Prescription Drug Costs: What is likely moving forward?

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Recent Projects

- Indication Specific Pricing
- Medicare Part B Payment Pilot
- Tracking of Recent Pricing Trends
- R&D Premiums

www.drugpricinglab.org

FiercePharma

Express Scripts rolls out value-based pricing for cancer meds
Drugs will cost more in cancer types where they work best

Pink Sheet

CVS Indication-Based Pricing For Cancer Drugs May Roll Out Later In 2016

Indication-Specific Pricing for Cancer Drugs

In 2010, spending on specialty drugs, a category dominated by drugs used to treat cancer, increased 13% to $68.7 billion. That year, 26 new cancer drugs were approved by the US Food and Drug Administration (FDA). The Medicare "price," which includes rebates and discounts, for these 26 drug arrived at $70,000 to $100,000 per month. New products showed overall survival improvements of nearly 3 months and often showed no improvement in overall survival.

As policymakers consider how to handle high-priced drugs, an important concern is the relative price of the drug. The price of the drug is not linked directly to its benefits. "Value," the benefit of a treatment with respect to its cost, has become an increasingly important consideration, following some explicit

For instance, a randomized trial showed improved median survival in metastatic breast cancer in 38 years, but the improvement was small and metastatic non-small lung cancer (NSCLC) was less than half that (15.8 years). The treatment costs were similar for both indications, $65,000 per month over the average duration of treatment. When costs are essentially the same but benefit differs widely, value is not the same. One rule of metrics of value is the cost per month of the gain. Using Medicare reimbursement rates, the cost per year of life gained with nab-paclitaxel is estimated at $493,000 in breast cancer and $409,000 in NSCLC, as measured by the change in median survival.

Linking pricing to the indication could address this

Figure 1: Excess Revenues Earned Through Premium Pricing of Products in The US As A Percentage Of The Company's Global Research And Development Expenditures, 2015

Health Affairs Blog

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

DrugPricingLab

Memorial Sloan Kettering
Recent Projects

• Gilead buy-out
• Copay assistance

Louisiana Budget Allocator

www.drugpricinglab.org
Mean annual total pharmacy spending among Medicare beneficiaries taking at least one drug from among the top eight classes of specialty drugs.
Access problem

Cancer Drugs Provide Positive Value In Nine Countries, But The United States Lags In Health Gains Per Dollar Spent
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>USA</td>
<td>16.8</td>
<td>6.47 (3.89 to 10.78)</td>
<td>6.10 (3.64 to 10.20)</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.
Available solutions, easily co-opted

- Value-based pricing:
  - Drug prices should align with the benefits those drugs deliver
    - DrugAbacus; ICER; most OECD HTA
    - Coverage/cost-sharing then favorable
- Value-based contracting/Outcomes based contracting:
  - Drug prices are set by companies, but then post hoc rebates/discounts for underperformance
Value-based price approach

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.

<table>
<thead>
<tr>
<th>Population</th>
<th>Care Value Price: $100K/QALY</th>
<th>Care Value Price: $150K/QALY</th>
<th>Max Price at Potential Budget Impact Threshold</th>
<th>Draft Value-Based Price Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL (n=2,636,179)</td>
<td>$5,404</td>
<td>$7,735</td>
<td>$2,177</td>
<td>$2,177</td>
</tr>
</tbody>
</table>
Outcomes based price for same drug (priced at $14k/year)

<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

Where will outcomes pricing take us?

- Across all such efforts in Italy only 1% reduction in pharma spending
- At best this is a distraction, at worst it is trojan horse for other policy goals
  - Looseening off-label marketing restrictions
  - Undoing Medicaid best price
What is the new outcomes based price?

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

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

Policy Solutions: Delivering Innovative Therapies
Address Regulatory and Legal Uncertainties to Value-Based Payment Arrangements

As we move toward value-driven health care, the limitations become clear. Biopharmaceutical companies are experiencing significant regulatory and legal uncertainty in developing new business models. Significant regulatory and legal uncertainty is slowing the development of new drug models.

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...

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.

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.

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

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
These ‘needed’ policy changes do not appear to be needed

**U.S. Repatha® Indication**

Repatha® is indicated as an adjunct to diet and:

- Maximally tolerated statin therapy for treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

- Other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C

The effect of Repatha® on cardiovascular morbidity and mortality has not been determined.
Thank you