Managing Specialty Pharmaceuticals: Balancing Access and Affordability

Commercial Health Plan Perspective

The Health Industry Forum
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Objectives:

- Define “specialty pharmaceuticals” from the commercial health plan perspective.
- Identify the cost of specialty pharmaceuticals, including oncology treatment, as a percentage of overall benefit expense for commercial health plans.
- Outline management techniques used by commercial health plans to provide affordable access to specialty pharmaceuticals.
- Describe how managing these expenditures supports the value proposition of integrated medical and pharmacy management.

The Definition of Specialty Pharmaceuticals Is Changing as Products Enter the Market.

WHAT MAKES A DRUG A "SPECIALTY"?

Defining a specialty pharmaceutical is a little trickier than saying "It's a biologic." A specialty drug targets a disease with a small-to-medium population that has serious unmet medical needs—and includes one or more of the following features:

- Usually a large-molecule injectable—but increasingly a small-molecule oral drug
- A premium price
- Coverage under the medical benefit—but increasingly coming under the pharmacy benefit
- Primarily prescribed and administered by a specialist (e.g., pulmonologist, oncologist, etc.)
- Often requires special handling and storage
- Requires disease-management services (e.g., patient education, monitoring, etc.)

Source: Cambridge Healthtech Institute, Insight Pharma Reports, "Specialty Pharmaceuticals: Driving Industry Growth into the Next Decade," October 2006

Observations About Health Plan Coverage of Specialty Pharmaceuticals.

- **Medical vs. Pharmacy Benefit**
- Two-thirds of plans cover self-injectable drugs under the pharmacy benefit exclusively; balance of plans cover them under both medical and pharmacy.
- On average, 70% of plans cover drugs requiring administration by a health professional (including office administered injectables, home health care and hospital infusion) under the medical benefit; with the balance of plans covering them under both medical and pharmacy.
- Approximately 5% of plans surveyed use a separate rider.
- **Cost and Utilization Trend**
- Specialty pharmacy accounts for 11-13% of total drug cost
- Reported 2006-2007 cost trend: 12-15%
- **Highest Priority Categories**
- Rheumatoid Arthritis; Blood modifiers; Oral Oncology; Growth Hormone; Infused Oncology; RSV; Hepatitis C; Multiple Sclerosis, Transplants

Source: EMD Serono Injectable Digest ™ 4th Edition

Focus is on Clinical Management and Delivery System First, Followed by Benefit Design.

- *Changes in Management Approaches (2007)*

- More Clinical and Utilization Management (80% of plans)
  - Clinical guidelines; Prior Authorization; Step Edits; Preferred Products
  - Responsibility for utilization management is shared by pharmacy and medical departments
  - Clinical reviews by P&T Committee, Medical Policy and Technology Assessment
- Provider Reimbursement (57% of plans)
  - Pharmacies (self-injectables); physicians (office-administered injectables)
  - Change in methodology
  - Discounts
- Implementing New Specialty Provider Strategies (54% of plans)
  - Mandatory use of Specialty Pharmacy Providers
  - Expectations of the specialty pharmacy delivery system
- Changes in Benefit Design (30% of plans)
  - Coverage determination
  - Patient cost share (self-injectables)

Source: EMD Serono Injectable Digest ™ 4th Edition

More Clinical and Utilization Management

Clinical Guidelines; Prior Authorization; Step Edits; Preferred Products

Responsibility for Utilization Management is shared by Pharmacy and Medical Departments

Clinical Reviews by P&T Committee, Medical Policy and Technology Assessment

Clinical and Utilization Management: Horizon BCBSNJ Experience

- Prior authorization, dispensing limits, dose optimization are critical; need to minimize impact on physicians' offices.
- ESA guideline management.
- Use of intermediary for web-based PA/guideline management and claim submission: Addresses J code / NDC dilemma.
- Medical necessity and re-determinations.
- Challenges of managing off-label use.
- Conflicting messages to physicians.
- Lack of outcomes data: Cost/benefit; ROI.
- Need for comparative effectiveness research.
- Lab and diagnostic testing pipeline.

Provider Reimbursement

Pharmacies (self-injectables)
Physicians (office-administered injectables)
Change in Methodology
Discounts

Provider Reimbursement: Horizon BCBSNJ Experience

- Specialist contracting / guidelines.
- Physician buy and bill: reimbursement based on actual acquisition cost.
- Pay for administration, eliminate margin on drug price.
- Class of trade considerations.
- Place of service cost differentials.
- Price points to drive appropriate care; avoid driving utilization to hospitals.
- Maximum Allowable Cost (MAC) pricing.
- Voluntary specialty pharmacy acquisition.
- Comprehensive audit program.

Focus Is On Specialists to Manage Cost and Insure Best Outcomes.

"Specialists are poised to become major players in the new healthcare economy…Getting (and staying) up to speed on such specialist-specific complexities as practice economics, referral flows, and product reimbursement-and-utilization management is crucial for both drug developers and marketers."

THE TWO TOP FOCUS-ON-THE-SPECIALIST DRIVERS

1. Managed Care Plans and Medicare HMOs face growing pressure to manage cost and use specialty products; they will gradually move away from a model where the primary care physician (PCP) is invariably the gatekeeper and start looking to specialists, or specialists working in concert with PCPs, to make the best treatment decisions.

2. Patients Their need for chronic care is expanding, which leads to growing pressure to keep up with complex new treatments and advances in the molecular understanding of their conditions.

Source: M. Goodman "A Very Specialty Moment" 2007. Michael Goodman is editor-in-chief of Cambridge Healthtech Institute's Insight Pharma line of strategic reports (www.insightpharmareports.com).

Implementing New Specialty Provider Strategies

Mandatory Use of Specialty Pharmacy Providers

Expectations of the Specialty Pharmacy Delivery System

Implementing New Specialty Provider Strategies: Horizon BCBSNJ Experience

- Any Willing Provider laws impact ability to select providers of choice.
- Established credentialing requirements for dispensing specialty pharmaceuticals.
- Implemented mandatory use of specialty pharmacies.
- Exclusive specialty pharmacy option available for employer groups.
- Contract with pharmacies specializing in oncology to provide same day service to physician practices.
- Oral oncology management.
- Preferred product support.
- Manufacturer contracting (direct and through intermediaries).

Effective Management of Specialty Pharmaceuticals is Closely Linked to the Distribution System.

- Effective Specialty Pharmacy Management Programs Rely on Patient Selection, Risk Mitigation and Data Collection/Analysis.
- Some specialty drugs are associated with increased risk due to potentially harmful adverse effects, requiring increased safety surveillance.
- The FDA may require a formal risk minimization action plan (RiskMAP), using tools such as targeted education and outreach, reminder systems, and performance-linked systems to conduct such surveillance.
- Even if not required, specialty pharmacies and other organizations involved in the distribution of specialty drugs are positioned to provide these services and are being asked to do so by health plans.

Source: The Promise of Specialty Pharmaceuticals: Are They Worth the Price? Sean D. Sullivan, PhD. *J Manag Care Pharm.* 2008;14(4)(suppl S):S3-S6

Expectations of the Specialty Pharmacy Delivery System (more than distribution): Horizon BCBSNJ Experience

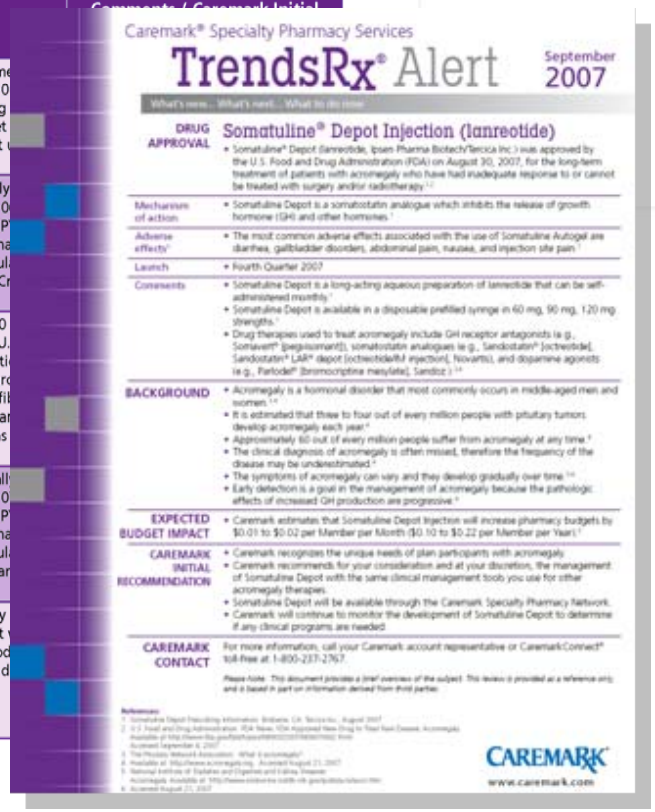
- Implement specialty-specific guideline management programs insuring consistent application across pharmacy and medical benefits.
- Manage waste (dose optimization; refill readiness).
- Conduct patient centric medication therapy management: optimize medication adherence (education, reminders, side-effect management).
- Serve as a resource and extension of the health plan's complex case management team, working with the patient, their physician(s), and other health professionals to coordinate care.
- Provide consumer education and support.
- Adhere to formulary and preferred product dispensing guidelines.
- Provide analytics and outcomes support for pipeline management.
- Provide plan-specific clinical and outcomes reporting.

Pipeline Management Requires Information, Analytics and Outcomes Support.

Specialty Pharmacy Pipeline Drugs to Watch

Anticipated Launches - 1st and 2nd Quarter 2007

Product Name	Proposed Indication	Route of Administration	FDA Phase of Study	Estimated Budget Impact or Disease Prevalence
Ambrisentan	The tx of pulmonary arterial hypertension (PAH)	Oral	Pending FDA Approval	Caremark estimates that Ambrisentan will increme increase pharmacy budgets by approximately $0.0 Member Per Month ($0.12 to $0.14 PMPY) during year on the market. The actual pharmacy budget will vary depending on your population's current medications for PAH.
Cimzia (certolizumab)	The tx of Crohn's disease	Injection-SC	Pending FDA Approval	Caremark estimates that Cimzia will incrementally increase pharmacy budgets by approximately $0.0 $0.09 Per Member Per Month ($0.78 to $1.09 PMP during its first year on the market. The actual pha budget impact will vary depending on your popul current use of medications for the treatment of Cr disease.
Kiacta (eprodisate)	The tx of secondary Amyloid A (AA) Amyloidosis	Oral	Pending FDA Approval	It is estimated that there are approximately 3,000 cases of amyloidosis diagnosed each year in the U. Canada. The disease results from an overproducti the protein serum amyloid A, in response to a chr inflammatory stimulus. The buildup of amyloid fi interferes with organ function, and results in a va health complications. Commonly affected organs the kidney, GI tract, liver, and spleen.
Mircera (Continuous Erythropoietin Receptor Activator)	The tx of anemia associated with chronic kidney disease	Injection-SC	Pending FDA Approval	Caremark estimates that Mircera will incrementall increase pharmacy budgets by approximately $0.0 $0.08 Per Member Per Month ($0.82 to $0.94 PMP during its first year on the market. The actual pha budget impact will vary depending on your popul current use of medications for the treatment of ar associated with chronic kidney disease.
Omnitrope (somatropin [rDNA origin])	The tx of growth disorders in children and adults	Injection-SC	Launched	It is anticipated that Omnitrope will not have any incremental impact on pharmacy budgets since it primarily be pulling market share from other prod currently marketed for the treatment of growth d in children and adults.



Caremark® Specialty Pharmacy Services

TrendsRx® Alert September 2007

What's new... What's next... What to do now

Somatuline® Depot Injection (lanreotide)

DRUG APPROVAL

- Somatuline® Depot (lanreotide, Ipsen Pharma Biotech/Tercica Inc.) was approved by the U.S. Food and Drug Administration (FDA) on August 30, 2007, for the long-term treatment of patients with acromegaly who have had inadequate response to or cannot be treated with surgery and/or radiotherapy.[1,2]

Mechanism of action
- Somatuline Depot is a somatostatin analogue which inhibits the release of growth hormone (GH) and other hormones.[1]

Adverse effects[1]
- The most common adverse effects associated with the use of Somatuline Autogel are diarrhea, gallbladder disorders, abdominal pain, nausea, and injection site pain.[1]

Launch
- Fourth Quarter 2007

Comments
- Somatuline Depot is a long-acting aqueous preparation of lanreotide that can be self-administered monthly.[1]
- Somatuline Depot is available in a disposable prefilled syringe in 60 mg, 90 mg, 120 mg strengths.[1]
- Drug therapies used to treat acromegaly include GH receptor antagonists (e.g., Somavert® [pegvisomant]), somatostatin analogues (e.g., Sandostatin® [octreotide], Sandostatin® LAR® depot [octreotide/ReFit injection], Novartis), and dopamine agonists (e.g., Parlodel® [bromocriptine mesylate], Sandoz).[3,4]

BACKGROUND

- Acromegaly is a hormonal disorder that most commonly occurs in middle-aged men and women.[3,4]
- It is estimated that three to four out of every million people with pituitary tumors develop acromegaly each year.[3]
- Approximately 60 out of every million people suffer from acromegaly at any time.[3]
- The clinical diagnosis of acromegaly is often missed, therefore the frequency of the disease may be underestimated.[3]
- The symptoms of acromegaly can vary and they develop gradually over time.[3,4]
- Early detection is a goal in the management of acromegaly because the pathologic effects of increased GH production are progressive.[3]

EXPECTED BUDGET IMPACT

- Caremark estimates that Somatuline Depot Injection will increase pharmacy budgets by $0.01 to $0.02 per Member per Month ($0.10 to $0.22 per Member per Year).[1]

CAREMARK INITIAL RECOMMENDATION

- Caremark recognizes the unique needs of plan participants with acromegaly.
- Caremark recommends for your consideration and at your discretion, the management of Somatuline Depot with the same clinical management tools you use for other acromegaly therapies.
- Somatuline Depot will be available through the Caremark Specialty Pharmacy Network.
- Caremark will continue to monitor the development of Somatuline Depot to determine if any clinical programs are needed.

CAREMARK CONTACT

For more information, call your Caremark account representative or CaremarkConnect® toll-free at 1-800-237-2767.

Please Note: This document provides a brief overview of the subject. This review is provided as a reference only and is based in part on information derived from third parties.

References:

1. Somatuline Depot Prescribing Information. Bridgewater, UK: Tercica Inc.; August 2007.
2. U.S. Food and Drug Administration. FDA News. FDA Approved New Drug to Treat Rare Disease, Acromegaly. Available at http://www.fda.gov/bbs/topics/NEWS/2007/NEW01692.html. Accessed September 6, 2007.
3. The Pituitary Network Association. What is acromegaly? Available at: http://www.acromegaly.org. Accessed August 21, 2007.
4. National Institute of Diabetes and Digestive and Kidney Diseases. Acromegaly. Available at http://www.endocrine.niddk.nih.gov/pubs/acromegaly/. Accessed August 21, 2007.

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Therapeutic Class Management Requires Plan-specific Advanced Clinical, Financial and Outcomes Reporting.

Estimated Financial Value

Services	Utilizing Members	Average Financial Value per Utilizing Member	* Estimated Total Financial Value
Hemophilia Assay Management	1	$6,276 - $7,671	$6,276 - $7,671
Multiple Sclerosis Total Healthcare Cost	18	$1,467 - $1,794	$26,414 - $32,284
Rheumatoid Arthritis Total Healthcare Cost	27	$2,456 - $3,002	$66,312 - $81,047
Grand Total			**$99,002 - $121,002**

Source: Caremark Data Warehouse & Internal Sources

Hemophilia Assay Management

is the management of hemophilia assays by rigidly dispensing factor concentrate assays as close to the prescribed dose as possible which results in cost savings and minimizing the impact of a patients' lifetime maximum usage.

Total Healthcare Costs

Total Healthcare Costs for Multiple Sclerosis (MS) and Rheumatoid Arthritis (RA) were calculated from a proprietary predictive model. The model uses a person's pharmacy claims to compute an Adherence Risk Score, which then correlates to a prediction of that person's future healthcare costs. Specifically, the Adherence Risk Score takes into account a person's compliance, persistency, and therapeutic complexity. In simplest terms, a person with poor adherence and several medications is at a greater risk of higher future Total Healthcare Costs than a person with excellent adherence to a single medication.

The predictive model was created with regression techniques that used both medical and pharmacy claims. Multiple clients representing both health plans and employers contributed data for the analysis, encompassing approximately 1.9 million eligible lives. The model was built using claims for services in 2003 and 2004, with an added inflation factor to predict costs in future dollars. The study population included 1,857 specialty patients (1,013 for MS and 844 for RA) who were each eligible for benefits during the entire study period and were at least 17 years old.

* This analysis is an estimate for information purposes only. These estimates do not represent an existing or future contractual guarantee provided by Caremark. This information is subject to change and will not represent any specific offer by Caremark of return on investment in the future.

Benefit Design

Coverage Determination

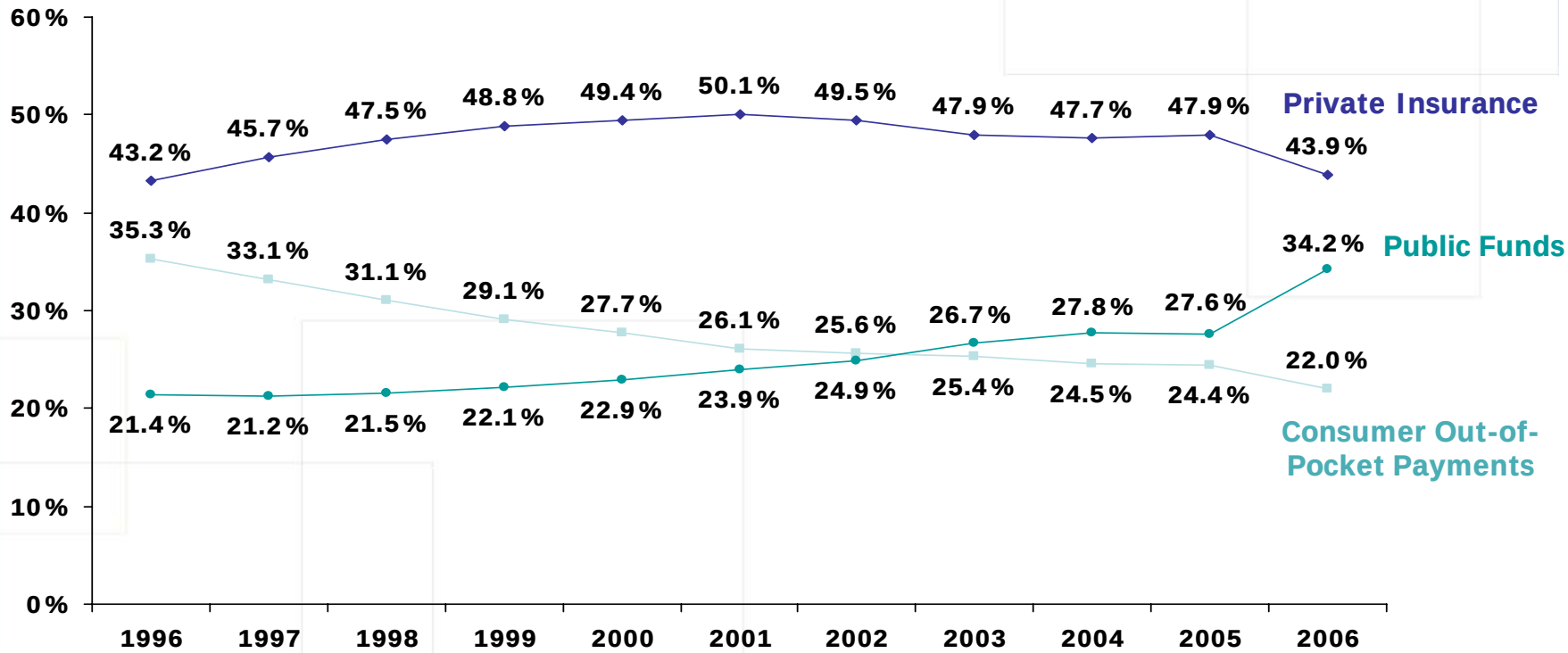
Medical vs. Pharmacy Benefit

Patient Cost Share (self injectables)

Benefit Design:
Horizon BCBSNJ Experience

- Medical vs. pharmacy benefit.
- When carve-outs lead to gaps in coverage.
- Goal: Meet employer demands and patient needs.
- Formulary management: more "me-too" drugs enable formulary management and opportunities for cost savings.
- Co-pay differentials may not be sufficient to drive use of preferred products.
- State regulations prohibit higher co-pay tier for specialty drugs.
- Coinsurance with out-of-pocket maximums – requires integrated medical and pharmacy claims processing.
- Impact of coverage mandates.
- What about vaccines?

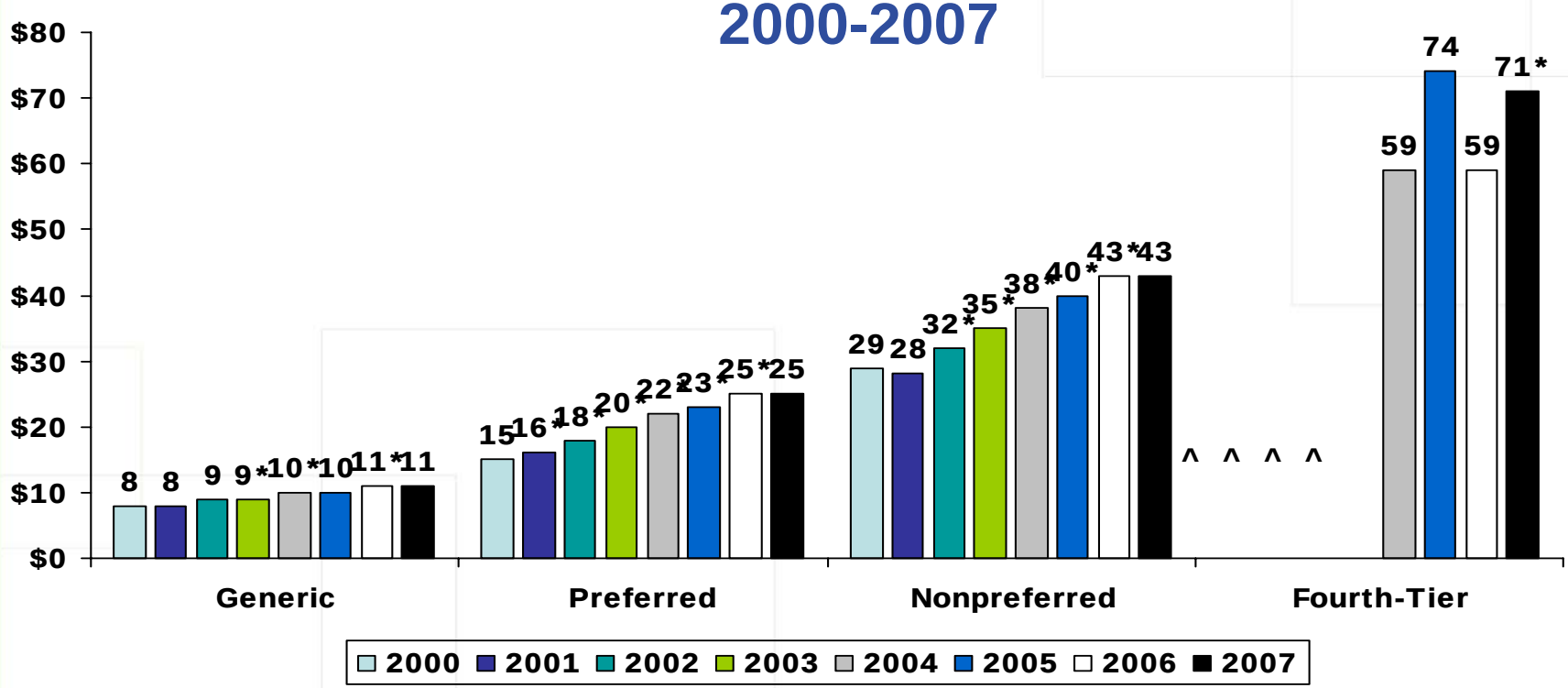
Distribution of National Prescription Drug Expenditures by Source of Payment, 1996-2006



Notes: Percentages may not total 100% due to rounding.

Source: Kaiser Family Foundation calculations using NHE data from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, at http://www.cms.hhs.gov/NationalHealthExpendData/ (see Historical; National Health Expenditures by type of service and source of funds, CY 1960-2006; file nhe2006.zip).

Among Covered Workers with Three or Four-Tier Prescription Drug Cost Sharing
Average Copayments
2000-2007



* Estimate is statistically different from estimate for the previous year shown (p<.05).

^ Fourth-tier drug copayment information was not obtained prior to 2004.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000-2007.

Managing Specialty Pharmaceuticals: Balancing Access and Affordability - Takeaways

- Use Pipeline Information for Planning and Strategy
  - Research and development process
  - Comparative effectiveness research
  - Pathway for approval of bio-generics to insure safety and effectiveness
- Establish Effective Distribution Channels: Contracting for Products and Services
  - Physicians/pharmacies for office-administered injectables
  - Pharmacies for self injectables and distribution to offices
  - Hospitals and facilities for injectables requiring special support services
- Use an Integrated Approach to Manage Utilization and Achieve Desired Outcomes
  - Integrate pharmacy and medical benefit management
  - Apply clinical guidelines consistently
- Apply Benefit Design Approaches to Meet Employer Demands and Patient Needs
  - Provide affordable access to specialty pharmaceuticals