



# **Managing Biopharmaceuticals in the Private Health Insurance Sector**

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**James C. Robinson**

Kaiser Permanente Professor of Health Economics  
Director, Berkeley Center for Health Technology  
University of California, Berkeley

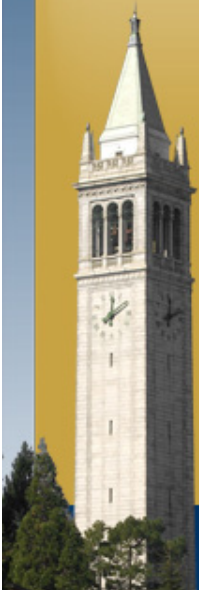
# OVERVIEW

- 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



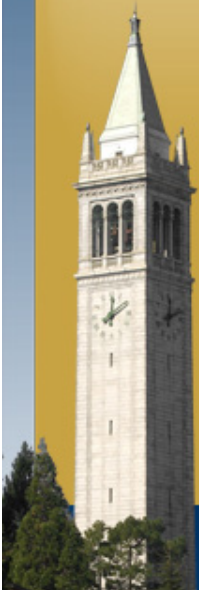
## Market Strategies: Biopharma and Insurers

- 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)



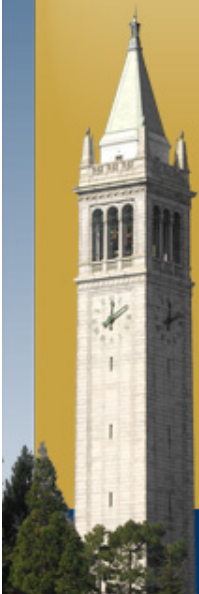
# Importance of Positive Sum Games in Biopharmacy

- 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?



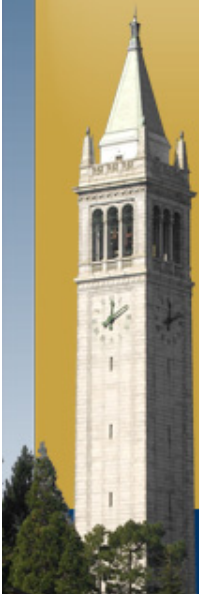
# Management Strategies for Private Insurers

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



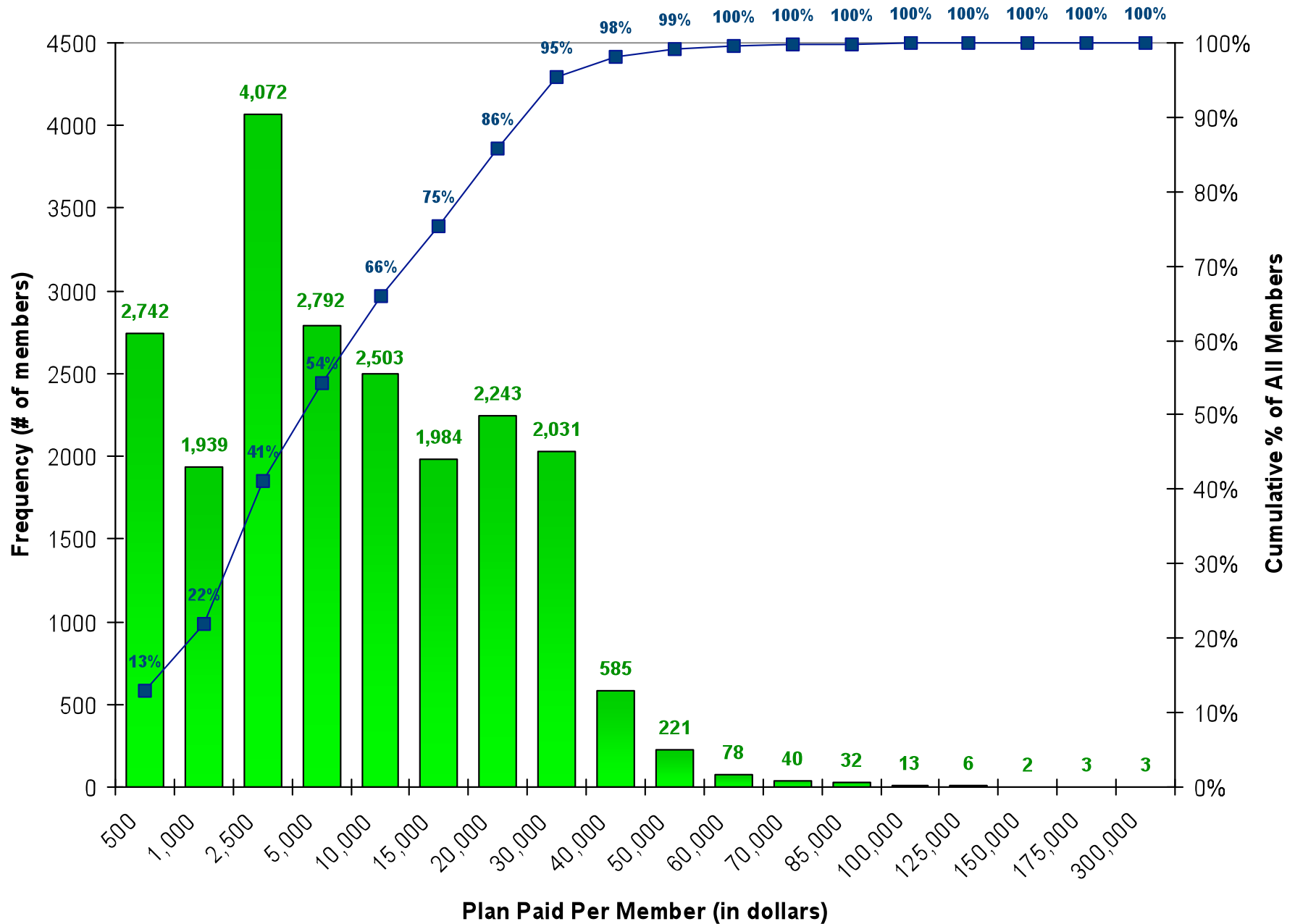
# Rheumatoid Arthritis as an Example

- 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



## Annualized Rx Spend Distribution Histogram

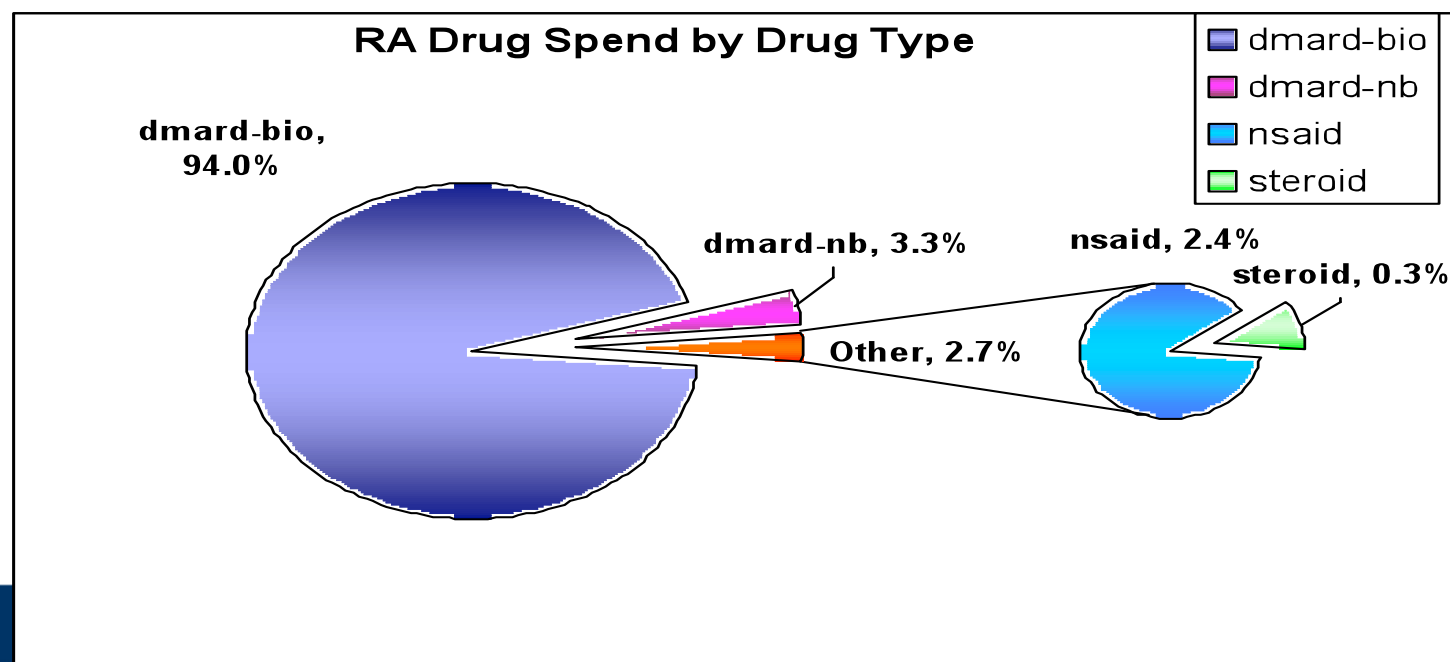
Based on Claims with Service Date between 07/01/2006 - 06/30/2008



## Top RA Drugs Utilized Based on Paid

Service Date between 7/1/2006 – 6/30/2008

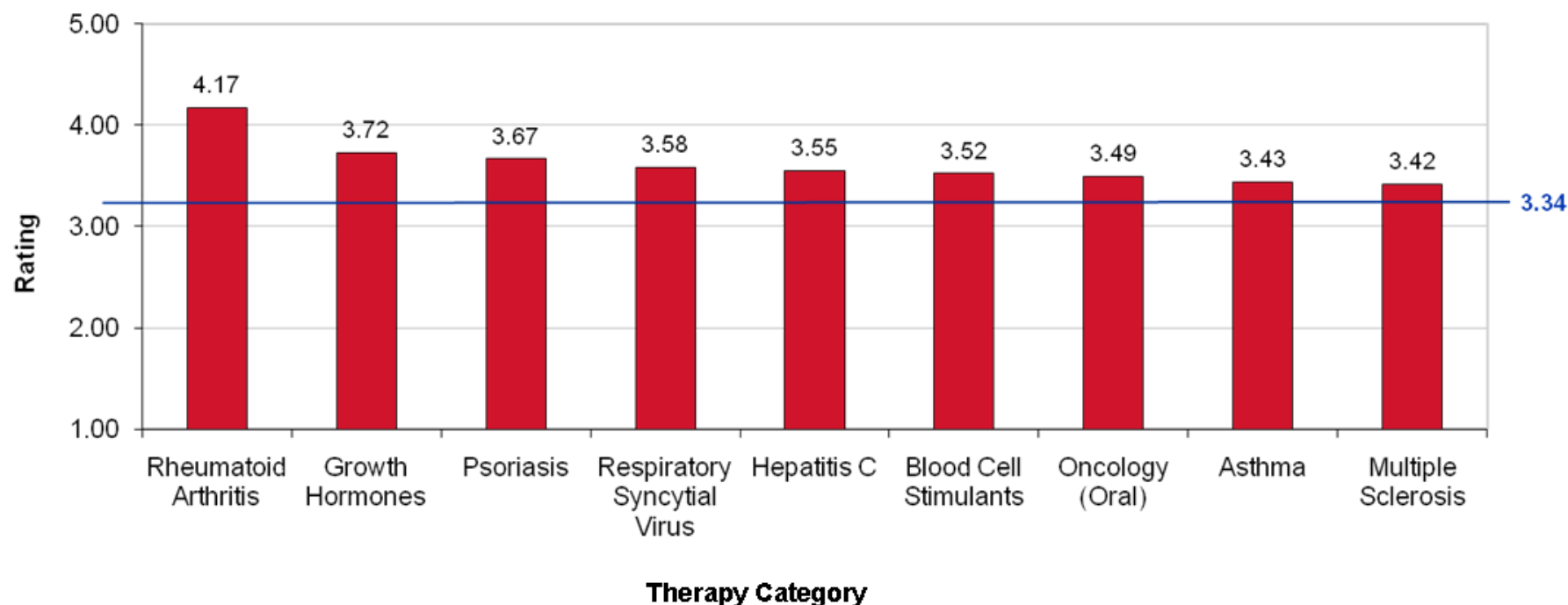
Drug	Paid	% of Paid	Mbrs	% of Mbrs
REMICADE	\$ 89,736,667	32.4%	2861	12.8%
ENBREL	\$ 85,261,154	30.8%	4172	18.7%
HUMIRA	\$ 61,731,384	22.3%	2987	13.4%
ORENCIA	\$ 11,423,856	4.1%	831	3.7%
RITUXAN	\$ 10,818,816	3.9%	528	2.4%
CELEBREX	\$ 4,015,979	1.5%	3055	13.7%
METHOTREXATE	\$ 3,213,967	1.2%	12283	55.1%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





# 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

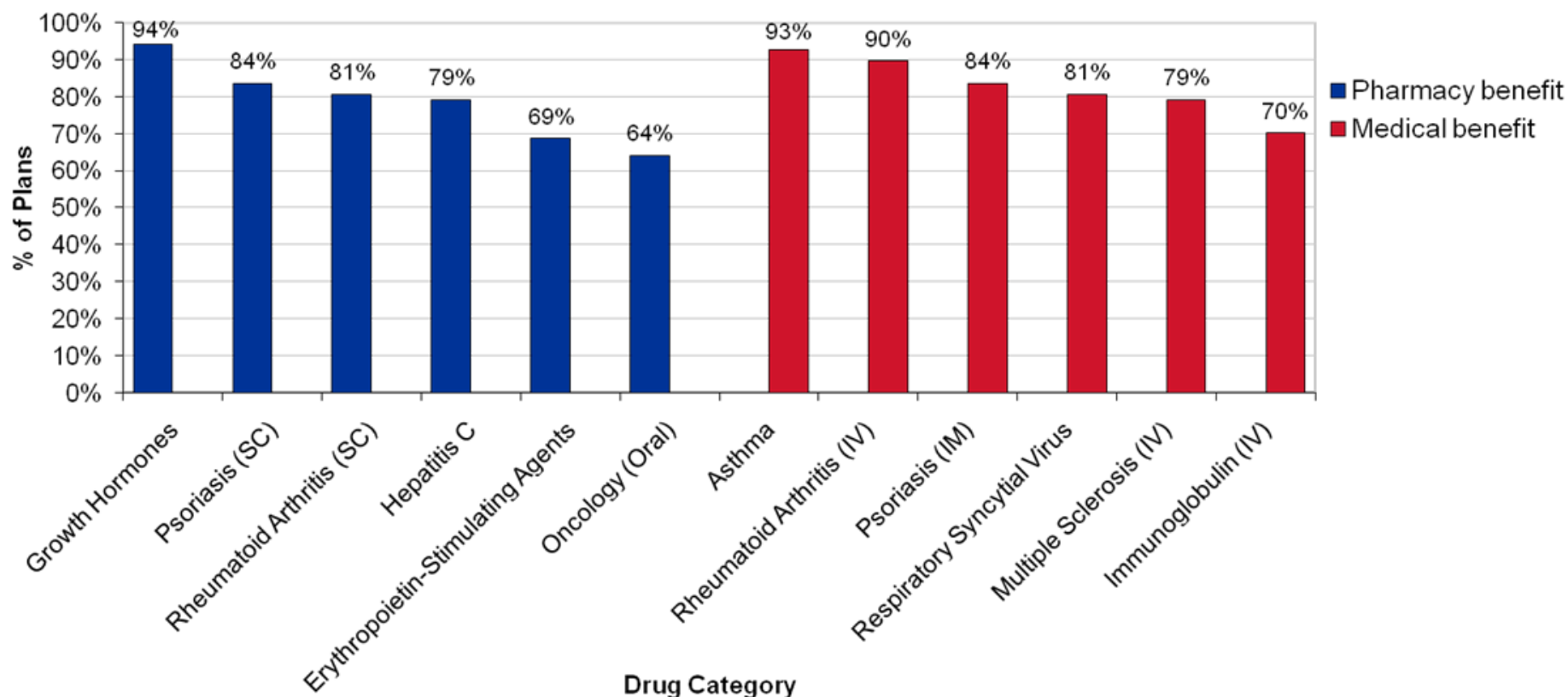
- The basic trade: manufacturers agree to help insurers contain use within evidence-based appropriateness, while insurers agree to help manufacturers identify patients who would benefit but are currently not on drug
- Cooperation on guidelines for appropriate use
  - FDA label, off-label: prior authorization
  - 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.



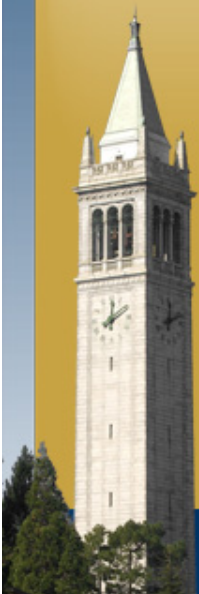
## **Compare and Contrast**

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

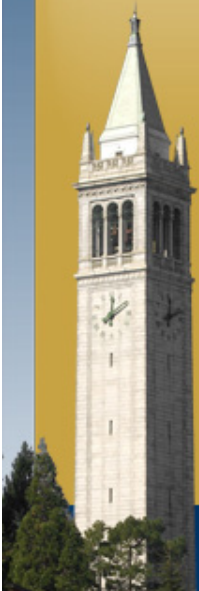
## Prior Authorization for RA in Private Insurance

- 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 information phone call from NHS 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 specialist) notification/education
- Monthly newsletters on general wellness and condition-specific topics (alternating months) and other educational material as needed
- Access to disease-specific communities at [www.accordant.com](http://www.accordant.com)
- 24/7 access to nurse specialists



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



## Disease Management Intervention Strategies



- **Promote Better Self-Management Skills**
  - Access, Education, Communication, Compliance
- **Prevent Disease Complications**
  - Risk Stratify, Assess, Monitor, Treat
- **Promote Drug Safety**
  - Education, Monitoring, Compliance, Interaction/Contraindications

- **Enhance Participant's Ability to Cope**
  - Psycho-social, Advance Directive, Community Resources
- **Promote "Stop-Healthy" Behavior**
  - Wellness/Prevention
- **Provide Care Coordination**



## Benefit Design: Cost Sharing

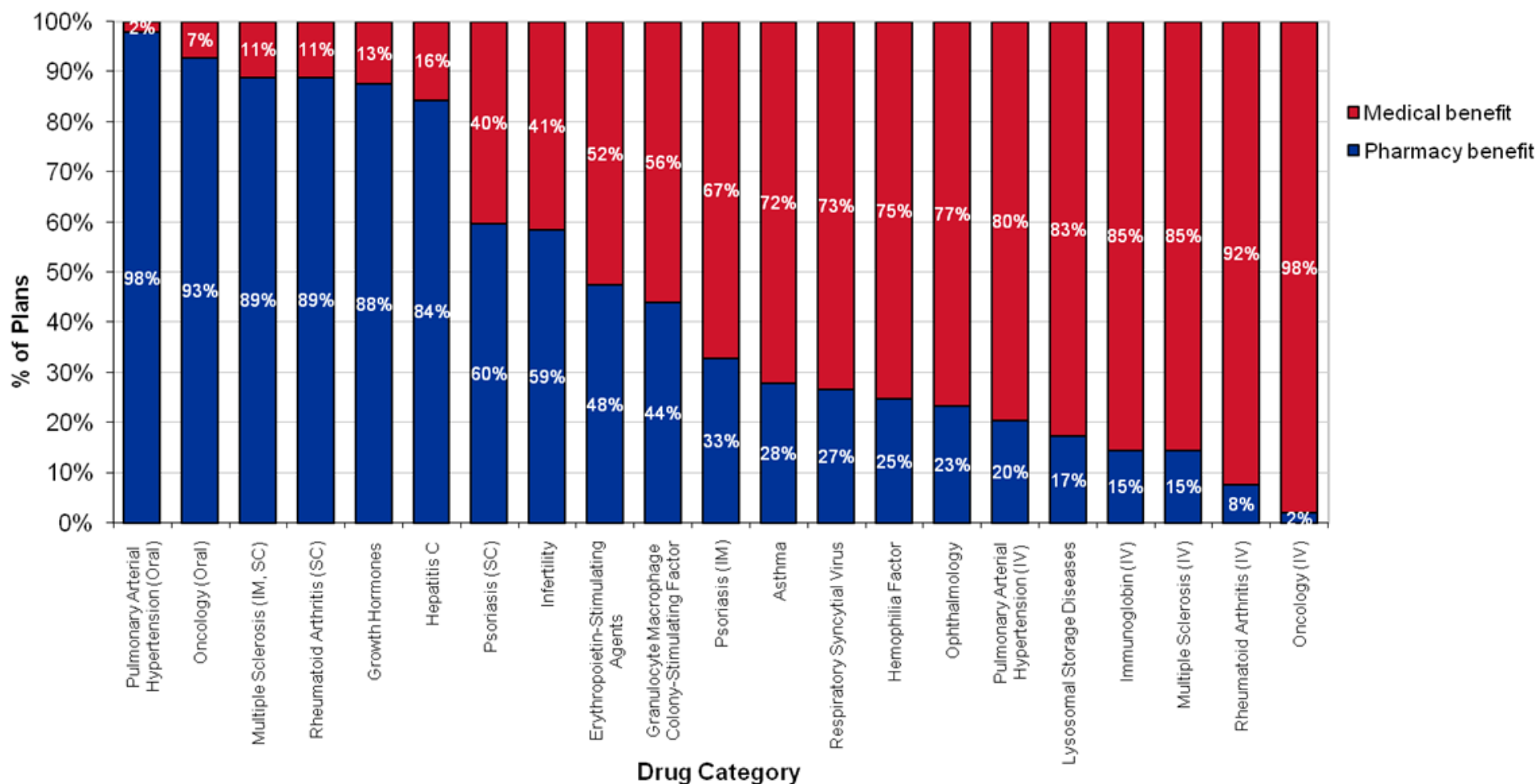
- Consumers must be conscious of the cost of care, and cost sharing can guide appropriate choices
- But some patients avoid effective and cost-effective treatments due to cost-sharing
- “Value-based insurance design” (VBID) shifts cost-effective drugs to “tier” with lower cost sharing
- VBID for immunology 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.

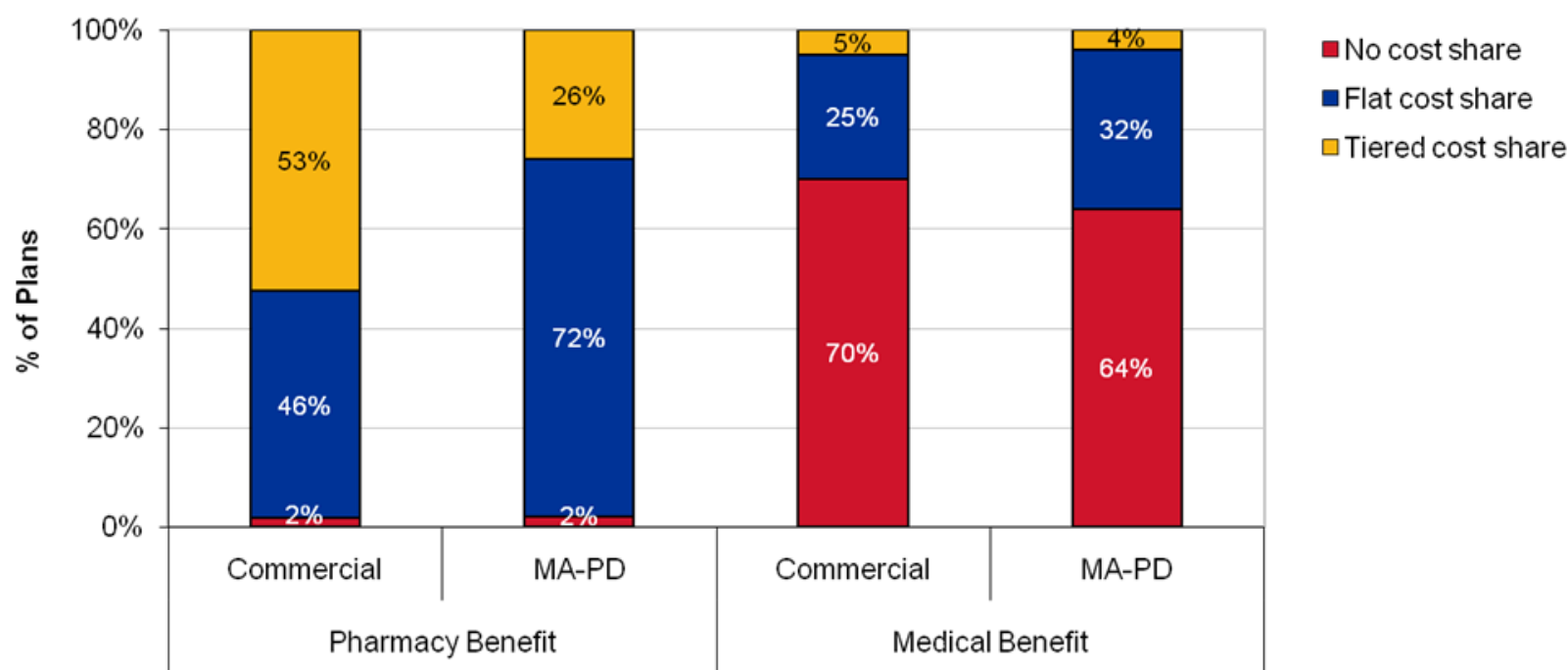




# Pharmacy and Medical Benefit Cost Share Methods



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



# Employer Trends 2000-2008

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

	2000	2001	2002	2003	2004	2005	2006	2007	2008
<b>Average Copayments</b>									
First-Tier Drugs, Often Called Generic	\$8	\$8	\$9	\$9*	\$10*	\$10	\$11*	\$11	\$10
Second-Tier Drugs, Often Called Preferred	\$15	\$16*	\$18*	\$20*	\$22*	\$23*	\$25*	\$25	\$26
Third-Tier Drugs, Often Called Nonpreferred	\$29	\$28	\$32*	\$35*	\$38*	\$40*	\$43*	\$43	\$46*
Fourth-Tier Drugs	^	^	^	^	\$59	\$74	\$59	\$71*	\$75
<b>Average Coinsurance</b>									
First-Tier Drugs, Often Called Generic	18%	18%	18%	18%	18%	19%	19%	21%	21%
Second-Tier Drugs, Often Called Preferred	NSD	23%	24%	23%	25%	27%	26%	26%	25%
Third-Tier Drugs, Often Called Nonpreferred	28%	33%	40%	34%*	34%	38%	38%	40%	38%
Fourth-Tier Drugs	^	^	^	^	30%	43%*	42%	36%	28%

**SOURCE:**

Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000–2008.

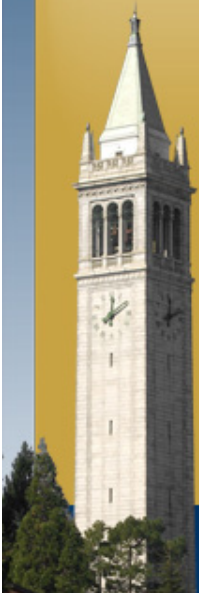
\* Estimate is statistically different from estimate for the previous year shown ( $p < .05$ ).

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

NSD: Not Sufficient Data.

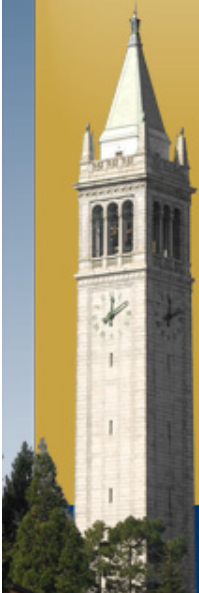
## Consumer Cost Sharing: The Basic Trade

- 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

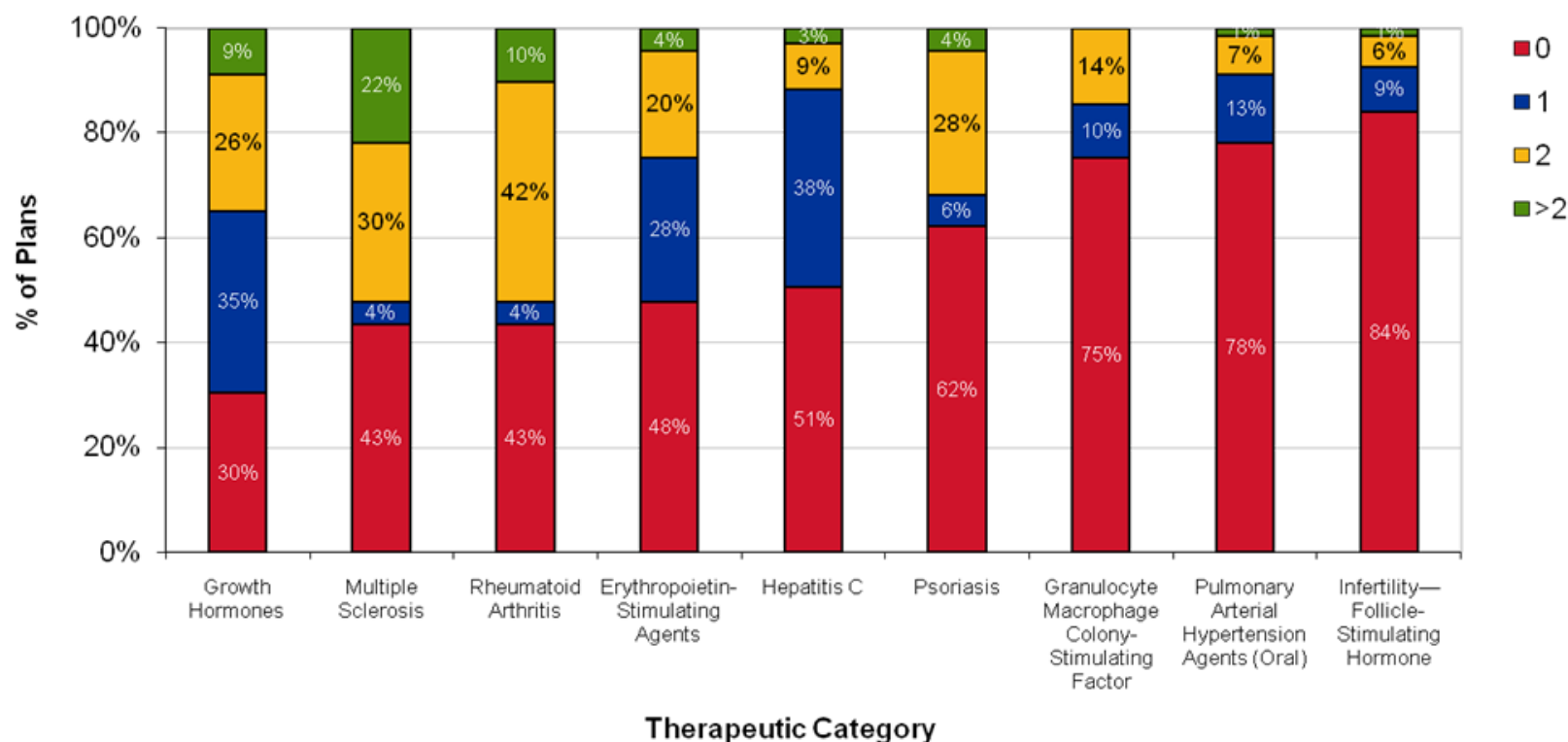
- Manufacturer's preference: list price, based on reference product price plus differentiator ( $V=R+D$ )
  - $V$ =Value-based price
  - $R$ =Reference product price
  - $D$ =Difference between new and reference drug
- Without therapeutic substitution, manufacturer wins
- With widespread therapeutic 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.



# 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

