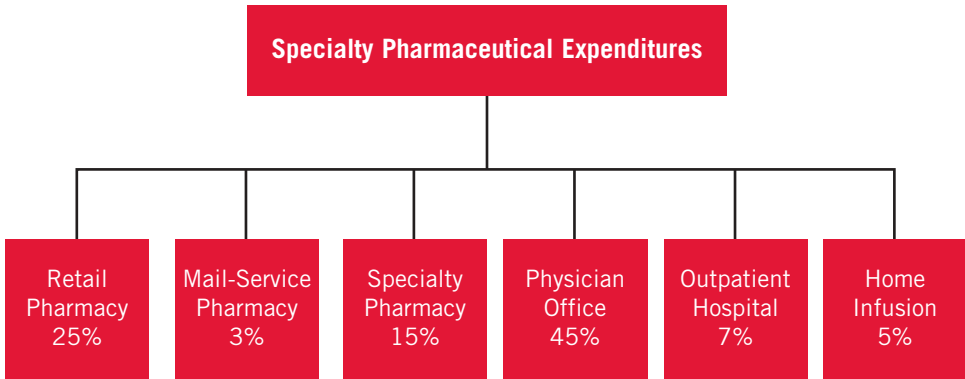
The evolving nature of specialty pharmacy care has challenged third-party payment systems traditionally set up to manage drug costs in two separate categories:

- ▶ **Pharmacy Benefit:** Coverage for relatively lower-cost prescription drugs taken orally and obtained at a retail or mail-service pharmacy.
- ▶ **Medical Benefit:** Coverage for high-cost biopharmaceuticals administered by injection or infusion in a physician's office.

When biotech medications first became available during the 1980s, payers often reimbursed for these medications through the medical benefit. Physicians administering the product would typically obtain it from the manufacturer, manage inventory, and submit a bill to the health insurer for reimbursement along with their professional services. Doctors often added a substantial markup to specialty products in order to create an additional revenue stream.

As the number and variety of specialty pharmaceuticals has increased, patients have assumed a greater role in managing their therapies. Many specialty drugs are now administered in home settings either by caregivers or by patients themselves. This has helped create the opportunity for payers to manage these products under the pharmacy benefit, where claims adjudication systems allow for much more active utilization and cost management. Managing specialty drugs within the pharmacy benefit is a clear trend among payers.

Many specialty drugs, however, require close physician monitoring, special mixing or compounding, or concurrent lab work and always must be administered in a physician's office, clinic, or outpatient hospital facility. Accordingly, specialty pharmaceuticals are often still reimbursed under the medical benefit.

EXHIBIT 5: Distribution Channels for Specialty Pharmaceuticals

SOURCE: Curascript Pharmacy, "2004 Specialty Pharmacy Management Guide & Trend Report," June 2005.

As a consequence of their complexity, specialty pharmaceuticals also flow through a wide variety of distribution channels (Exhibit 5). Distribution varies greatly according to the specialty product's administration requirements, the payer's pharmacy 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.

VALUE-ADDED SERVICES OF SPECIALTY PHARMACIES

To meet the challenges associated with the diverse billing issues, distribution channels, and service requirements that go hand-in-hand with specialty drugs, payers are increasingly turning to specialty pharmacies. Specialty pharmacies have evolved to meet these challenges, and now typically provide a broader range of services than other distribution channels (Exhibit 6).

EXHIBIT 6: Specialty Pharmacies Typically Provide a Broader Range of Services Than Other Distribution Channels

Specialty Distribution Channels	Inventory Availability	Access to Specialty Pharmacists	Compliance Monitoring	Nursing and Social Work Support Services	Clinical Management of Disease-Specific Programs	Home Nursing Services Coordination	Pharmacy and Medical Billing and Reimbursement	Capabilities Utilization and Formulary Management Support Services
Retail Pharmacy								
Mail-Service Pharmacy			✓					
Specialty Pharmacy	✓	✓	✓	✓	✓	✓	✓	✓
Physician Office	✓							
Outpatient Hospital/Clinic	✓	✓		✓		✓		
Home Infusion	✓	✓	✓	✓		✓		

SOURCE: Curascript Pharmacy, "2004 Specialty Pharmacy Management Guide & Trend Report," June 2005.

Specialty pharmacies are geared toward helping patients achieve the best possible clinical outcomes while helping payers hold down costs. A range of specific services make that possible:

- **Inventory Availability:** Ensuring the immediate availability, continuous supply, and appropriate handling of specialty drugs and related supplies.
- **Access to Specialty Pharmacists:** Providing 24/7 access to pharmacists with detailed knowledge of the condition being treated, drug side effects, and proper administration methods.
- **Compliance Monitoring:** Helping patients take their medications consistently, in the right amount and dosage, and for the full length of treatment.
- **Nursing and Social Work Support Services:** Supporting patients with appropriate levels of education, monitoring, psychological support, and community resourcing.
- **Clinical Management of Disease-Specific Programs:** Implementing programs tailored to the unique needs of patients with specific diseases.
- **Home Nursing Services Coordination:** Coordinating nursing services with other care so that patients receive support for on-going home infusion and self-injection in a cost-effective manner.
- **Pharmacy and Medical Billing and Reimbursement:** Managing billing and reimbursement under both the pharmacy and medical benefit depending on client needs.
- **Capabilities Utilization and Formulary Management Support Services:** Monitor and supervise the utilization of specialty drugs to minimize wastage, ensure the medical necessity of on-going treatment, and enhance clinical outcomes.

The unique ability to provide the full range of these services is the cornerstone of specialty pharmacy's value proposition. By carefully coordinating these services, specialty pharmacies increase the chances that patients will get the greatest benefit from their treatment while also ensuring that resources are used wisely.

SPECIALTY PHARMACY BENEFIT STRATEGIES

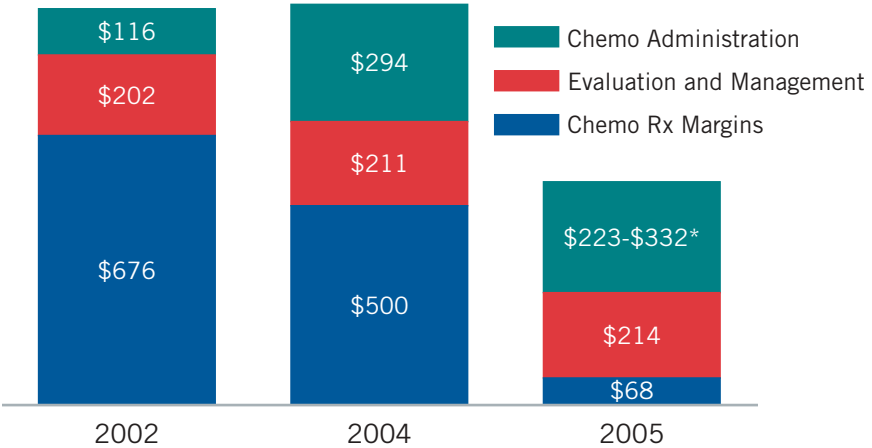
With employers, managed care organizations, and other plan sponsors becoming increasingly aware of the upward trend in specialty pharmacy expenditures, many are evaluating strategies to help them more aggressively manage costs in clinically appropriate ways. Specialty pharmacies offer payers a range of cost management, utilization management, and clinical care management options that can be customized to meet specific needs. Current areas of focus include:

- **Use of preferred, limited, or single-source distribution networks:** Consolidating vendors can allow payers to better coordinate care, manage utilization, streamline billing, and achieve higher discounts on a range of products.
- **Discourage physician “buy and bill” practice:** As evidenced in Exhibit 7, payers may realize substantial savings by eliminating the large drug margins that physicians, including oncologists, have traditionally added to drugs they buy and bill as part of the medical services they provide. Provisions passed in the Medicare Modernization Act are likely to accelerate this trend.
- **Use of prior authorization and/or utilization management programs:** Implementing prior authorization requirements on key specialty drugs helps ensure clinically appropriate and cost-effective utilization based on best practice guidelines. *One major plan estimates that prior authorization saves \$10 for every \$1 spent administering such programs.*⁷
- **Use of therapy management:** Therapy management requires a high degree of care coordination, adherence to very specific standards of care, and improved data gathering and reporting capabilities to closely track health outcomes and expenditures.
- **Implementation of formulary management:** A number of disease states treated by specialty pharmaceuticals now have multiple products with similar therapeutic effects. Formulary management allows plans to encourage the use of the most cost-effective products and obtain price discounts with manufacturers. Increased competition in the marketplace is likely to expand formulary management opportunities.

⁷Ho, S. PacifiCare, “Specialty Pharmacy: The Third Party Perspective,” presented at PCMA Specialty Pharmacy Annual Meeting, October, 2005.

EXHIBIT 7: Oncologist “Buy and Bill” Revenues for Specialty Pharmaceuticals Decreases

Trend in net revenue per physician (for every \$1,000 in 2002 revenue)



* Range with low end representing no change in commercial plans' reimbursement and high end representing plans matching CMS. Assumes commercial plans match Medicare Chemo Rx margins.

SOURCE: Ho, S. PacifiCare, “Specialty Pharmacy: The Third Party Perspective,” presented at PCMA Specialty Pharmacy Annual Meeting, October, 2005.

COMPETITION IN THE SPECIALTY PHARMACEUTICAL MARKETPLACE

Among specialty pharmaceuticals in use today, many manufacturers are seeking FDA approval to use products to treat additional conditions (Exhibit 8). To the extent that these new conditions were previously untreated, this will expand the use of specialty drugs. At the same time, if a specialty drug receives FDA approval for a condition where one or more existing treatments are available, price competition within the therapy class may increase.

EXHIBIT 8: Existing Specialty Pharmaceuticals Used to Treat an Increasing Number of Conditions

Drug	FDA-Approved Indication(s)	Other Indications in Development
Rebif	MS	RA, NSCLC, Hepatitis C, Crohn's disease, ulcerative colitis
Humira	RA	Crohn's disease, juvenile RA, psoriasis, ankylosing spondylitis
Enbrel	RA, ankylosing spondylitis, psoriasis, psoriatic arthritis	Idiopathic pulmonary fibrosis, asthma, juvenile RA
Remicade	RA, Crohn's disease	Psoriasis, ulcerative colitis, juvenile RA, ankylosing spondylitis, hepatitis C, COPD, psoriatic arthritis
Rituxan	Non-Hodgkin's lymphoma	Small lymphocytic consistent lupus, RA, MS
Xolair	Allergic asthma	Allergic rhinitis, peanut allergy

SOURCE: Curascript Pharmacy, "2004 Specialty Pharmacy Management Guide & Trend Report," June, 2005.

A second way price competition may emerge among specialty drugs would be if the FDA approved a regulatory pathway for the approval of "generic" versions of originator biologic products that have lost patent/exclusivity protection. Unlike conventional drugs, there is no established process whereby a follow-on version of a biologic can be approved by the FDA. With a dozen biotech drugs — many with substantial sales — expected to lose patent protection by the end of 2006, there are increasing calls for the FDA and Congress to act.⁸

⁸ Curascript Pharmacy, "2004 Specialty Pharmacy Management Guide & Trend Report," June, 2005.

MEDICARE MODERNIZATION ACT AND SPECIALTY PHARMACY

The Medicare Modernization Act (MMA) contained a number of important provisions likely to shape the specialty pharmacy marketplace for years to come. These provisions include changes in physician reimbursement for specialty pharmaceuticals as well as the new Part D coverage for outpatient prescription drugs. These changes will likely accelerate changes in two areas:

- **Physician Reimbursement:** MMA's revised payment methodology for physician-administered drugs is likely to hasten the decline of “buy and bill” practices. In addition, if a competitive acquisition program (CAP) for Medicare Part B drugs is effectively implemented, physicians will have the option of obtaining specialty products from a vendor that will assume responsibility for billing.
- **Increasing Use of Self-Administered Products:** The new Medicare Part D benefit may serve to expand the use of self-administered products. Since Medicare historically only covered drugs administered by a physician, it was not uncommon for doctors to prescribe such drugs over self-administered alternatives, especially if the Medicare beneficiary did not have supplemental drug coverage.

CONCLUSION

Given the anticipated number of new specialty treatments expected to come to market — and the potential future availability of follow-on specialty drugs — it is urgent that payers focus on effective cost and utilization management strategies today. In a number of areas, the implementation of the Medicare Modernization Act (MMA) will likely accelerate the pace of change. Regardless of which specialty pharmacy benefit strategies are used, society must prepare to invest greater resources in specialty pharmacy care if the promise of biotechnology is to be delivered to patients and their families.



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