Managing Specialty Pharmaceuticals: Balancing Access and Affordability

Commercial Health Plan Perspective

The Health Industry Forum
July 16, 2008

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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 Healthcare 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.

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.

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**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Proposed Indication</th>
<th>Route of Administration</th>
<th>FDA Phase of Study</th>
<th>Estimated Budget Impact or Disease Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambisentan</td>
<td>The tx of pulmonary arterial hypertension (PAH)</td>
<td>Oral</td>
<td>Pending FDA Approval</td>
<td>Caremark estimates that Ambisentan will increase pharmacy budgets by approximately $0.12 to $0.14 PMM during its first year on the market. The actual pharmacy budget impact will vary depending on your population's current use of medications for PAH.</td>
</tr>
<tr>
<td>Cinzla (cetuximab)</td>
<td>The tx of G0hn's disease</td>
<td>Injection-SC</td>
<td>Pending FDA Approval</td>
<td>Caremark estimates that Cinzla will increase pharmacy budgets by approximately $0.08 to $0.10 PMM during its first year on the market. The actual pharmacy budget impact will vary depending on your population's current use of medications for the treatment of G0hn's disease.</td>
</tr>
<tr>
<td>Klaxta (ercolinatate)</td>
<td>The tx of secondary Amyloid A (AA) Amyloidosis</td>
<td>Oral</td>
<td>Pending FDA Approval</td>
<td>It is estimated that there are approximately 1,000 cases of amyloidosis diagnosed each year in the United States and Canada. The disease results from an overproduction of the protein amyloid A, in response to a chronic inflammatory stimulus. The buildup of amyloid fibrils interferes with organ function, and results in a variety of health complications. Commonly affected organs include the kidney, GI tract, liver, and spleen.</td>
</tr>
<tr>
<td>Mircea (Continuous Erythropoietin Receptor Activator)</td>
<td>The tx of anemia associated with chronic kidney disease</td>
<td>Injection-SC</td>
<td>Pending FDA Approval</td>
<td>Caremark estimates that Mircea will increase pharmacy budgets by approximately $0.08 to $0.10 PMM during its first year on the market. The actual pharmacy budget impact will vary depending on your population's current use of medications for the treatment of anemia associated with chronic kidney disease.</td>
</tr>
<tr>
<td>Omnipor (somatropin [hDNA origin])</td>
<td>The tx of growth disorders in children and adults</td>
<td>Injection-SC</td>
<td>Launched</td>
<td>It is anticipated that Omnipor will not have any incremental impact on pharmacy budgets since it will primarily be pulling market share from other products currently marketed for the treatment of growth disorders in children and adults.</td>
</tr>
</tbody>
</table>
Therapeutic Class Management Requires Plan-specific Advanced Clinical, Financial and Outcomes Reporting.

### Estimated Financial Value

<table>
<thead>
<tr>
<th>Services</th>
<th>Utilizing Members</th>
<th>Average Financial Value per Utilizing Member</th>
<th>* Estimated Total Financial Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemophilia Assay Management</td>
<td>1</td>
<td>$6,276 - $7,671</td>
<td>$5,276 - $7,671</td>
</tr>
<tr>
<td>Multiple Sclerosis Total Healthcare Cost</td>
<td>10</td>
<td>$1,467 - $1,794</td>
<td>$26,414 - $32,284</td>
</tr>
<tr>
<td>Rheumatoid Arthritis Total Healthcare Cost</td>
<td>27</td>
<td>$2,456 - $3,002</td>
<td>$85,312 - $88,1,047</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td></td>
<td></td>
<td><strong>$99,002 - $121,002</strong></td>
</tr>
</tbody>
</table>

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 patient's 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, persistence, 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 claims 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 D13 for MS and 544 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 guarantees 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.

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

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.

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