



BERKELEY CENTER  
FOR HEALTH TECHNOLOGY

# Role of Market Competition in the HTA Process: Perspective from the US Market

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# This Presentation



- Old views and new realities of the US market
- Payer strategies and impacts: utilization management, consumer cost sharing, price discounting
- Implications for evidence needs



# Four 'Consumers' for Evidence

- Pharmaceutical firms co-produce drugs and evidence about those drugs. This evidence is used by 'consumers' with different needs:
  1. The regulatory body: market authorization
  2. Purchasers and payers: coverage and pricing
  3. Physicians: prescription and monitoring
  4. Patients: adoption and adherence
- The needs and demands of these four consumers of evidence are changing throughout the world, but especially in the United States



# Pollev Question: Which is the Greatest Challenge for Successful Adoption of a New Drug in the United States?



1. FDA (market authorization)
2. Payers (coverage and reimbursement)
3. Physicians (decision to prescribe)
4. Patients (decision to adhere)

<http://pollev.com/morse>

# Traditional View of the US Market

1. Market authorization: Rigorous FDA review prior to launch, with little attention after launch.
2. Coverage and reimbursement: Lenient payer coverage criteria, with little demand for HTA; 'Free pricing' with only limited discounting
3. Physician prescription: High volumes and revenues, due to payment incentives favoring selection of most expensive products
4. Patient adherence: High adherence due to a culture of aggressive treatment and direct-to-consumer advertising



# The US Market as a Field of Dreams

- The combination of rigorous pre-market review (a barrier to market competition), generous payer coverage, high physician prescription, and enthusiastic patient adherence generates strong revenues and profitability for innovative firms
- Profits earned in the US market support global industry R&D investment
- Roche/Genentech products have been first-in-class, best-in-class; the firm has earned half its global net revenues in this one market
- It's been a field of dreams



# The New Reality of the US Market

1. Market authorization: FDA is moving to accelerated review, requiring less evidence prior to launch but more evidence after launch
2. Coverage and reimbursement: Payers are pushing back strongly on coverage criteria and demanding significant price concessions
3. Physician prescription: Utilization management and new payment methods from payers discourage choice of expensive drugs
4. Patient adherence: Utilization management and high cost sharing are reducing adherence and threatening outcomes



# The Importance of Evidence Strategy

- The changing landscape is creating the demand for new evidence on performance, especially in competitive indications
- Roche/Genentech products now face competition in every therapeutic class. The firm enjoys a window of opportunity to transition from dependence on its Big Three oncology products and build strong positions with its newer products
- Its evidence strategy is central to its success
- This is true in all geographic markets, but of special importance in the US, due to the historical reliance there for global profitability



# Payer Strategies



1. Tighter coverage criteria
2. Administrative controls on physician prescription
3. High consumer cost sharing to decrease patient demand
4. Increased pressure for discounts and rebates, reducing net prices and profits



# Coverage Criteria

- Goal is to limit use of expensive drugs, encourage use of cheaper alternatives, and induce manufacturers to offer discounts
- Narrow formularies: more drugs excluded from coverage altogether
- Prior authorization: prescriptions denied where physician has not sufficiently documented the patient fits strict coverage criteria
- Step therapy: patients are required to 'try and fail' cheaper products before moving to more expensive options
- These trends are coming more slowly in oncology than in competitive indications such as MS, immunology



# Payer Coverage Criteria Increasingly are More Restrictive than FDA Label and Clinical Guidelines

RESEARCH BRIEF

## Variation in Private Payer Coverage of Rheumatoid Arthritis Drugs

James D. Chambers, PhD; Colby L. Wilkinson, BA; Jordan E. Anderson, BA;  
and Matthew D. Chenoweth, MPH

Prior authorization criteria developed by 10 largest (by enrollment) private US health care payers:

### Rheumatoid Arthritis:

- 69% are more restrictive than FDA label
- 33% are more restrictive than guidelines from American College of Rheumatology

### Multiple Sclerosis:

- 46% are more restrictive than FDA label

- Am J Pharm Benefits. 2017;9(5):155-159
- J Managed Care & Specialty Pharmacy 2016; 22(10)

# Systematic Literature Survey: Utilization Management Reduces Drug Use, with Adverse Outcomes

SYSTEMATIC REVIEW

## The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review

Yujin Park, PharmD; Syed Raza, MS; Aneesh George, MS;  
Rumjhum Agrawal, MPharm; and John Ko, PharmD, MS

Systematic review of peer-reviewed articles (n=59) published 2005-18 on drug utilization management by US payers:

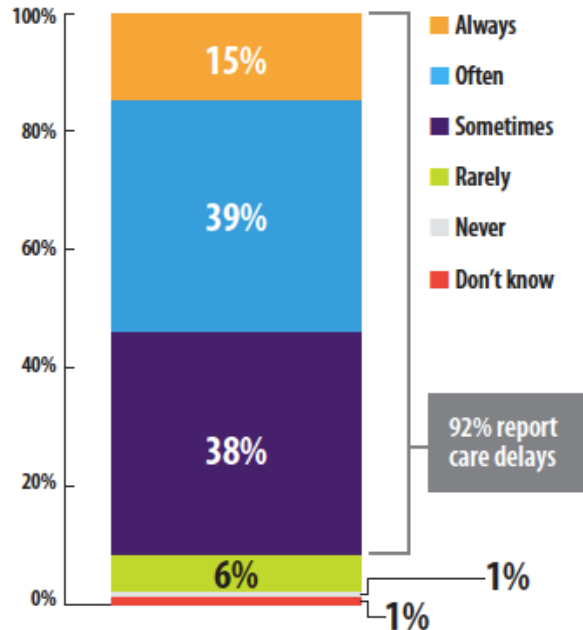
- 90% of studies find formulary exclusions, prior authorization, and step therapy to reduce drug use and spending
- Some reductions in drug spending were offset by increases elsewhere
- 10/12 studies using clinical endpoints report adverse outcomes

Journal of Managed Care & Specialty Pharmacy 2017 Vol. 23, No. 8

# Physician Views of the Impact of Prior Authorization on Patients

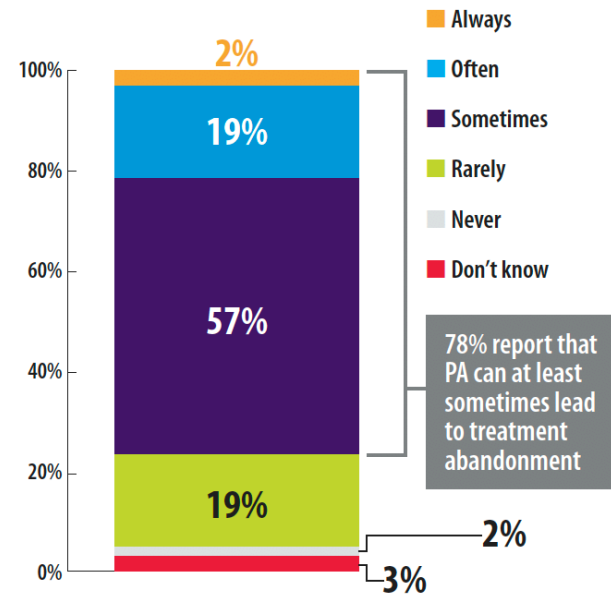
## Care delays associated with PA

**Q:** For those patients whose treatment requires PA, how often does this process delay access to necessary care?



## Abandoned treatment associated with PA

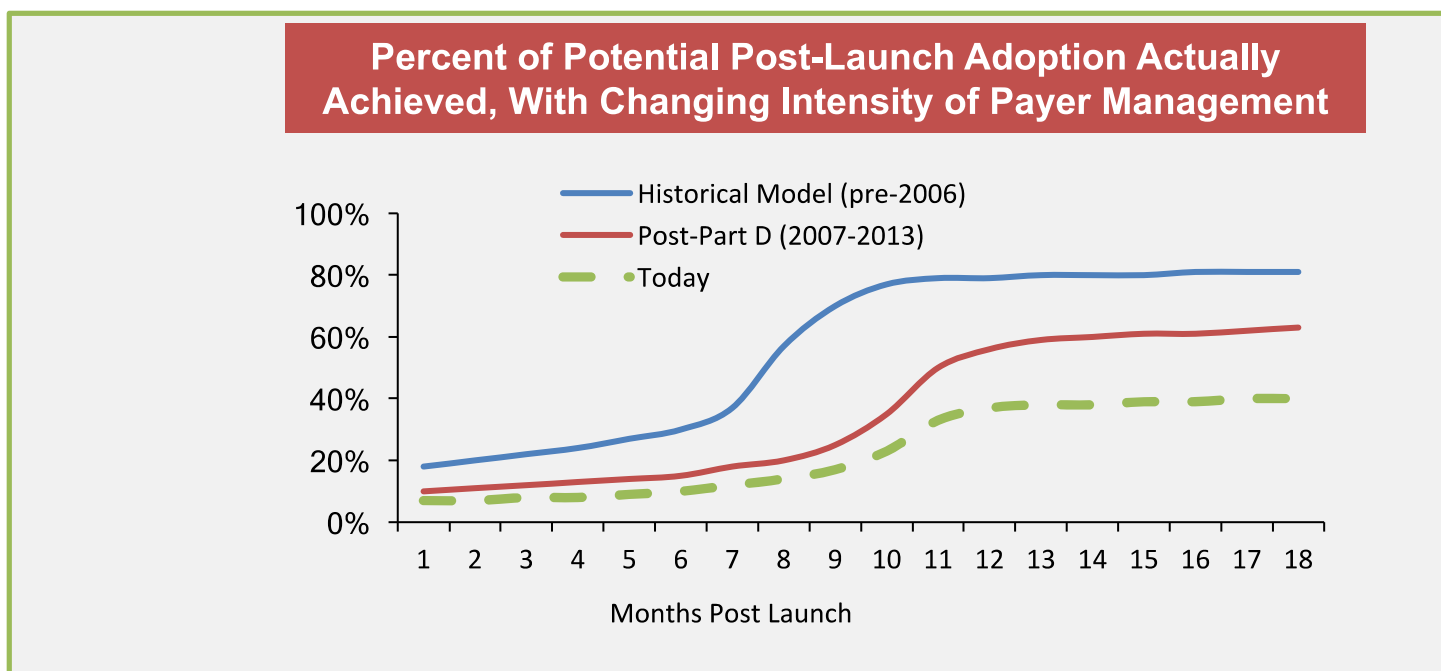
**Q:** For those patients whose treatment requires PA, how often do issues related to this process lead to patients abandoning their recommended course of treatment?



Total does not equal 100% due to rounding.

Source: 2017 AMA Prior Authorization Physician Survey

# More Intense Prior Authorization, Step Edits, and Consumer Cost Sharing Are Slowing Physician Prescription and Patient Adherence after Launch



† Source: QuintilesIMS, Payer and Managed Care Insights, Novartis

# Price Negotiations Reduce Net Prices

**Net price growth for protected brands is forecast to be 2-5% through 2021**

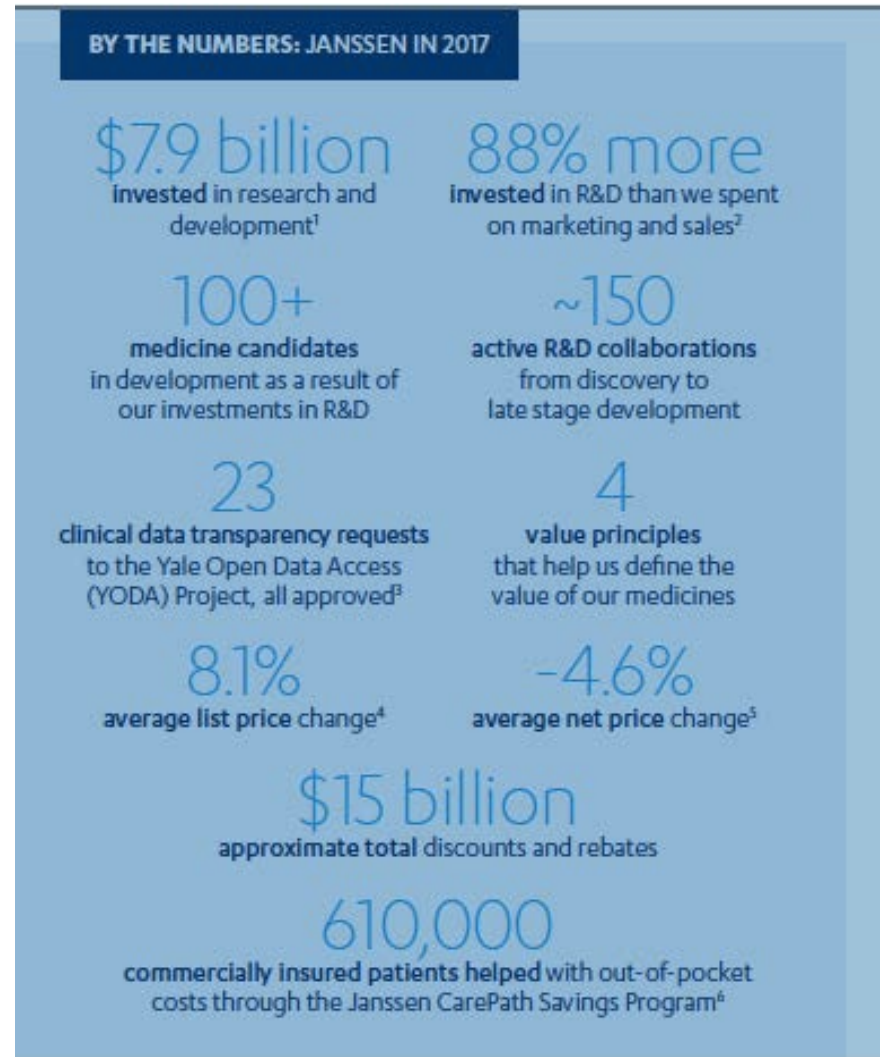
Protected Brand Invoice and Net Price Growth



Source: QuintilesIMS, National Sales Perspectives, QuintilesIMS Institute, Mar 2017

# Some Major Pharmaceutical Firms Report Negative Net Price Increases

- Janssen (J&J) reports list price increases (across portfolio) of 8%, but net price changes (after rebates) of negative 5%



# Implications for Evidence Strategy



1. FDA
2. Payers
3. Physicians
4. Patients



# 1. Evidence Strategy for FDA

- Accelerated FDA review does not imply a reduction in need for evidence, but a change
- Under the 21<sup>st</sup> Century Cures Act, FDA is mandated to develop strategy for using RWE for life cycle monitoring of drugs. It now is debating how to combine evidence from:
  - Insurance claims data
  - Data from electronic medical records
  - Patient self-reported (survey) data on quality of life, functional ability
  - Sensor-based data: wearables, implantables
  - Social media: FB, twitter, Google searches



## 2. Evidence Strategy for Payers

- Payers in the US are beginning to use traditional HTA evidence, though still do not explicitly define cost/QALY thresholds
- In contrast to many other markets, the emphasis is less on evidence of outcomes for populations and more on appropriateness for individuals
  - In the absence of indication-specific pricing, payers are enforcing indication-specific prior authorization requirements
- Precision medicine, with ever-smaller patient populations, cannot rely on traditional forms of evidence



### 3. Evidence Strategy for Physicians

- Drug firms need evidence on the clinical and cost benefits for particular patients, in response to administrative barriers to prescription
- Results from lab tests, imaging, & molecular Dx need to be available in electronic documentation
  - This evidence needs to be tailored to the criteria and demands of different payers
- Moving forward, payers will work with physicians on new 'episode of care' payment methods based on clinical pathways and guidelines;
  - Evidence for these pathways and guidelines will cover the entire course of care, not just the incremental contribution of the drug



## 4. Evidence Strategy for Patients

- Pharmaceutical firms in the US employ large staffs to support patients (1) understand their insurance coverage (2) help pay their cost sharing obligations, and (3) help physicians with documentation of patient's treatment history
- Firms need to develop evidence that can be used by patients in discussions with physicians of treatment alternatives, taking into account prior authorization and cost sharing requirements
- My answer to PolIEv Question: Adherence failures are the most important obstacle to market adoption and success of a new drug in the United States



# Eternal Vigilance

- The US market no longer features free pricing and unmanaged patient access
- Global firms cannot rely on profits from the US market to cover investment in R&D unless they adapt their product and pricing strategies
- These new strategies require evidence tailored to the demands by FDA, payers, physicians, and patients





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