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FOR HEALTH TECHNOLOGY

Evolution of Insurer Strategies for Managing Biopharmaceuticals in the US

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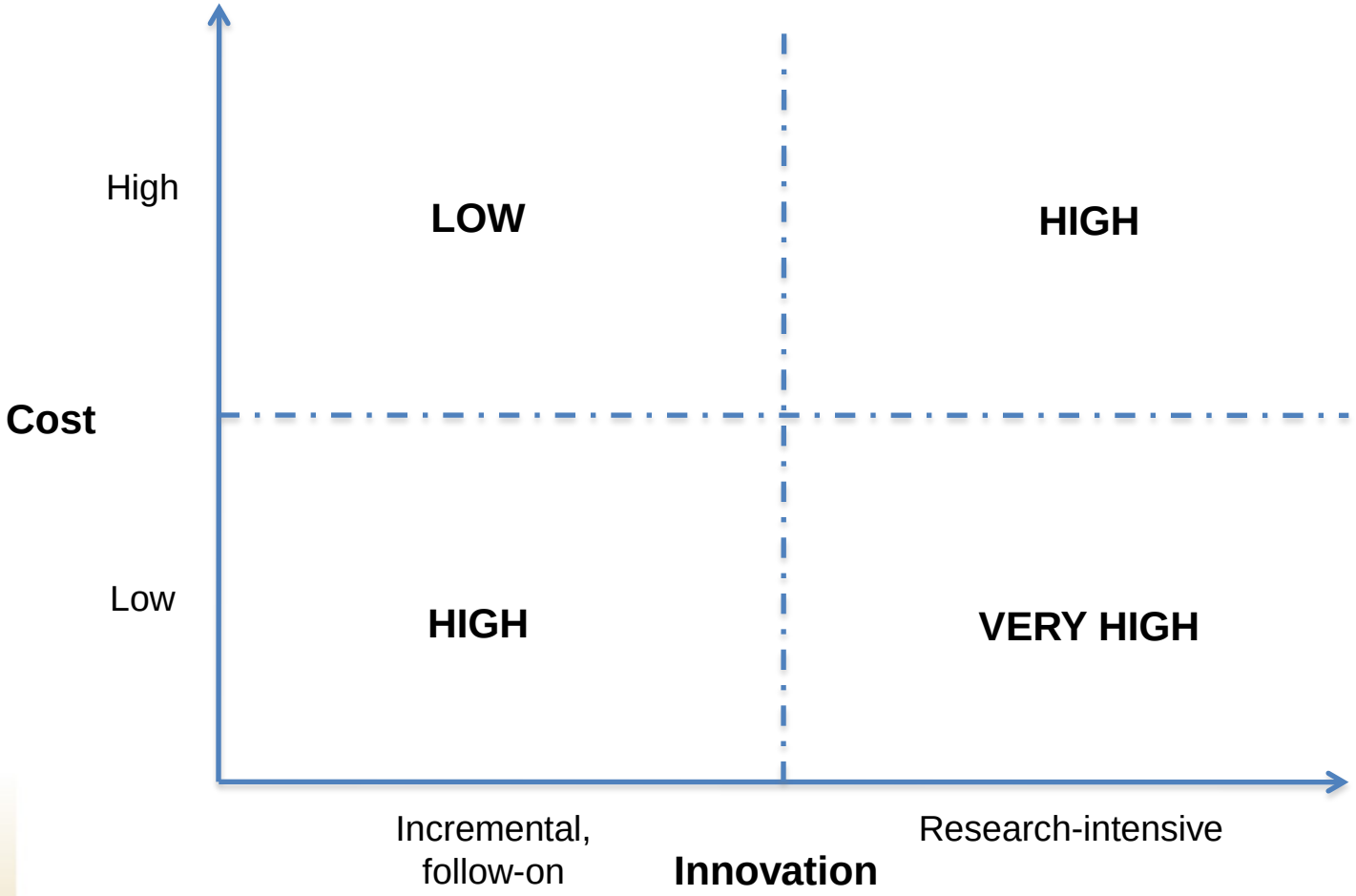
OVERVIEW

- The goal: balancing innovation and affordability
- Failure of insurer strategies to manage costs
- New, emerging strategies
  - Clinical pathways
  - Changes in payment for drugs and drug distribution
  - Changes in payment for the entire course of care
- Assessment

The Social Goal in Managing Biopharmaceuticals

- New drugs are increasingly targeted and effective against serious illnesses such as cancer and immune deficiencies
- They are the source of new industries, jobs, taxes, and exports for a knowledge-based economy
- But the costs of research and development are high, and hence prices must be high to encourage investment in the face of high risk
- All health systems face rapidly rising costs, and threaten the solvency of public and private payers
- How to balance innovation and affordability?

The Value of a New Drug Depends Both on Type of Innovation and Level of Cost



Traditional Cost Management Strategies in the US for Biopharmaceuticals

1. Pressure on professional fees for specialists (e.g., oncology, rheumatology)
2. Prior authorization requirements prior to reimbursing office-infused biopharmaceuticals
3. Cost sharing (% coinsurance) for patients

Each of these has created unintended effects

1. Pressure on Professional Fees Leads to Emphasis by Physicians on Drug Mark-ups

- Oncology and other specialty practices now make most revenue from profits on drugs rather than professional services; drugs are purchased from manufacturers at discount and are reimbursed by insurer for at substantial mark-up
  - This is referred to as “buy and bill”
- It creates incentives for physicians to use the most expensive drugs, more frequently, at higher doses
- Insurers have attacked “buy and bill” incentive by reducing drug mark-up (following lead of Medicare’s “average sales price” ASP model)
  - This has created another set of problems

Unforeseen and Undesired Impacts

- Insurer attacks on “buy and bill” have generated short term savings but create long term problems
- ASP + x% reimbursement discourages use of generic chemotherapies
- Reductions in drug markups have led to physicians referring infusion to higher cost hospital settings
- It also increases physician receptiveness to hospital offers to purchase the entire practice and employ the physician, which concerns insurers as a path towards monopoly power by care providers

2. Prior Authorization Leads to Backlash

- Insurers possess strong lever against office-infused drug use, as they can refuse to reimburse the physician after the physician has purchased and administered the drug (buy and bill)
- Insurers demand supportive data on patient indication, severity level, failure on other therapies
- This “prior authorization” is administratively expensive for both insurers and physicians and leads to considerable hostility
- Public opinion and regulators tend to sympathize with the patients and physicians, not the insurers
- Another “backlash against managed care”?

3. Consumer Cost Sharing Imposes Very High Burdens on the Most Sick Patients

- Insurers have imposed 25-50% coinsurance requirements on many biopharmaceuticals, which imposes very high costs on patients taking oral and self-injected drugs for cancer, rheumatoid arthritis…
- This is creating a backlash by the media and by public policy and regulation
- Federal legislation requires coverage of “essential health benefits” and all cancer drugs
  - Major debate over cost sharing for Medicare Part D
- Many states are placing limits on cost sharing requirements, but employers are shifting to non-regulated insurance products or dropping insurance

New Emerging Strategies for Managing Biopharmaceuticals

1. Clinical pathways
2. Payment methods for drugs and drug distribution
3. Payment methods for the course of care
4. Population-based methods of payment

1. Clinical Pathways

- The foundation of the emerging strategies is to encourage physicians to develop and adopt clinical pathways, and to adhere to them
- Clinical pathways specify:
  - Drug selection, ordering, dosages by indication, severity
  - Ordering and timing of lab and imaging tests
  - Patient monitoring for drug toxicity and disease progression
  - Transition to palliative and hospice care, if necessary
- Pathway adherence increases costs of patient assessment, care management, and monitoring but reduces emergency hospital visits and redundant tests, drugs

2. Payment Methods for Drugs and Distribution

- Some insurers seek to wean physicians from focus on drug sales by increasing professional fees for visits while reducing drug mark-up
- Others create new categories of reimbursed services for patient assessment and care planning (so as not to create incentives just for more routine visits)
- Some insurers vary the drug mark-up based on whether the physician and patient are adhering to a clinical pathway
- Some insurers increase mark-up for generic chemotherapies (e.g., ASP + 400%) and reduce it for high-priced biologics (e.g., ASP + 10%)

3. Payment for the Course of Care

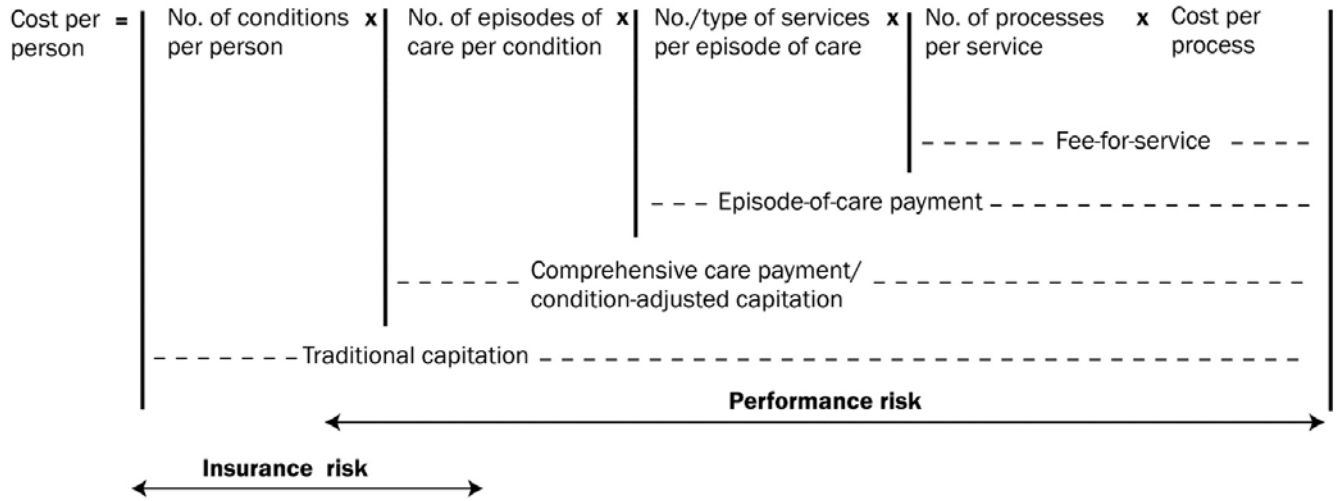
- Some insurers seek to overcome the fragmentation of payment (professional services, tests, drugs, etc.) by paying for an “episode of care” (EOC)
- EOC can exclude drug costs in order to protect physician from financial risk, but eliminate mark-up altogether and reimburse drug at cost
- Alternatively, EOC can include drug costs in order to give an incentive for the physician to manage costs
  - In this case, physician retains all savings from moving to lower cost care pathways
  - EOC is adjusted by indication, severity, stage of illness
  - EOC also is limited by “stop loss” level, after which physician receives additional payment, to protect against the cost of very complicated cases

4. Payment for an Entire Patient Population

- Some insurers seek to pay physicians based on the total costs of care incurred by affiliated patients, to give them the incentive to manage specialty referrals, hospital services, drugs, tests, etc.
- All must calculate expected “total cost of care” target and then compare this to actual costs, with the difference being interpreted as “savings” to be shared with the physician or paid prospectively
- Three models:
  - Fee-for-service with shared savings bonus
  - Capitation for a limited range of services
  - Global payment for full range of services

The Range of Payment Alternatives

EXHIBIT 1
Variables For Which The Provider Is At Risk Under Alternative Payment Systems



SOURCE: Author's analysis.

Harold D. Miller,
From Volume To Value: Better Ways To Pay For Health Care,
Health Affairs, Vol 28, Issue 5, 1418-1428

Assessment

- It has proven very difficult for insurers to manage the cost of specialty drugs
- The emphasis now is on transition to formal, evidence-based clinical pathways, with payment incentives to adopt and adhere
- It often is difficult to influence physician behavior through payment incentives
- But it's a bad idea to pay doctors to do A when you want them to do B
- Insurer strategies continue to evolve

“The Americans can be counted on to do the right thing, after having tried every alternative.”

Winston Churchill