The Drug Pricing Problem

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www.drugpricinglab.org
Recent Projects

- Indication Specific Pricing
- Medicare Part B Payment Pilot
- Tracking of Recent Pricing Trends
- R&D Premiums
- Outcomes-based contracting vs value-based pricing
- Gilead Buy-Out

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Express Scripts rolls out value-based pricing for cancer meds

Drugs will cost more in cancer types where they work best

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Indication-Specific Pricing for Cancer Drugs

In 2015, spending on specialty drugs, a category dominated by drugs used to treat cancer, reached $125 billion. That year, 8 new cancer drugs were approved by the US Food and Drug Administration (FDA). The Medicare “price” for these drugs ranged from $97,000 to $125,000 per year, with responses showing overall survival improvement of nearly 6 months and others showing no improvement in overall survival. As policy makers continue to hear high priced drugs, one important concern is that the price of the drug is not currently linked to its efficacy. “Value” the benefit of a treatment with respect to cost, has become an increasingly important consideration, following a recent publication in the New England Journal of Medicine. For instance, fulvestrant (Abraxane) and paclitaxel (Taxol) are two drugs that are used in the treatment of metastatic breast cancer, with the former costing $9000 per year but the latter costing $2000 per year. Other drugs have variable pricing in different countries and with the advent of value-based pricing, these drugs will be priced at a lower cost per year of life gained. Using Mida as reimbursement rates, the cost per year of life gained with fulvestrant is estimated at $440,000 in breast cancer and $419,000 in NSCLC, as measured by the change in median survival. Linking pricing to the indication could address this.

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R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices

Outcomes-Based Drug Contracts Do Not Move Us Closer to Value

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Forbes / PHARMA & HEALTHCARE / #MEDICINE

The U.S. Government Should Buy Gilead For $156 Billion To Save Money On Hepatitis C
Recent Projects

• Gilead Buy-Out
• Copay assistance
• Louisiana budget allocator
• DPL Policy Tracker

Annals of Internal Medicine

Should The U.S. Government Buy a Drug Company To Save Money?

March 17, 2017 - 3:40 PM ET
Heard on All Things Considered

DPL Policy Tracker

The DPL Policy Tracker keeps tabs on federal policy proposals to address US drug pricing issues. To begin, select filter options for proposed solutions.

Methods FAQs

Filter by:

Potential Policy Solutions Proposal Source

Policy Category

All Policy Categories All Sources

Importation / Re-importation Enable re-importation (made in USA) or importation (made overseas).

Loosen restrictions on re-importation to allow individuals, hospitals and other providers to purchase drugs in other countries that were either a) manufactured in the US, or b) manufactured in another country that meets or exceeds US safety standards (to be assessed by the FDA) for drug manufacturing.

American Hospital Association

$0.76B

Let’s Begin

Methods FAQs References
Recent Projects

- Value-based pricing
- Outcomes-based contracting
- DPL Learn Tool

Learn

Value-Based Pricing for Drugs: Theme and Variations

Anna Kaltenboeck, MA¹; Peter B. Bach, MD²

Author Affiliations | Article Information
JAMA. Published online April 30, 2018. doi:10.1001/jama.2018.4871

Money-Back Guarantees for Expensive Drugs: Wolf’s Clothing but a Sheep Underneath

Shan Mailkabady, MBBS; Peter B. Bach, MD

Article, Author, and Disclosure Information

Learn

Drug Pricing Tutorials

Certain aspects of the payment and reimbursement processes in the US may distort incentives and negatively influence drug prices. Explore our tutorials to learn more.

Get Started

www.drugpricinglab.org

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Memorial Sloan Kettering
Recent Projects

- Proposed rule 340B
- Part B incentives

DPL White Paper

Does the 6% in Medicare Part B drug reimbursement affect prescribing?

Peter B. Beth
Joern Ott

<table>
<thead>
<tr>
<th>Article (Year)</th>
<th>Population studied</th>
<th>Comparison</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elliott et al. (2006)*</td>
<td>Medicare beneficiaries with low-risk and metastatic prostate cancer</td>
<td>Use of androgen suppression therapy before and after a reimbursement change due to a low change that decreased the margins, compared between low risk and metastatic patients.</td>
<td>Reduction in reimbursement of 66% associated with an OR of 0.609 reduction of use in low risk with no change in metastatic patients.</td>
</tr>
<tr>
<td>Johnson et al. (2006)*</td>
<td>Medicare beneficiaries with lung cancer</td>
<td>Use of five different drugs for lung cancer that all experienced shifts in margins due to a low change in 2005.</td>
<td>Use of drugs with the largest decline in margins fell the most after the rule change. Use of drugs with unchanged margins increased.</td>
</tr>
<tr>
<td>Collette et al. (2006)*</td>
<td>Medicare decedents who had any cancer, treated in physician offices or hospital outpatient departments</td>
<td>Utilization of chemotherapy in the months preceding death before and after a low change that decreased margins and competing importance settings, where physicians often presumed to be more affected by incentives</td>
<td>Use of chemotherapy prior to death declined in physician offices following a reduction in margins, but did not decline in the hospital outpatient departments.</td>
</tr>
<tr>
<td>Rusten et al. (2006)*</td>
<td>Medicare beneficiaries with breast cancer (1992-2002)</td>
<td>Within-patient population evaluation of prescribing frequency in relation to margins (reimbursement – acquisition cost)</td>
<td>Increase margin of 29% led to an increase in prescribing likelihood of 6% – 17%.</td>
</tr>
<tr>
<td>Cost et al. (2010)*</td>
<td>Medicare beneficiaries with metastatic colorectal cancer</td>
<td>Use of two alternative drugs for colorectal cancer, one which went generic and one that did not.</td>
<td>Use of the drug that went generic declined since the margin on the drug was reduced. Use of the alternative drug was maintained.</td>
</tr>
</tbody>
</table>

www.drugprofilinglab.org

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Orkambi and NY’s Drug Cap program

Table ES5. Incremental Cost-Effectiveness Ratios Compared to Best Supportive Care (BSC) for the Base Case

<table>
<thead>
<tr>
<th>Treatment vs. BSC</th>
<th>Cost Per LY Gained</th>
<th>Cost Per QALY Gained</th>
<th>Cost Per PEx Averted</th>
</tr>
</thead>
<tbody>
<tr>
<td>CF Individuals with a Gating Mutation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kalydeco Plus BSC</td>
<td>$1,476,543</td>
<td>$956,762</td>
<td>$463,571</td>
</tr>
<tr>
<td>CF Individuals Homozygous for F508del Mutation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orkambi Plus BSC</td>
<td>$1,280,892</td>
<td>$890,739</td>
<td>$334,495</td>
</tr>
<tr>
<td>Symdeko Plus BSC</td>
<td>$1,367,400</td>
<td>$974,348</td>
<td>$424,212</td>
</tr>
<tr>
<td>CF Individuals Heterozygous for F508del Mutation and Residual Function Mutation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kalydeco Plus BSC</td>
<td>$1,340,171</td>
<td>$941,110</td>
<td>$373,541</td>
</tr>
<tr>
<td>Symdeko Plus BSC</td>
<td>$1,174,508</td>
<td>$840,508</td>
<td>$390,600</td>
</tr>
</tbody>
</table>

BSC: best supportive care; LY: life year; QALY: quality adjusted life years; PEx: pulmonary exacerbation

Bloomberg

- VRTX: I want to be clear… We will not be giving rebates to states... We don’t need to and we’re not required to by law.”
The Competitive Acquisition Program

• Introduced in 2003 Medicare Modernization Act
• Created opportunity for intermediary to provide Part B drugs to physicians/hospitals rather than buy and bill
• Providers had to choose either CAP or buy and bill
• Little uptake by vendors or providers

• What problems it could solve:
  – Many doctors say they are ‘under water’ on drugs. This takes drugs off their books
  – Anything sophisticated, like indication specific pricing, outcomes contracts, or refunds for wasted drug – better handled by large well financed intermediary

• What problems it worsens:
  – Logistics – this when rolled out applied to essentially every Part B drug
  – But this really should just be done for the top 20 or so drugs where there is the greatest potential for savings
Distribution of payments and profits for Part B drugs (2014). All of the ‘action’ is in the last several drugs.
Statement of the problem

- Pharma’s Central Dogma “You must pay this opportunity cost”:
  - Pay more than cost of production and distribution
  - Glean rewards down the road due to incentivized innovation

- What are these opportunity costs?
  - Unaffordable drugs
  - Collapsing insurance structures
  - Declining value of drugs
  - Diminished Access
Prices Matter

NEW CANCER DRUGS

PRICE

$100,000

$10,000

$1,000

$100

$10

$1


YEAR

APPROVALS

0 10 20 30 40

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Value Declining

Prices of Gleevec vs. iPhone over time

- **Price of iPhone/GHz with contract**
- **AWP of 1 week treatment of 400mg Gleevec**

Year:
- 2005
- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015

Cost ($):
- $3,000
- $2,500
- $2,000
- $1,500
- $1,000
- $500
- $-

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Value (benefits in relation to costs) declining

Figure 2: Price per life year gained versus approval date

The best fit line is: Price per life year gained = $54,100 + $8,500 x Approval year. Approval Year = 0 for 1995, 1 for 1996, etc. For purposes of display, we re-coded one value from $802,000 to $400,000.

Source: Authors
Erosion of insurance

Figure 6: Medicare Part D Standard Benefit Parameters, 2006-2017

NOTE: Where applicable, estimates are rounded to nearest whole dollar.
SOURCE: Kaiser Family Foundation analysis of data from the Centers for Medicare & Medicaid Services.
Cancer Drugs Provide Positive Value In Nine Countries, But The United States Lags In Health Gains Per Dollar Spent
BMJ Open  Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries

Steven G Morgan, Augustine Lee

<table>
<thead>
<tr>
<th>Country</th>
<th>CRNA %</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>6.8</td>
<td>2.37 (1.14 to 3.98)</td>
<td>2.17 (1.29 to 3.68)</td>
</tr>
<tr>
<td>Canada</td>
<td>8.3</td>
<td>2.92 (1.77 to 4.84)</td>
<td>2.76 (1.66 to 4.59)</td>
</tr>
<tr>
<td>France</td>
<td>1.6</td>
<td>0.54 (0.27 to 1.08)</td>
<td>0.47 (0.24 to 0.95)</td>
</tr>
<tr>
<td>Germany</td>
<td>3.7</td>
<td>1.22 (0.64 to 2.33)</td>
<td>1.00 (0.52 to 1.91)</td>
</tr>
<tr>
<td>Netherlands</td>
<td>4.0</td>
<td>1.35 (0.72 to 2.53)</td>
<td>1.19 (0.63 to 2.24)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>4.8</td>
<td>1.62 (0.85 to 3.10)</td>
<td>1.69 (0.88 to 3.24)</td>
</tr>
<tr>
<td>Norway</td>
<td>2.4</td>
<td>0.80 (0.41 to 1.59)</td>
<td>0.66 (0.33 to 1.31)</td>
</tr>
<tr>
<td>Sweden</td>
<td>2.4</td>
<td>0.78 (0.47 to 1.32)</td>
<td>0.80 (0.47 to 1.36)</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2.9</td>
<td>0.97 (0.54 to 1.75)</td>
<td>0.86 (0.48 to 1.57)</td>
</tr>
<tr>
<td>UK</td>
<td>3.1</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td><strong>USA</strong></td>
<td><strong>16.8</strong></td>
<td><strong>6.47 (3.89 to 10.78)</strong></td>
<td><strong>6.10 (3.64 to 10.20)</strong></td>
</tr>
</tbody>
</table>

Results reported in bold are significant at p=0.05.

Adjusted ORs based on sample-weighted logistic regression models that control for age group, sex, health status and household income.

CRNA, cost-related non-adherence, sample-weighted prevalence.
Value Based Pricing

- Explicitly/mathematically derives the price of a drug based on the drug’s features
- Concedes multiple failures of the market
- Makes the ‘prize for innovation’ clear
  - Big breakthroughs = big $$’s
- Makes patient costs low when prices appropriate (even if high)
  - Current system drug price primarily drives level of patient cost
### Table. Comparison of Value-Based Pricing and Adjacent Concepts

<table>
<thead>
<tr>
<th>Concept</th>
<th>Definition</th>
<th>Rests on Existing Evidence of Benefit</th>
<th>Aligns Price With Benefit at Market Entry</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value-based pricing</td>
<td>Price of a drug set on the magnitude of its benefit</td>
<td>Yes</td>
<td>Yes</td>
<td>Pricing of dupilumab according to ICER value-based price</td>
</tr>
<tr>
<td>Indication-specific pricing</td>
<td>Drug price specific to each of its uses</td>
<td>Yes</td>
<td>Yes</td>
<td>Tisagenlecleucel sold at 2 different prices for 2 different cancer indications</td>
</tr>
<tr>
<td>Outcomes-based contracts</td>
<td>Manufacturer refunds or rebates payer when an agreed-upon outcome is unmet</td>
<td>No</td>
<td>No</td>
<td>Amgen agreement with Harvard Pilgrim to refund cost of evolocumab for treated patients who have a myocardial infarction while taking the drug</td>
</tr>
<tr>
<td>Mortgage pricing</td>
<td>Commits a payer to pay for expensive treatments over time</td>
<td>No</td>
<td>No</td>
<td>No known examples</td>
</tr>
<tr>
<td>Value-based insurance design</td>
<td>A health benefit design that reduces out-of-pocket expense for high-value medical care and treatments</td>
<td>Yes</td>
<td>No</td>
<td>Prime Therapeutics program to reduce copayment and increase amount dispensed for insulins; Pitney Bowes’ initiative to reduce or eliminate cost sharing for statins and clopidogrel</td>
</tr>
</tbody>
</table>

Abbreviation: ICER, Institute for Clinical and Economic Review.
Value and Value-Based Price Benchmarks

Costs: PCSK9 inhibitors carry high price tags. Praluent has a wholesale acquisition cost of $14,600, while Repatha is priced at $14,100. For the purposes of ICER’s review, these costs were averaged for a WAC of $14,350.

Potential Budget Impact: In addition to their high cost, PCSK9 inhibitors have a potentially large eligible patient population.

The table at right provides value-based price benchmarks. The value-based price benchmark considers the price at which the drug would meet commonly accepted cost-effectiveness thresholds, as well as an analysis of the potential short-term budget impact. The value-based price benchmark represents the price needed to remain within accepted thresholds. Any price beyond the benchmark will likely create a need for extra mechanisms to manage affordability. Details of the assumptions and calculations that go into our value-based price benchmarks are available on ICER’s website.

For PCSK9 inhibitors, the value-based price benchmark represents a reduction of 85% from the average wholesale acquisition price of the two agents.
Align reimbursement with Value
Value Frameworks Are Expanding For Drugs & Devices

Value Frameworks in Oncology: What are they and how will they be used?

Inculcating the Patient Voice in the Development of Value Models

THE WALL STREET JOURNAL
How Much Should Cancer Drugs Cost?
Memorial Sloan Kettering doctors create pricing calculator that weighs factors such as side effects, extra years of life

FiercePharma
What's a pricey cancer drug really worth? New value-based 'abacus' has some ideas

Health Affairs Blog
Value Pricing For Drugs: Whose Value, What Price?
Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease

Marc S. Sabatine, M.D., M.P.H., Robert P. Giugliano, M.D., Anthony C. Keech, M.D., Narimon Honarpour, M.D., Ph.D., Stephen D. Wiviott, M.D., Sabina A. Murphy, M.P.H., Julia F. Kuder, M.A., Huei Wang, Ph.D., Thomas Liu, Ph.D., Scott M. Wasserman, M.D., Peter S. Sever, Ph.D., F.R.C.P., and Terie R. Pedersen, M.D.

cardiovascular clinical benefit requires time. Overall, 74 patients would need to be treated over a period of 2 years to prevent a cardiovascular death, myocardial infarction, or stroke.

<table>
<thead>
<tr>
<th>Year Approved</th>
<th>Drug</th>
<th>Number needed to treat to prevent one event</th>
<th>Price/ patient/month</th>
<th>Cost of treating over two years per avoided MI</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>Repatha</td>
<td>74</td>
<td>~$1200</td>
<td>$2,123,800</td>
</tr>
</tbody>
</table>

No survival benefit
What is the new outcomes based price?

- Refund for MI patients: who have a heart attack
- Current price = $14,100/year
- MI refund = $13,620/year (ICER benchmark = $2,177/year)

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Amgen And Harvard Pilgrim Agree To First Cardiovascular Outcomes-Based Refund Contract For Repatha® (Evolocumab)

Harvard Pilgrim Refines the Utilization Management Criteria to Help High-Risk Cardiovascular Patients Access Repatha

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Evolocumab (N=13,784)</th>
<th>Placebo (N=13,780)</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction</td>
<td>468 (3.4)</td>
<td>639 (4.6)</td>
<td>0.73 (0.65–0.82)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Outcomes-based contracting

“Stepping back from specific examples, the approach of “if you don't like it, get your money back” seems more the nonsense of late-night infomercials than a method for serious health policy reform.”
**Solution:** The FDA should update its regulations to allow manufacturers to proactively share truthful, non-misleading information on clinical and economic outcomes with payers and providers after approval.

Further, biopharmaceutical manufacturers must adhere to a complex set of government price-reporting rules for calculating Average Sales Price in Medicare Part B and Best Price in Medicaid. These highly technical price-reporting rules were not established with new approaches to contracting in mind (such as indication-based pricing or outcomes-based arrangements). While the price-reporting rules

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### Regulatory, Legal Uncertainties Are Barriers To Value-Based Agreements

Alison Sexton Ward, Mark Linthicum, Michelle Drozd, Alison R. Vandigo

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### FDA Regulation Of Manufacturer Communications

Our interviewees also voiced concerns about the FDA regulations governing manufacturers’ communications regarding information not included in the product labeling. These regulations preclude manufacturers from proactively communicating economic evidence not contained in the FDA-approved label, preventing or limiting potentially beneficial VBAs.

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### Pricing Laws For Medicare And Medicaid

The third regulatory concern consistently mentioned in our interviews was Medicare/Medicaid price reporting requirements, specifically the Medicare Part B average sales price (ASP) and the Medicaid best-price rules. Manufacturers are required to report their drug sales to all U.S.

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FDA to adapt some of its existing rules and practices. Currently, drug makers are largely prevented from offering price concessions based on how a drug is used unless all of the prescribing options are listed precisely and completely on the drug’s label. When a drug maker secures approval for a

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Under these rules, if a drug maker enters into a contract with a private health plan to discount a drug based on how it’s being used (or the clinical results that it achieves) then the discount that’s offered when the drug is used in settings that are judged to yield less value would become the new benchmark for calculating the Medicaid best price. The rebates offered to a
Thank you