Managing Biopharmaceuticals in the Private Health Insurance Sector

CMS “Region IX University”
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James C. Robinson
Kaiser Permanente Professor of Health Economics
Director, Berkeley Center for Health Technology
University of California, Berkeley
OVERVIEW

- Zero sum and positive sum games
- Market strategies for manufacturers and insurers
  - Immunology example: Rheumatoid arthritis
- Appropriate utilization
  - Care management, companion diagnostics
  - Benefit design and consumer cost sharing
- Distribution and physician practice economics
- Performance-based pricing
Market Strategies: Biopharma and Insurers

- Are manufacturers and insurers engaged in a zero sum game in the market?
  - Zero sum: your gain is my loss, and vice versa.
  - Manufacturers favor premium pricing, extended patent protection, coverage without restrictions, no financial barriers for patients, favorable reimbursement for physician practices
  - Insurers favor commodity pricing, biosimilars, prior authorization, consumer cost sharing, reduced payments for distribution through physician practices

- Can this be changed to a positive sum game?
  - We both gain overall from playing, even if our interests diverge at times (zero sum sub-games)
Biologics offer major therapeutic benefits to patients, especially for those with most severe conditions

- Cancer, auto-immune conditions, genetic illness
- The biopharmaceutical sector is a valuable economic sector, building on science and technology, providing high-skill, high-wage, export-oriented jobs
- High revenues are needed to fuel R&D and innovation
- Biologics are very expensive per patient and are rising at double-digit rates of expenditure growth
- Cost growth is principal cause of un-insurance and under-insurance as well as strains on federal and state budgets
- Health plans, both public and private, must manage cost growth trends as well as cost levels
- How to balance innovation and affordability?
Management Strategies for Private Insurers

1. Enhancing appropriate utilization
   – Prior authorization and early intervention
   – Care management: safety monitoring and patient education

2. Benefit design and consumer cost sharing
   – Tiered formulary for specialty drugs

3. Distribution and physician practice economics
   – Specialty pharmacy and buy-and-bill

4. Performance-based pricing
Rheumatoid Arthritis as an Example

- Major condition afflicting both seniors and working adults
- Major expenditure category for Medicare and employment-based insurance
- Significant medical costs and productivity costs
- Rapid introduction of effective but costly new biologics
- Multiple (branded, not biosimilar) products create emerging potential role for price competition, formulary strategies for biologics
- RA hence provides insight into the future evolution of the market for biopharmaceuticals for oncology and other major conditions
Top RA Drugs Utilized Based on Paid
Service Date between 7/1/2006 – 6/30/2008

<table>
<thead>
<tr>
<th>Drug</th>
<th>Paid</th>
<th>% of Paid</th>
<th>Mbrs</th>
<th>% of Mbrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMICADE</td>
<td>$89,736,667</td>
<td>32.4%</td>
<td>2861</td>
<td>12.8%</td>
</tr>
<tr>
<td>ENBREL</td>
<td>$85,261,154</td>
<td>30.8%</td>
<td>4172</td>
<td>18.7%</td>
</tr>
<tr>
<td>HUMIRA</td>
<td>$61,731,384</td>
<td>22.3%</td>
<td>2987</td>
<td>13.4%</td>
</tr>
<tr>
<td>ORENCIA</td>
<td>$11,423,856</td>
<td>4.1%</td>
<td>831</td>
<td>3.7%</td>
</tr>
<tr>
<td>RITUXAN</td>
<td>$10,818,816</td>
<td>3.9%</td>
<td>528</td>
<td>2.4%</td>
</tr>
<tr>
<td>CELEBREX</td>
<td>$4,015,979</td>
<td>1.5%</td>
<td>3055</td>
<td>13.7%</td>
</tr>
<tr>
<td>METHOTREXATE</td>
<td>$3,213,967</td>
<td>1.2%</td>
<td>12283</td>
<td>55.1%</td>
</tr>
<tr>
<td>LEFLUNOMIDE</td>
<td>$2,766,610</td>
<td>1.0%</td>
<td>2532</td>
<td>11.4%</td>
</tr>
<tr>
<td>HYDROXYCHLOROQUINE</td>
<td>$1,381,051</td>
<td>0.5%</td>
<td>5627</td>
<td>25.2%</td>
</tr>
<tr>
<td>KINERET</td>
<td>$990,552</td>
<td>0.4%</td>
<td>71</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

RA Drug Spend by Drug Type

- dmard-bio, 94.0%
- dmard-nb, 3.3%
- nsaid, 2.4%
- steroid, 0.3%
- Other, 2.7%
Highest-Priority Therapy Categories

On a scale from 1 to 5, where 1 = lowest priority and 5 = highest priority, rate the priority to manage each drug category.

Mean = 3.34
Enhancing Appropriate Utilization: Patient Identification

- The basic trade: manufacturers agree to help insurers contain use within evidence-based appropriateness, while insurers agree to help manufacturers identify patients who would benefit but are currently not on drug

- Cooperation on guidelines for appropriate use
  - FDA label, off-label: prior authorization
  - Severity: step therapy v. early intervention
  - Leapfrog over step therapy for early responders

- Companion diagnostic for early identification of patients who would benefit from treatment?
Prior Authorization Required by Drug Category

Indicate which of the following therapeutic classes/products require PA for coverage under each benefit.

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Pharmacy Benefit</th>
<th>Medical Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growth Hormones</td>
<td>94%</td>
<td>84%</td>
</tr>
<tr>
<td>Psoriasis (SC)</td>
<td>81%</td>
<td>79%</td>
</tr>
<tr>
<td>Rheumatoid Arthritis (SC)</td>
<td>69%</td>
<td>64%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>93%</td>
<td>90%</td>
</tr>
<tr>
<td>Oncology (Oral)</td>
<td>84%</td>
<td>81%</td>
</tr>
<tr>
<td>Asthma</td>
<td>70%</td>
<td>79%</td>
</tr>
</tbody>
</table>

Compare and Contrast
Compared to the 2007 data, the 2008 survey data identified:
- Higher use of prior authorization for psoriasis and lower use of prior authorization for self-administered multiple sclerosis therapies.
Prior Authorization for RA in Private Insurance

- Criteria for coverage and payment to physicians and pharmacy
  - Diagnosis of RA made by specialists, not physician generalist
  - Drug authorization for RA (on-label use)
  - Step therapy: patient must have failed on 6 month of MTX + NSAIDs
  - During that time period, patient must have:
    - No decrease in number of swollen or painful joints,
    - No decrease in pain or disability,
    - No improvement in global assessment that includes patient activity/functional assessment, OR
    - Radiographic evidence of disease progression
  - OR patient cannot tolerate MTX due to documented side effects
Enhancing Appropriate Utilization: Care Management

- All patients using high-cost and potentially toxic biologics should be in care management (CM)
- The basic trade: Insurers agree that a major goal of CM is to maintain continuance of therapy (as is often appropriate) by resolving financial barriers, adverse effects, convenience problems.
- Manufacturers agree that goals of CM also include safety monitoring, identifying patients who should discontinue therapy.
Accordant DM program

What Can Members Expect from the Accordant Program?

- Introductory wellness/case phased call from AHS nurse
- Quarterly condition-specific assessment calls
- A personal Disease Management nurse
- Individualized interventions and condition-specific education
- Assistance with coordination of care and resource needs
- Physician (PCP and specialists) notification/elevation
- Identify members on general wellness and condition-specific topics (alternating monthly) and other educational material as needed
- Access to disease-specific communities at www.accordant.com
- 24/7 access to nurse specialists

Call Center is staffed Monday through Thursday 8 AM to 10 PM EST.

Disease Management Intervention Strategies

- Promote Better Self-Management Skills
  - Access, Education, Communication, Compliance
- Prevent Disease Complications
  - Risk Stratify, Assess, Monitor, Refer
- Promote Drug Safety
  - Education, Monitoring, Compliance, Interactions/Continuations
- Enhance Patient’s Ability to Cope
  - Psychosocial, Advance Directives, Community Resources
- Promote “Stay Healthy” Behaviors
  - Wellness/Prevention
- Promote Care Coordination
Benefit Design: Cost Sharing

- Consumers must be conscious of the cost of care, and cost sharing can guide appropriate choices.
- But some patients avoid effective and cost-effective treatments due to cost-sharing.
- “Value-based insurance design” (VBID) shifts cost-effective drugs to “tier” with lower cost sharing.
- VBID for immunology biologics?
  - Complications: benefit design and cost share differ between office administered infused drugs (e.g., Remicade, Rituxan) v. self-administered injected drugs (e.g., Enbrel, Humira).
Benefit Coverage of Specialty Pharmaceuticals by Drug Category

Indicate the benefit under which each drug is typically covered for your most common benefit structure.

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Medical benefit</th>
<th>Pharmacy benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary Arterial Hypertension (Oral)</td>
<td>2%</td>
<td>96%</td>
</tr>
<tr>
<td>Oncology (Oral)</td>
<td>7%</td>
<td>93%</td>
</tr>
<tr>
<td>Multiple Sclerosis (IN, SC)</td>
<td>11%</td>
<td>89%</td>
</tr>
<tr>
<td>Rheumatoid Arthritis (SC)</td>
<td>11%</td>
<td>99%</td>
</tr>
<tr>
<td>Growth Hormone</td>
<td>13%</td>
<td>88%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>16%</td>
<td>84%</td>
</tr>
<tr>
<td>Psoriasis (SC)</td>
<td>40%</td>
<td>60%</td>
</tr>
<tr>
<td>Infertility</td>
<td>41%</td>
<td>59%</td>
</tr>
<tr>
<td>Erythropoiesis-Stimulating Agents</td>
<td>52%</td>
<td>44%</td>
</tr>
<tr>
<td>Granulocyte-Macrophage Colony-Stimulating Factor</td>
<td>56%</td>
<td>44%</td>
</tr>
<tr>
<td>Psoriasis (IM)</td>
<td>67%</td>
<td>33%</td>
</tr>
<tr>
<td>Asthma</td>
<td>72%</td>
<td>28%</td>
</tr>
<tr>
<td>Respiratory Syncytial Virus</td>
<td>73%</td>
<td>27%</td>
</tr>
<tr>
<td>Hemophilia Factor</td>
<td>75%</td>
<td>25%</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>77%</td>
<td>23%</td>
</tr>
<tr>
<td>Pulmonary Arterial Hypertension (IV)</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>Lysosomal Storage Diseases</td>
<td>83%</td>
<td>17%</td>
</tr>
<tr>
<td>Immunoglobulin (V)</td>
<td>85%</td>
<td>15%</td>
</tr>
<tr>
<td>Multiple Sclerosis (IV)</td>
<td>85%</td>
<td>15%</td>
</tr>
<tr>
<td>Rheumatoid Arthritis (IV)</td>
<td>82%</td>
<td>8%</td>
</tr>
<tr>
<td>Oncology (IV)</td>
<td>98%</td>
<td>2%</td>
</tr>
</tbody>
</table>
Pharmacy and Medical Benefit Cost Share Methods

Describe the most common share methodology for specialty drugs covered under each line of business.

- **Commercial Pharmacy Benefit**
  - No cost share: 2%
  - Flat cost share: 46%
  - Tiered cost share: 53%

- **MA-PD Pharmacy Benefit**
  - No cost share: 2%
  - Flat cost share: 26%
  - Tiered cost share: 72%

- **Commercial Medical Benefit**
  - No cost share: 5%
  - Flat cost share: 25%
  - Tiered cost share: 70%

- **MA-PD Medical Benefit**
  - No cost share: 4%
  - Flat cost share: 32%
  - Tiered cost share: 64%
### Employer Trends 2000-2008

Among Covered Workers with Three, Four, or More Tiers of Prescription Cost Sharing, Average Copayments and Average Coinsurance, 2000–2008

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<thead>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Average Copayments</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-Tier Drugs, Often Called Generic</td>
<td>$8</td>
<td>$8</td>
<td>$9</td>
<td>$9*</td>
<td>$10*</td>
<td>$10</td>
<td>$11*</td>
<td>$11</td>
<td>$10</td>
</tr>
<tr>
<td>Second-Tier Drugs, Often Called Preferred</td>
<td>$15</td>
<td>$16*</td>
<td>$18*</td>
<td>$20*</td>
<td>$22*</td>
<td>$23*</td>
<td>$25*</td>
<td>$25</td>
<td>$26</td>
</tr>
<tr>
<td>Third-Tier Drugs, Often Called Nonpreferred</td>
<td>$29</td>
<td>$28</td>
<td>$32*</td>
<td>$35*</td>
<td>$38*</td>
<td>$40*</td>
<td>$43*</td>
<td>$43</td>
<td>$46*</td>
</tr>
<tr>
<td>Fourth-Tier Drugs</td>
<td>^</td>
<td>^</td>
<td>^</td>
<td>^</td>
<td>$59</td>
<td>$74</td>
<td>$59</td>
<td>$71*</td>
<td>$75</td>
</tr>
<tr>
<td><strong>Average Coinsurance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First-Tier Drugs, Often Called Generic</td>
<td>18%</td>
<td>18%</td>
<td>18%</td>
<td>18%</td>
<td>18%</td>
<td>19%</td>
<td>19%</td>
<td>21%</td>
<td>21%</td>
</tr>
<tr>
<td>Second-Tier Drugs, Often Called Preferred</td>
<td>NSD</td>
<td>23%</td>
<td>24%</td>
<td>23%</td>
<td>25%</td>
<td>27%</td>
<td>26%</td>
<td>26%</td>
<td>25%</td>
</tr>
<tr>
<td>Third-Tier Drugs, Often Called Nonpreferred</td>
<td>28%</td>
<td>33%</td>
<td>40%</td>
<td>34%*</td>
<td>34%</td>
<td>38%</td>
<td>38%</td>
<td>40%</td>
<td>38%</td>
</tr>
<tr>
<td>Fourth-Tier Drugs</td>
<td>^</td>
<td>^</td>
<td>^</td>
<td>^</td>
<td>^</td>
<td>30%</td>
<td>43%*</td>
<td>42%</td>
<td>36%</td>
</tr>
</tbody>
</table>

**Source:**

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

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

NSD: Not Sufficient Data.
Consumer Cost Sharing: The Basic Trade

- Insurer places a drug in tier with minimal cost sharing if:
  - The patient is an appropriate candidate (according to coverage criteria, prior authorization, companion diagnostic), and
  - The patient cooperates with care management program, and
  - The drug is obtain through appropriate distribution channel (e.g. specialty pharmacy) and physician practice, and
  - The drug is priced based on performance (see below)

- Otherwise, drug is placed in tier with high cost sharing
Distribution and Physician Practice: The Basic Trade

- Manufacturer cooperates with insurer in moving practices from markups to specialty pharmacy (and/or B&B without big markup), good data capture, coordination of office administration with care management program.

- Insurer agrees not to design reimbursement and consumer benefits that discriminate against office administered drugs, and to raise professional fees to replace drug markups.
Performance-based Pricing

- Manufacturer’s preference: list price, based on reference product price plus differentiator ($V=R+D$)
  - $V$=Value-based price
  - $R$=Reference product price
  - $D$=Difference between new and reference drug
- Without therapeutic substitution, manufacturer wins
- With widespread therapeutic substitution, insurer wins
- With limited but growing substitution, is there a trade?
Number of Preferred Products by Therapeutic Category

Indicate the number of preferred products for each of the following therapeutic classes/products.

Therapeutic Category

- Growth Hormones
- Multiple Sclerosis
- Rheumatoid Arthritis
- Erythropoetin-Stimulating Agents
- Hepatitis C
- Psoriasis
- Granulocyte Macrophage Colony-Stimulating Factor
- Pulmonary Arterial Hypertension Agents (Oral)
- Infertility—Follicle-Stimulating Hormone

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Performance-Based Pricing

- Performance-based price: \( P = R + D + E \)
  - \( P \): performance-based price
  - \( R \): reference price of lowest cost therapeutic equivalent, using comparative effectiveness studies to determine equivalence
  - \( D \): difference between new and reference drug, updated with new evidence on efficacy, safety, patient experience
  - \( E \): efficiencies from cooperation: criteria for appropriate use, care management, consumer cost sharing, distribution, physician practice support, data capture and analysis
Conclusion and summary

- Public policy is wavering between replacing and supporting market forces in health care
- Positive sum game for manufacturers and insurers: areas of potential cooperation
  - Patient identification and care management
  - Value-based insurance design and cost sharing
  - Distribution and physician practice support
  - Performance-based pricing $P = R + D + E$
- Immunology as a leading example