Prescription Drug Costs: What is likely moving forward?

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Drug Pricing Lab
Memorial Sloan Kettering

Recent Projects

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

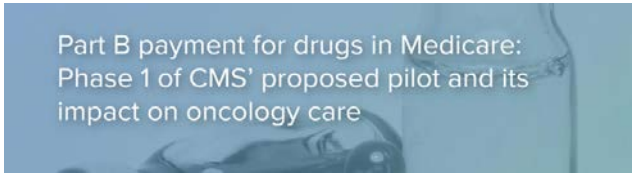
FiercePharma

Express Scripts rolls out value-based pricing for cancer meds

Drugs will cost more in cancer types where they work best

Pink Sheet
Pharma intelligence

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



Opinion

VIEWPOINT

Indication-Specific Pricing for Cancer Drugs

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Health Outcomes Research Group, Memorial Sloan-Kettering Cancer Center, New York, New York.

Author Reading at jama.com

In 2013, spending on specialty drugs, a category dominated by drugs used to treat cancer, totaled $73 billion.[1] That year, 8 new cancer drugs were approved by the US Food and Drug Administration (FDA). The Medicare "price," which includes patient co-insurance, for these 8 drugs ranged from $7000 to $12 000 per month,[2] with some products showing overall survival improvements of nearly 6 months and others showing no improvement in overall survival.

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

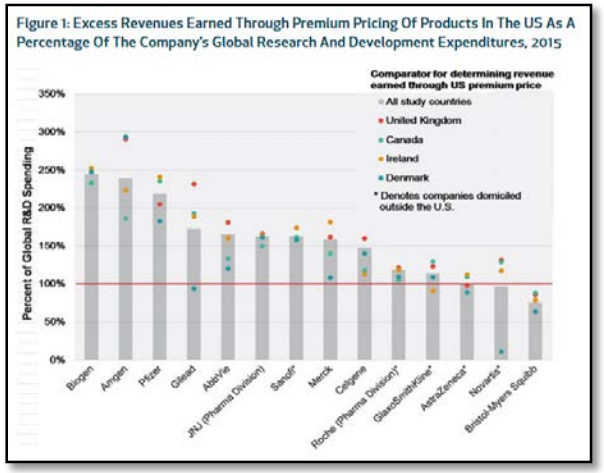
For instance, nab-paclitaxel (Abraxane) improves median survival in metastatic breast cancer by 0.18 years, but the improvement in survival for metastatic non–small lung cancer (NSCLC) is less than half that (0.08 years). The treatment costs are similar for each indication, both per month and over the average duration of treatment. When costs are essentially the same but benefit differs widely, value is not the same. One crude metric of value is the cost per year of life gained. Using Medicare reimbursement rates, the cost per year of life gained with nab-paclitaxel is estimated at $145 000 in breast cancer and $400 000 in NSCLC, as measured by the change in median survival.

Linking pricing to the indication could address this

The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective

Tuesday, May 17, 2016 - 10:00am
Location: 2123 Rayburn
The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective
Subcommittees: Health (114th Congress)

Mr. Welch. I=d like to introduce into the record an article examining congressional comments regarding Medicare=s Part B pilot proposal.



Health Affairs Blog

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

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Recent Projects

- Gilead buy-out
- Copay assistance
- Louisiana budget allocator

Forbes / PHARMA & HEALTHCARE / #MEDICINE

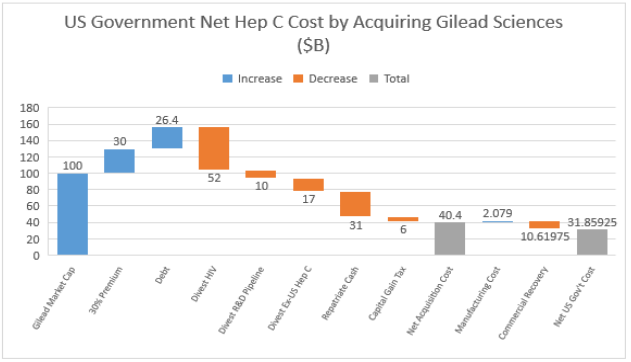
JAN 17, 2017 @ 06:00 AM 32,179 VIEWS EDITOR'S PICK The Little Black Book of Billio

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

Analysis of Federal Gilead Acquisition to Provide Low Cost Hepatitis C Therapeutics

As of December 29, 2016

Peter S. Bach: Memorial Sloan Kettering Cancer Center
Mark R. Trusheim: MIT Center for Biomedical Innovation
Nancy Yu: Memorial Sloan Kettering Cancer Center



npr WBGO

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

March 17, 2017 · 3:49 PM ET
Heard on All Things Considered

Louisiana Budget Allocator

Annals of Internal Medicine®

LATEST ISSUES CHANNELS CME/MOC IN THE CLINIC JOURNAL CLUB WEB EXCLUSIVES AUTHOR INFO

‹ PREV ARTICLE | THIS ISSUE | NEXT ARTICLE ›

IDEAS AND OPINIONS | 20 DECEMBER 2016

Copay Assistance for Expensive Drugs: A Helping Hand That Raises Costs

Peter A. Ubel, MD; Peter B. Bach, MD

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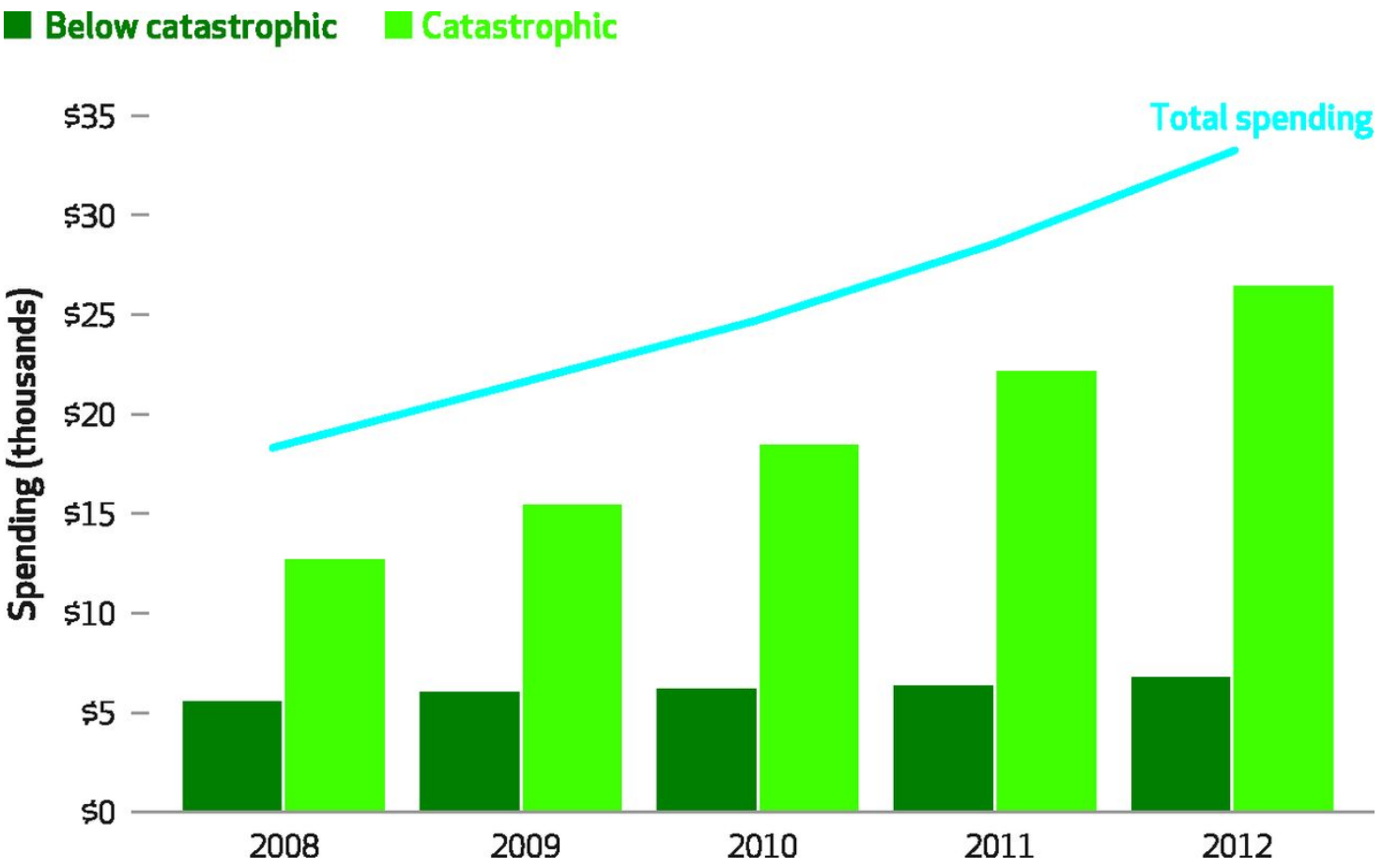
www.drugpricinglab.org

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



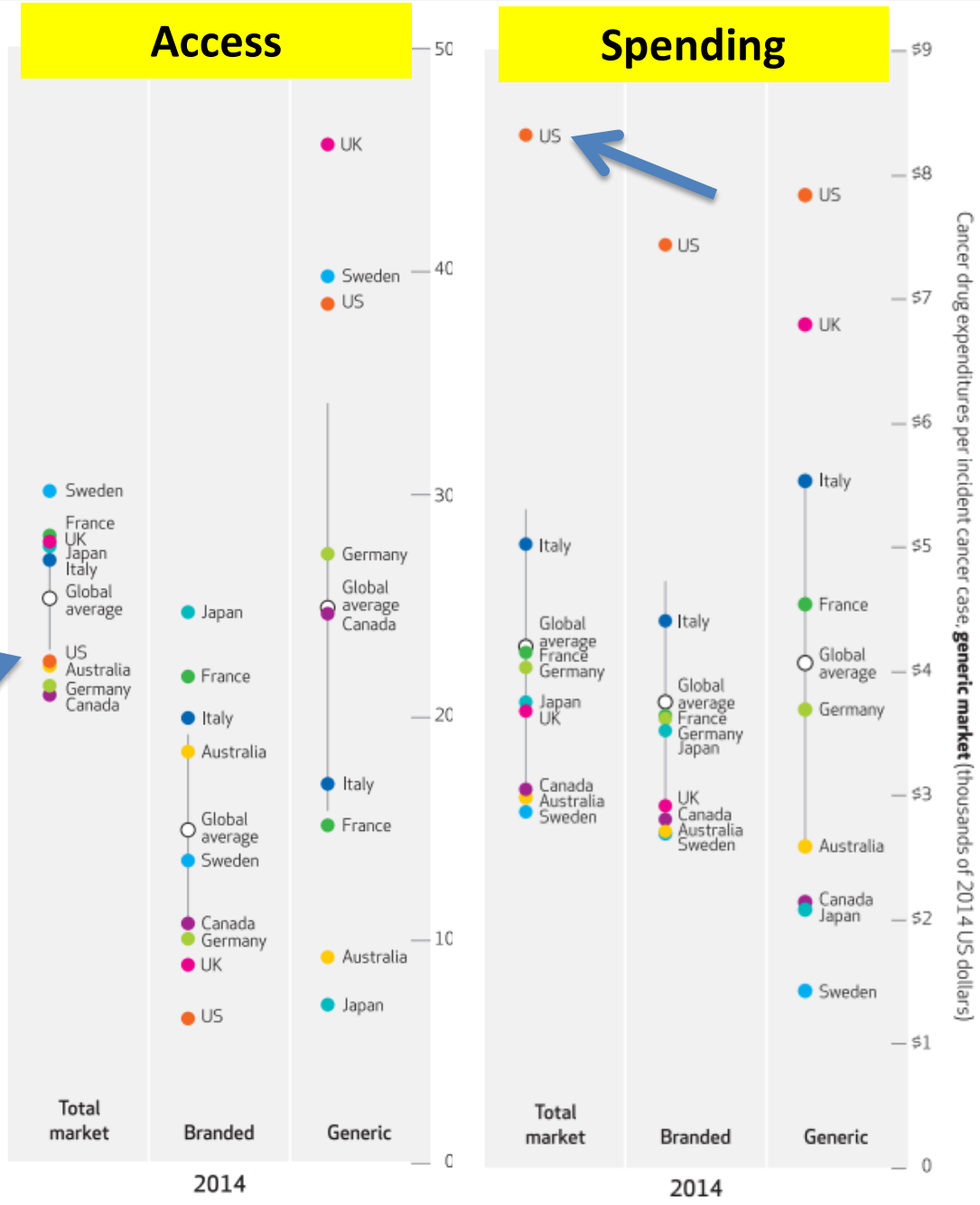
HealthAffairs
Erin Trish et al. Health Aff 2016;35:1564-1571

Access problem

CANCER DRUGS

By Sebastian Salas-Vega and Elias Mossialos

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 3 National prevalence and adjusted odds of cost-related non-adherence among respondents to the 2014 Commonwealth Fund International Health Policy Survey of Older Adults

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

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

ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

CEPAC Comparative Effectiveness Public Advisory Council

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.

PCSK9 Value Based Price Benchmarks

Population	Care Value Price: $100K/QALY	Care Value Price: $150K/QALY	Max Price at Potential Budget Impact Threshold	Draft Value-Based Price Benchmark
TOTAL (n=2,636,179)	***$5,404***	***$7,735***	***$2,177***	***$2,177***

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Outcomes based price for same drug (priced at $14k/year)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Evolocumab and Clinical Outcomes in Patient

Marc S. Sabatine, M.D.,
Narimon Honarpour, M.
Julia F. Kuder, M.A., Hue
Peter S. Sev
for the FO

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.

		PCSK9 inhibitors		
Year Approved	Drug	Number needed to treat to prevent one event	Price/ patient/ month	Cost of treating over two years per avoided MI
2015	Repatha	74	~$1200	$2,123,800

No survival benefit

Sabatine, Marc S., et al. "Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease." *New England Journal of Medicine* (2017).

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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
  - Loosening 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

Outcome	Evolocumab (N=13,784)	Placebo (N=13,780)	Hazard Ratio (95% CI)	P Value*
Myocardial infarction	468 (3.4)	639 (4.6)	0.73 (0.65–0.82)	<0.001

- Current price = $14,100/year
- MI refund = $13,620/year (ICER benchmark = $2,177/year)

Memorial Sloan Kettering Cancer Center

PhRMA
RESEARCH + PROGRESS = HOPE

Policy Solutions: Delivering Innovative T

SOLUTION #2

Address Regulatory and Legal U
Value-Based Payment Arrangem

As we move toward value-driven health care, the limi
become clear. Biopharmaceutical companies are exp
private payers and providers that recognize improvements in care and better outcomes for patients. But
significant regulatory and legal uncertainty is slowing the development of sensible new business 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

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

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

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.

BROOKINGS

HEALTH360

A fair plan for fairer drug prices

Kavita Patel and **Scott Gottlieb** · Monday, July 11, 2016

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

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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