Value-Based Pricing and Purchasing for Drugs, Biotechnology, and Medical Devices

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James C. Robinson
Editor-in-Chief, Health Affairs

OVERVIEW

- Fundamental principles
- Cost-based pricing (CBP)
  - Cost effectiveness analysis
- Value-based pricing
  - Reference-based pricing in practice
- Value-based purchasing
- Common ground?

Basic Principles: Value-based Pricing (1)

- Fundamental role of prices is to allocate resources (capital, talent) to highest-value use
- In biomedical arena, this means prices (and hence profits) should direct investment both inside firms and across firms (investors) to drugs, devices, biologics where clinical and economic benefits are greatest, relative to costs and risks
- High prices for breakthroughs, low for me-too

Basic Principles: Value-based Pricing (2)

- Risks are very high (scientific uncertainty) for unmet needs: prices must exceed costs substantially (Schumpetrian competition)
- For follow-on, mature, ineffective, and risky products, prices should be low
- Prices and profits should reward the generation of new data, reduction of uncertainty and risk
- Technological innovation is central to a dynamic economy and pricing is central to encouraging innovation

Basic Principles: Value-base Purchasing

- The extra value created by innovation should be shifted as soon as possible from producers to consumers
- Competition is principal mechanism
  - Alternative therapies, generics
- Important role for insurers, hospitals in evaluating value, stimulating price competition, increasing price-consciousness among patients, physicians

Basic Principles: Value-base Purchasing (2)

- Sophisticated purchasers reward innovative producers
- The biomedical industries have long enjoyed unsophisticated purchasers and price-unconscious demand by patients and physicians
- This has permitted extensive innovation and inefficiency and unjustified variation in use
- Better information and aligned incentives

Menu of Pricing Options

- Cost-based pricing
  - Administered pricing and regulation
  - Cost-effectiveness and $/QALY
- Value-based pricing
  - Willingness to pay: patients and society
  - Reference-based pricing

Cost-Based Pricing (CBP)

- CBP would ensure that value shifts to consumers
- Heritage of regulated utilities and hospitals
- In biomedical arena, administered pricing is circular: identify “average price” as indicator of cost and base reimbursement on that
- CBP makes good press: “high prices needed to pay for expensive R&D costs”

Problems with Cost-Based Pricing

- Price signals determine which products will come to market (Darwinian allocation of R&D budgets)
  - Price-based costing
- Many products incur costs but never revenues
- Prices on successful products must reimburse costs of failures, plus reward risk-taking
- Impossible to measure costs for any one product
- CBP has failed in other industries

Cost-Effectiveness and $/QALY

- Regulators seek $/QALY as social WTP
  - Circular reasoning: $100K/QALY based on what?
  - For monopoly therapies, “cost” is the price
  - CEA very costly, can slow product access to market
- CEA tends to over-estimate costs, as these fall over time
- CEA tends to under-estimate benefits (indication spread) and risks (ignorance is bliss)
- Role of CEA is upper limit on social WTP (coverage policy)

Value-based Pricing (VBP)

- Producers have adopted rhetoric of VBP
- But those who choose (consumers, MD) are price insensitive. For them, if clinical benefit is positive, value is positive. MDs have their own incentives.
- In larger society, competition drives price down below value, shifting value to consumer
  - What is VBP for water, aspirin?
- Producers exploit insurance (consumer price insensitivity) and then complain about role of insurers (VB purchasing)

Value-based Pricing in Practice

- V=R+D
- Choice of R is key
  - Choice of initial indication, formulation, nation for launch
  - Virtue: R is higher for unmet needs
  - Virtue: D requires data, stimulates research, registries
- Reference-pricing in Europe
- VBP is best principle for pricing

The Effective Price: Distribution and Incentives

- List prices set by VBP are only first step
- Negotiated prices fall below list price
  - Tiered formularies, indemnity pricing for devices?
- Marked-up prices exceed list price
  - Physician buy & bill, hospital device carve-outs
- Distribution price adjustments affect incentives for physicians, hospitals, consumers

Value-based Purchasing: Principles

- Sophisticated purchasers stimulate producers to innovate, find efficiencies, improve performance
- Push-back is essential lest launch prices never fall
- Push on unit prices, appropriate use
- Negotiate with producers based on volume
- Enforce volume guarantees by changing incentives for consumers, physicians, hospitals

Value-based Purchasing: Insurers

- Directly negotiate drug prices through PBM
- Incentives for consumers: tiered formulary to encourage generics, preferred brands
- Incentives for physicians and hospitals
  - Fight “buy and bill” with specialty pharmacy
  - Episode pricing for devices?
  - Fight device carve-out and mark-up by hospitals
- Coverage policy and medical management

Value-Based Purchasing: Hospitals

- Negotiate lower device prices on basis of volume
- Tech assessment and adoption committees
- Seek to enlist cooperation with physicians
  - Gainsharing and non-financial incentives
  - Transparency on conflicts of interest, counter-detailing
  - Employment, joint ventures, service lines
- Difficult to manage PPI under Medicare DRGs

Distribution Incentives

- Do the ends justify the means?
  - If product is under-utilized, do DTC, detailing, buy & bill, consulting arrangements enhance social welfare?
  - What if product is over-utilized?
  - What about products with serious side effects?
- Perception is part of reality
  - Industry faces social skepticism on over-selling

Common Ground?
VB Pricing meets VB Purchasing

- As a practical matter, there is no socially ideal price
- Producers push high launch prices, which gradually erode under competition from me-too, generics
- Purchasers use cost-sharing, payment incentives, medical management to push for lower prices
- The outcome of this mud-wrestling match is not the worst that can be imagined, even if it does not fit a policy pundit's ideal

Common Ground?
Products and Services

- Biomedical products are just one (major) component of the process of care (services)
- Common ground between producers and purchasers may be found if products are integrated into services in better manner
  - Disease management and pharmaceuticals
  - Case management and biologics
  - Service lines and medical devices

Innovation in Technology, Organization and Care Processes

- The health care system is highly innovative in technologies but rigid in forms of organization and processes of care
- Service lines, episode pricing, case management, and other initiatives hold promise to promote innovation in organization and processes
- Technology producers can be part of the solution