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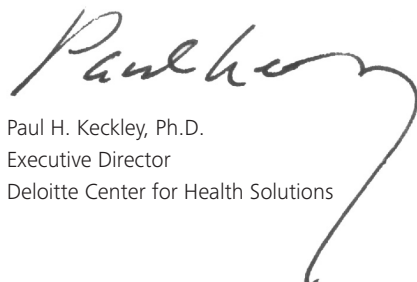
Value-based pricing for pharmaceuticals: *Implications of the shift from volume to value*

Introduction

Health care reform and industry trends are driving pharmaceutical (pharma) companies to rethink strategy in their U.S. pursuits. The move to bundled payments, accountable care, comparative effectiveness research (CER), evidence-based medicine (EBM),¹ and payments linked to performance are the direct result of regulatory and market pressures to reduce health costs without compromising safety and quality.

For pharma companies, these trends represent a paradigm shift in the structure of the U.S. market and call for innovative approaches to commercialization and pricing. In a new value-driven health care system, pharma companies will need to provide pharmaceuticals that demonstrate real, measurable value to stakeholders.

As a result, value-based pricing – the alignment of incentives between purchasers and manufacturers – is getting increased attention. In this Issue Brief, we summarize what is known to date about value-based pricing and identify opportunities for additional exploration.



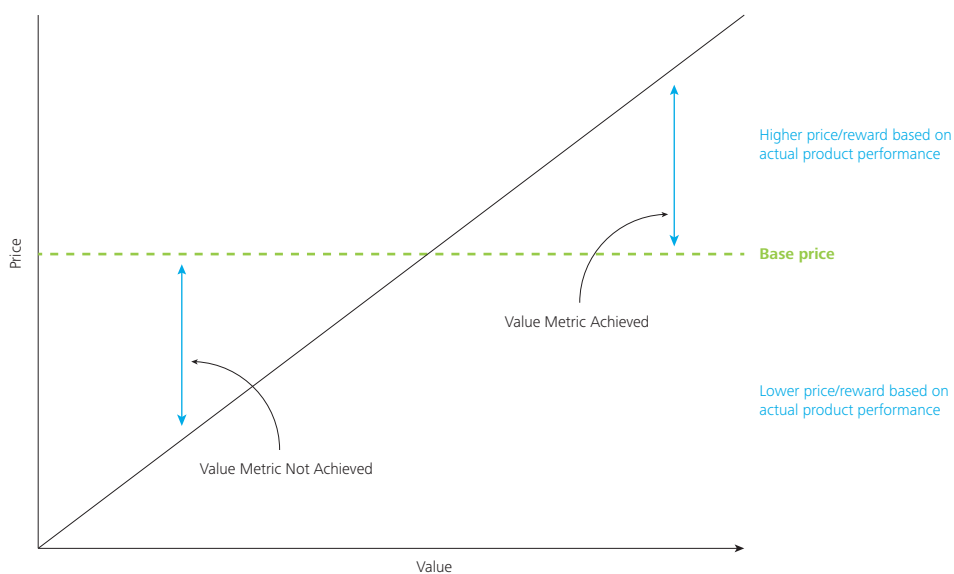
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Definition: What is value-based pricing for pharmaceuticals?

Under value-based pricing agreements, payers and pharma companies agree to link payment for a medicine to value achieved, rather than volume.² Agreements dictate price (and/or coverage) relative to actual (i.e., observed in real-world) performance (Figure 1).³

Figure 1: Value-based pricing agreements



Source: U.S. Bureau of Labor Statistics, Division of Industry Employment Projections. Occupational Outlook Handbook, 2010-11 Edition.

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In this Issue Brief, **pharmaceuticals** are defined as branded (not generic) medications, both “large molecule” biologics and “small molecule” drugs, available only by prescription. **Pharmaceutical (pharma) companies** include biotechnology and pharmaceutical companies. **Payers** include health plans, pharmacy benefit managers (PBMs), most group purchasing organizations (GPO), and employers. Payers typically do not take “title to and physical possession of pharmaceuticals, but instead reimburse providers for the purchases they or their beneficiaries have made” (prices involved in the transactions in which payers engage are not the purchase prices of pharmaceuticals from pharma companies or wholesalers).⁴ If, however, the PBM owns retail and/or mail order pharmacies, such as CVS Caremark and Express Scripts, then the PBM’s pharmacy is a service provider to consumers. **Prescribers and providers** include hospitals, integrated delivery systems/networks, physicians, retail and mail order pharmacies/ pharmacists, and various wholesalers. Providers purchase and generally “take both title and physical possession” of prescription medications, either directly or indirectly providing them to consumers.⁵

A successful value-based pricing arrangement is “incumbent upon a clear definition of when the medication works, and when it does not work.”⁶ There must be a formal, well-defined, consensus value metric (Figure 2). Value attributes (e.g., outcome or performance variables of interest) must be collected, measured, valued, aggregated, and converted (using a decision rule) to evaluate whether the value metric was achieved. Also, there must be a consensus program of data collection, typically initiated early in the commercial life cycle. Value is relative to some alternative;⁷ incremental value over other treatment options is the basis for a higher price. The price must be linked explicitly by formula to the value metric of this program of data collection. A clear payment or reimbursement mechanism is required.

Figure 2: Selected value metrics from literature

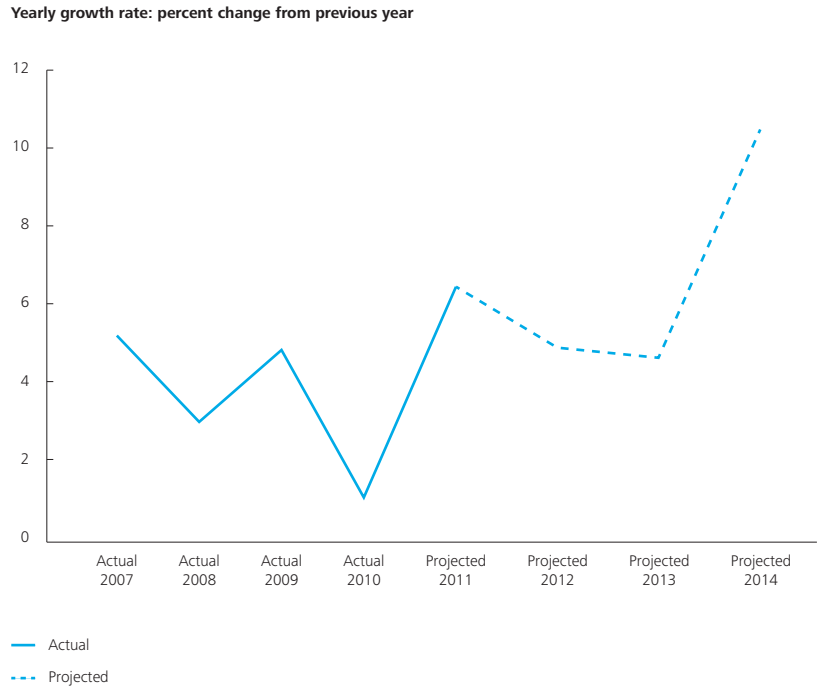
Source	Value metric
Huber B and Doyle J. <i>Oncology Medication Development and Value-based Medicine</i> . Quintiles. 2010.	<p>Composed of the following attributes:</p> <ul style="list-style-type: none"> • Features (what it is) <ul style="list-style-type: none"> - Molecule - Mechanism of action (MOA) • Benefits (what it does) <ul style="list-style-type: none"> - Efficacy - Safety - Risk-benefit analysis (acute, chronic, and long-term perspectives, and vs. other interventions) • Value (why it matters) <ul style="list-style-type: none"> - Cost-effectiveness <ul style="list-style-type: none"> - Including impact of therapy on service provision - Burden-of-illness (BOI) - Consumer quality-of-life (QoL) - Consumer satisfaction/utility - Convenience <ul style="list-style-type: none"> - Medication convenience and compliance by consumer - Relative total value compared with other management options
Faden RR and Chalkidou K. “Determining the Value of Medications – The Evolving British Experience.” <i>New England Journal of Medicine</i> . 2011;364(14):1289-91.	<p>Composed of the following attributes:</p> <ul style="list-style-type: none"> • Basic price threshold <ul style="list-style-type: none"> - Cost per quality-adjusted life year (QALY) or other outcome metric • Value <ul style="list-style-type: none"> - BOI <ul style="list-style-type: none"> - Unmet treatment need or severity of illness - Extent of medication innovation involved - Wider societal benefits

Background: Impetus for value-based pricing for pharmaceuticals

Pharmaceuticals are widely used: 57 percent of U.S. health care consumers take prescription medications and nearly half of such users take three or more prescription medications daily,⁸ according to Deloitte’s *2011 Survey of Health Care Consumers in the United States*. National spending on pharmaceuticals increased 1.2 percent in 2010, according to U.S. National Health Expenditures (NHE) data (Figure 3). By 2014, spending on specialty pharmaceuticals is estimated to “constitute up to 40 percent” of U.S. pharmaceuticals spending.⁹ The growing prevalence of chronic disease is likely to increase the use of life-long chronic disease pharmaceuticals;¹⁰ by 2020, 157 million American adults are projected to have at least one chronic illness.¹¹ Spending for pharmaceuticals in year 2020 is forecast to be \$512.6 billion.¹²

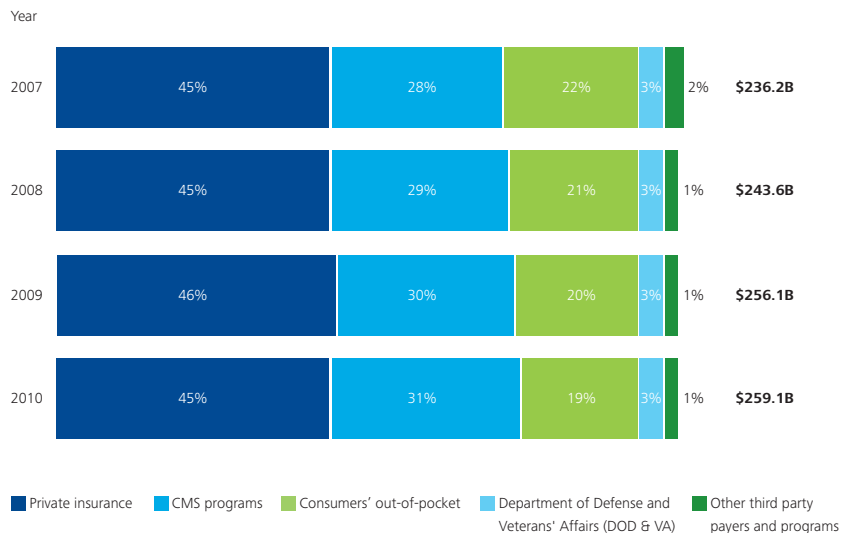
According to NHE data, private insurance paid 45 percent (\$117.0 billion); the Centers for Medicare & Medicaid Services (CMS) programs (Medicare, Medicaid, & Children’s Health Insurance Program [CHIP]) paid 31 percent (\$81.3 billion); and consumers paid 19 percent (\$48.8 billion) of the total \$259.1 billion spent on pharmaceuticals in 2010 (Figure 4).

Figure 3: Yearly growth rate in national expenditures for pharmaceuticals



Note: Retail outlet sales of pharmaceuticals
 Source: NHE, Centers for Medicare & Medicaid Services (CMS)
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Figure 4: National expenditures for pharmaceuticals, by payer (2007-2010)



Note: CMS programs include Medicare, Medicaid, and CHIP
 Source: NHE, CMS
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Figure 5: Among covered workers with three, four, or more tiers of prescription cost-sharing, average co-payments and average co-insurance (2000-2011)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Average co-payments												
First-Tier	\$8	\$8	\$9	\$9*	\$10*	\$10	\$11*	\$11	\$10	\$10	\$11	\$10
Second-Tier	\$15	\$16*	\$18*	\$20*	\$22*	\$23*	\$25*	\$25	\$26	\$27	\$28*	\$29
Third-Tier	\$29	\$28	\$32*	\$35*	\$38*	\$40*	\$43*	\$43	\$46*	\$46	\$49*	\$49
Fourth-Tier	^	^	^	^	\$59	\$74	\$59	\$71*	\$75	\$85	\$89	\$91
Average co-insurance												
First-Tier	18%	18%	18%	18%	18%	19%	19%	21%	21%	20%	17%	18%
Second-Tier	NSD	23%	24%	23%	25%	27%	26%	26%	25%	26%	25%	25%
Third-Tier	28%	33%	40%	34%*	34%	38%	38%	40%	38%	37%	38%	39%
Fourth-Tier	^	^	^	^	30%	43%*	42%	36%	28%	31%	36%	29%

Note: In general, first-tier includes generic pharmaceuticals; second-tier preferred brand pharmaceuticals; third-tier non-preferred brand pharmaceuticals; and fourth-tier specialty pharmaceuticals.

* Estimate is statistically different from estimate for previous year shown (p<.05).

^ Fourth-tier pharmaceuticals co-payment or co-insurance information was not obtained prior to 2004.

NSD: Not Sufficient Data

Source: *Survey of Employer-Sponsored Health Benefits, 2000-2011*. Kaiser Family Foundation and Health Research and Educational Trust. 2011

Payers increasingly are looking to control costs¹³ through utilization management (pharmacy formulary coverage, prior authorization, quantity limits, and step therapy), network design (physician contracting and prescription medication distribution), and benefit design (tiered consumer cost-sharing and payment limits).^{14,15} Among consumers covered by employer-sponsored health insurance plans in 2011, almost all (98 percent) had prescription medication coverage and the majority (88 percent) had tiered cost-sharing; over three-quarters (77 percent) were in plans with three or more tiers of cost-sharing (versus 27 percent in 2000).¹⁶ As consumers' out-of-pocket expenses (co-payment/co-insurance) for pharmaceuticals have been increasing (Figure 5), they have been buying more generics or not filling prescriptions. Among prescription medication users in the *Deloitte 2011 Survey of Health Care Consumers in the United States*, 36 percent reported asking the doctor to prescribe a generic instead of a branded prescription medication due to cost,

23 percent reported asking the doctor to prescribe a prescription medication that was on their insurance plan formulary (when the one prescribed was not on formulary), and 40 percent purchased a generic instead of a prescribed brand because of price information/advice received at the pharmacy counter.¹⁷ According to *The Commonwealth Fund's Biennial Health Insurance Survey of 2010*, the percentage of U.S. adults aged 19–64 who reported not filling a prescription because of cost was 26 percent (48 million) in 2010, up from 18 percent (29 million) in 2001.¹⁸

Payers have substantial bargaining power with pharma companies on the basis of price:¹⁹

- Dominant pharmacy benefit managers (PBMs) have purchasing leverage due to their high-volume, ability to place pharmaceuticals on a higher formulary tier in order to obtain a better price, and depth and breadth of technical expertise.

Figure 6: Detailed analysis of publicly disclosed U.S. value-based pricing agreements (selected, recent examples)

Year	Disease or therapeutic area	Name of pharmaceutical(s)	Pharma Company	Payer	Contract Details	Rationale	Results
2009	Type 2 diabetes	Januvia (sitagliptin) and Janumet (sitagliptin/ metformin)	Merck	Cigna	Merck agreed to peg what insurer Cigna paid (bigger discounts in return for a better placement on Cigna’s formulary – assuring lower consumer out-of-pocket expenses [co-payment/co-insurance]) for Januvia and Janumet to how well individuals with Type 2 diabetes were able to control blood sugar.	<ul style="list-style-type: none"> • Improve consumer compliance to achieve health benefit. • Improve consumer compliance to achieve health benefit. • Provide financial incentives to payers to treat individuals with Type 2 diabetes better and focus on results. 	<ul style="list-style-type: none"> • Secured better placement on Cigna’s formulary because outcomes improved after a year. • Merck gave Cigna additional discounts (versus receiving reimbursement by Cigna) for achieving improved outcomes. • Drove volume. • Did not disadvantage competitors’ access. • Potential a free-rider problem. • Diabetes medications from competing companies also benefited from these compliance activities.
2009	Osteoporosis	Actonel (Risedronate)	Procter & Gamble (P&G), Sanofi-Aventis	Health Alliance	Established Fracture Protection Pilot Program (outcome-based reimbursement program). The Alliance for Better Bone Health (P&G and Sanofi-Aventis) agreed to reimburse Health Alliance for medical costs of treating covered non-spinal, osteoporosis-related fractures in post-menopausal, Health Alliance eligible female members correctly taking Actonel prior to the fracture (maximum number per 1,000 users over one year), by proportionally reducing Health Alliance’s cost of purchasing Actonel.	<ul style="list-style-type: none"> • Arrangement arose due to questions of Actonel’s efficacy in preventing non-spinal fractures. • Provide strong health benefit. • Payer would be reimbursed if Actonel did not achieve health benefit. 	<ul style="list-style-type: none"> • Manufacturers were able to reach more patients by alleviating the payer’s efficacy concerns. • During first nine months of pilot, P&G’s reimbursement to Health Alliance was 79 percent lower than the predefined limit established in the deal. • Incidence of non-spinal fractures was consistent with Actonel clinical trial data.

Note: Information provided in this table is sourced from the following references.

Sources:

NEHI. "Paying for Value: Exploring Innovative Pricing Arrangements for Biopharmaceuticals." NEHI Issue Brief. March 2012.

Health Alliance Announces First Fracture Protection Program for Actonel(R)(risedronate sodium) Tablets. Health Alliance Medical Plans, Inc., Press Release. PRNewswire. April 14 2009.

Figure 7: U.S. Indicators of future value-based relationships (selected, recent examples)

Year	Disease or therapeutic area	Name of pharmaceutical(s)	Pharma Company	Payer	Contract Details	Rationale	Results
2011	Various	Various	AstraZeneca	Large national health plan	“Four-year, U.S.-focused agreement to conduct real-world studies. Partnership is meant to expand to include additional parties, including government payers, hospitals, and other drug makers.”	<ul style="list-style-type: none"> • “Prospective and retrospective observational studies analyzing medicines already on the market will determine how to effectively and economically treat undisclosed diseases.” • “Building relationships with specific public and private organizations to strengthen the existing real-world evidence data set so that it represents care given across different healthcare settings and reimbursed through different types of health insurance coverage.”²⁰ 	Not yet available.
2011	Various	Work will primarily focus on pharmaceuticals in Phase II and III, but no limitations on areas covered by the arrangement	Sanofi	United BioSource Corporation (Medco Health Solutions; now a part of Express Scripts)	Multi-year partnership for real-world evidence assessments during development and approval processes; ability to define relative value for pharmaceuticals early in development.	<ul style="list-style-type: none"> • More precisely identifies consumer populations with great unmet medical need. • Helps to determine consumer populations in which pharmaceuticals are most effective. • Generates real-world comparative effectiveness data. • Develops and implements novel care models to support practice of care, compliance, and consumer outcomes.²¹ 	Not yet available.
2011	Exclusive to three chronic conditions affecting senior citizens: Alzheimer’s disease, pain, and cardiovascular disease (collaboration may expand).	Various	Pfizer	Competitive Health Analytics (Humana)	Five-year partnership (evolved from previous collaborations between the two parties) to improve the quality, outcomes, and costs of health care for senior citizens.	<ul style="list-style-type: none"> • Brings leadership from Humana and Pfizer together to identify a research agenda that would be mutually beneficial. 	Not yet available.
2011	Various	Various	Pfizer	United BioSource Corporation (Medco Health Solutions; now a part of Express Scripts)	Partnership is to identify and evaluate consumer subgroups in which investigational pharmaceuticals and marketed pharmaceuticals are shown to be most effective in improving care and health.	<ul style="list-style-type: none"> • Personalized medicine capabilities. • More effectively match individuals with pharmaceuticals that will benefit them the most, thereby improving consumer outcomes. 	Not yet available.

Note: Information provided in this table is sourced from the following reference.
 Source: Licking EF. “Pharma/Payer Deals: 2011 Saw Important Step In Shift To Value-based RGD.” *The Pink Sheet*. 2012;74(2).

- The federal government has the power to “acquire or reimburse for branded pharmaceuticals at levels equal to or lower than paid by private purchasers.”

Facing payers’ pricing power, pharma companies are trying to avoid losing product differentiation (commoditization). Additionally, health care reform (i.e., bundled payments, accountable care, CER, EBM, and payments linked to performance) is increasing pressure on pricing and reimbursement of, and access to, pharmaceuticals.

Value-based pricing (which measures and rewards value; volume-based pricing does not)²² offers pharma companies the ability to substantiate product value propositions. Agreements could provide far greater transparency to the contribution of the pharmaceutical to the value-outcome of the consumer, and distribute risk differently between the payer and the pharma company.

Looking across the value spectrum: Examples of previous value-based agreements

Value-based pricing agreements for pharmaceuticals

Value-based pricing agreements have been in use for a decade, with increased prevalence in the last five years. In the U.S., the earliest known examples were those used to increase market share by being the initial, major occupant of a market segment, including Proscar (finasteride) by Merck in 1994,²³ Clozaril (clozapine) by Sandoz in 1995,²⁴ Zocor (simvastatin) by Merck in 1998,²⁵ and Diovan (valsartan) and Diovan HCT (Valsartan/Hydrochlorothiazide) by Novartis and Cialis (tadalafil) by Lilly/ICOS in 2004.²⁶ Recent examples demonstrate that pharma companies are incorporating stakeholder values into their pricing agreements (Figure 6) and forming stakeholder partnerships to understand value definitions and obtain value-based data (Figure 7).

Many of the countries in which the government plays a role in pricing and price negotiations of pharmaceuticals (unlike in the U.S.) have focused on reducing costs through value-based pricing agreements as a response to budgetary pressures.²⁷ In Denmark, for example, Bayer entered into a “no cure, no pay” initiative on Levitra (vardenafil) for erectile dysfunction in 2005; patients not satisfied with the treatment were eligible for a refund.²⁸ In 2007, after the United Kingdom’s (U.K.) National Institute for Health and Clinical Excellence (NICE) initially concluded that Velcade (bortezomib) was too expensive relative to its estimated

benefit to the population, Johnson & Johnson offered (in response) to forgo charges for patients who did not have an adequate medication response.²⁹ In Sweden, Willis, et al, (2010) conducted a case study of Duodopa (levodopa/carbidopa) in advanced Parkinson’s disease to gain insights into value-based pricing agreements in combination with conditional coverage.^{30,31} The study concluded that: (1) stakeholders benefited from analysis of real-world (postmarket) data (in addition to pre-launch, trial-based data); and (2) conditional coverage allowed for effective risk-sharing (between a payer and pharma company) and sufficient access to pharmaceuticals by consumers.

These examples provide insight about the types of pharmaceuticals that might be candidates for future agreements. “Products with simple methods for measuring the treatment effects (e.g., decreased blood pressure or cholesterol level), as well those products with clearly defined outcomes (e.g., did the tumor respond to treatment or not) are likely candidates. In addition, products with high budget impact due to high cost and/or high volume appear to be good candidates, as they represent areas of increased scrutiny for payers (e.g., oncology treatments or those for chronic versus acute diseases). It appears as though payers may be more willing to engage in these schemes in areas with high unmet need, high cost, variable treatment duration, and uncertain long-term benefits. In contrast, manufacturers appear to be willing to engage in these schemes if required for access or in competitive disease areas such as oncology and osteoporosis.”³²

Payer demand for value-based pricing agreements for pharmaceuticals

Private and public payers around the globe are encouraging increased use of value-based pricing agreements for pharmaceuticals. As discussed earlier, U.S. commercial health plans have engaged with pharma companies on value-based pricing agreements. Government payers and policy makers seem aligned with the move towards value based pricing. Consider the following examples of payer demand for innovative and value-based pricing agreements:

- The U.S. CMS is shifting from a volume-payment to a value-payment system for medical products.³³ CMS will use “reasonable and effective” criteria for reimbursing medical devices and pharmaceuticals with an emphasis on patient outcomes.³⁴

- The Australian Pharmaceutical Benefits Pricing Authority (PBPA) is now more frequently suggesting alternative pricing agreements in negotiations with pharma companies; pharma companies are encouraged to discuss the potential requirement for an agreement as early in this process as possible.³⁵ As of June 2010, there were 90 alternate pricing agreements (deeds of agreement),³⁶ including value-based, either in place or in development.³⁷
- Germany recently changed its reimbursement system to a value-based pricing system. Pharma companies have one year to prove the value of new pharmaceuticals when compared to existing offerings.³⁸ Achieving value will result in obtaining a premium price compared to the competition; not achieving value will result in a price based on similarly effective, existing (and often generic) pharmaceuticals.
- Beginning in January 2014, the U.K. will engage in universal value-based pricing. The existing Pharmaceutical Pricing Regulation Scheme (PPRS)³⁹ will be replaced with value-based pricing for branded medicines sold to the National Health Service (NHS).⁴⁰ The U.K. will begin with a basic price threshold, expressed as cost per QALY or other outcome metric, and then include three factors: (1) BOI in terms of unmet treatment need or severity of illness; (2) extent of medication innovation involved; and (3) wider societal benefits.⁴¹

Closer look: Value-based insurance pricing in U.S. payer negotiations

In the U.S., the health care industry faces unprecedented pressure to demonstrate quality and cost-effectiveness. The industry's "quest for value" parallels global efforts in pharmaceuticals to employ value-based pricing where "positive outcomes are the ultimate goal."⁴² Value-based pricing for pharmaceuticals, along with value-based insurance design and value-based purchasing, are common themes in the industry's transition away from incentives based on fee-for-service (FFS).

"Value-based insurance design is oriented toward maximizing the value of dollars spent on health care rather than focusing on lower cost for the short term (major target is disease management and appropriate medication utilization, encouraged by no-cost or minimal co-payments for pharmacotherapy to avoid future expensive and complicated treatment from worsening conditions)."⁴³ Numerous studies report strong results in the U.S. from value-based insurance design programs. Novartis employees realized cost savings (the program was largely cost-neutral to Novartis, although it is possible the company saved money by reducing other medical costs)

in a value-based insurance design program for asthma, hypertension, and diabetes medication. After three years, hypertension medication compliance increased 9.4 percent (use rose five percent per program participant, on average).⁴⁴ Pitney Bowes employees realized cost savings (the program produced some savings for the company) in a diabetes and asthma value-based insurance design program where predictive modeling was used to determine which employees should be in a chronic disease management program providing the most favorable (tier 1) access to the right medication. As a result, diabetes medication compliance increased (by 13 percent among fixed-combination oral diabetes medication users) after three years, program participants relied less on asthma rescue therapy (declined 18 percent) after five years, and emergency room visits declined (decreased 26 percent for diabetes and 22 percent for asthma program participants) after five years.^{45,46,47} In an analysis using data from Thomson Reuters' Advantage Suite, a diabetes pharmacy program combining value-based insurance design and disease management produced increased compliance of 3.7 percentage points with prescription medications and adherence to diabetes guidelines in the program's first year. Over three years, the program saw a return on investment of \$1.33 for every dollar spent.⁴⁸

Value-based purchasing is a payment methodology that rewards quality of care through payment incentives and transparency.⁴⁹ CMS began implementing value-based purchasing⁵⁰ pilots and demonstrations in 2003. Achieving success, nearly 80 percent (\$25.3 million) in total Medicare savings was awarded to half of participating groups in the first three years of the Physician Group Practice (PGP) Demonstration. "CMS also reported substantial improvements (an average total increase of 15.8 percentage points) in composite quality scores (CQS) for acute myocardial infarction (MI), coronary artery bypass graft (CABG), heart failure, pneumonia, and hip/knee replacements by end of year three in Hospital Pay-for-Performance: Premier Demonstration. Quality improvement continued into the fourth year, resulting in a total of \$36.5 million in performance incentives awarded to participating hospitals."⁵¹ Further, the Affordable Care Act (ACA; section 3001 as modified by section 10335) establishes a value-based purchasing program for hospitals serving Medicare beneficiaries starting in fiscal year 2013. According to a Deloitte evaluation, the ACA's hospital value-based purchasing program is expected to:⁵²

- Shift payments from volume-based to results-based; 46 measures⁵³ of consumer safety, clinical process improve-

ments, consumer safety, and consumer satisfaction will be used to award bonuses to hospitals based on overall performance.

- Require collaboration across traditional sectors (physician, hospital, long-term, and post-acute care) of the delivery system.
- Be dynamic; 20 additional measures are added in fiscal year 2014.
- Build on previous programs tested by the government; predecessor was CMS' Hospital Inpatient Quality Reporting Program.
- Put providers at financial risk; funding for hospitals is provided by reductions in base diagnosis-related group (DRG) payments for poor performers starting at one percent in fiscal year 2013 and two percent in 2014.

Barriers to implementing value-based pricing for pharmaceuticals

The quest for valid and reliable measures of value

Among payers and pharma companies, difficulties may arise when developing consensus on value metrics and price thresholds (highest price or reward for achieving a value metric and lowest price or penalty for not achieving it). According to the Economist Intelligence Unit survey, pharma companies consider "value to consist of attributes such as the degree of improved efficacy over existing products or the cost-benefit implications of a new drug for overall treatment. Payers, on the other hand, tend to look more towards improved longevity and quality of life. Other studies point to differences in value perception among other groups, such as physicians, pharmacists, and patients."⁵⁴ Stakeholders will need to answer tough questions when developing the value metric, such as: Which value attributes will comprise the value metric? How will each attribute be weighted? Are surrogate attributes allowed; or will consumer variability (e.g., genetic factors, level of compliance, or lifestyle choices) be factored in? Not all payers might be interested in collaborating with pharma companies.

Assessment of value would require adequate consumer data prior to use of the pharmaceutical so changes from the baseline could be assessed (for the user group and comparison group), but it might be difficult to reach an agreement on the start date for the first value metric assessment (if there are differing views regarding the adequate time to achieve response). Payers will likely want to assess value as early as possible, while pharma companies will likely want to ensure that there is adequate time to determine if value has occurred. Additionally, when a medication is indicated for combination and not monotherapy (e.g., it must be used with one or more other drugs) to treat a single disease/condition, it will need to be determined how to measure value.

If value metrics and the overall value-based pricing agreements are not designed appropriately, there is a potential to assume additional risk without true additional upside benefit. There are many measurement issues that will have to be addressed in order to determine if the pharmaceutical has achieved its value metric. Value attributes will need to be routinely collected using a validated measurement tool; such tools will need to be developed if they do not currently exist. Disagreements could occur regarding the time interval for when value metric assessments are conducted (e.g., every six months, every two years). Reaching an appropriate sample size in order to detect a value effect could take time – new pharmaceuticals could have slow uptake if situations such as the following occur: a cautious approach is adopted by providers and consumers in using the pharmaceutical in the real world, providers are uncomfortable about reimbursement, or providers have to adopt a new process or protocol when using the pharmaceutical. Evaluating a response in non-randomized data raises concerns about selection bias. In the real world, compliance is often very different than what is seen in randomized clinical trials; this will need to be taken into account. Many value-based pricing agreements will be conducted over a certain number of years. This can be a challenge when consumers often transition between health plans; consumers may have left the plan before the outcome was achieved.

The intersection of value-based pricing in pharmaceuticals and requirements in the ACA

The ACA mandates that non-grandfathered health plans offered in the individual and small group markets (both on and off health insurance exchanges), Medicaid benchmark and benchmark-equivalent, and Basic Health Programs must provide minimum, or essential, benefits/services in a minimum of 10 categories (which includes prescription medications) beginning in 2014.^{55,56} The Department of Health and Human Services (HHS) guidance released in December 2011 allows states four choices for designing a benchmark insurance package, but leaves the specifics to regulators who design the essential benefits package.⁵⁷ The guidance stipulates that all plans may choose the specific prescription medications covered on formulary, but must offer at least one medication in the same category or class as set forth in the benchmark plan (this reflects the flexibility permitted in Medicare Part D, except that HHS does not intend to adopt the protected class of medication policy within Medicare Part D).⁵⁸ This guidance is intended to encourage competition within pharmacy benefits. Value-based pricing arrangements will have to successfully navigate the variation of states' plans, as well as the ongoing changes to essential health benefits (by HHS or plans).

The availability of valid, real-time data for value metric assessments requires widespread electronic exchange of health information among stakeholders and disparate sources (e.g., health care providers using electronic health records, consumers operating personal health records); this extensive network needs to be further built, as it is not currently widespread, well connected, or interoperable. New programming and analysis techniques might need to be developed as data exchanges expand in order to handle the increased combination of disparate data sources.⁵⁹ Financial questions will have to be addressed: Which stakeholder(s) would bear the costs for the electronic exchange of value attribute data (e.g., creating or expanding exchanges, inputting data into systems); developing any new validated tools for measuring value attributes; developing data protocols; evaluating value metric performance; or performing data reconciliation and adjudication?

CER conducted by the Patient-Centered Outcomes Research Institute (PCORI),⁶⁰ "could create uncertainty about the fate" of a company's medications; "non-supportive findings," especially those that differ with value metric assessment findings, "could substantially impact business."⁶¹

The potential for adverse unintended consequences

A potential increase in bureaucratic hurdles for pharma companies, due to value metric assessment requirements, could delay the release of new pharmaceuticals.⁶² Adverse selection could occur if pharma companies are reluctant to enter into value-based pricing agreements that include high-risk or the sickest individuals. (Treating such individuals could have a negative effect on achieving value unless value metrics take into account the nature/health of the user.) Value-based pricing may require studying a multitude of patient subpopulations (where different levels of outcomes are expected in each) in a real-world setting.

Value-based pricing agreements could impose administrative burdens, requirements, or stipulations (associated with the value metric assessment) on providers and consumers, such as providers' additional monitoring of consumers.⁶³ There could be legal issues that need to be evaluated prior to entering into value-based pricing agreements. Pharma companies cannot run afoul of anti-kickback laws (state and federal) or Medicaid best price law and Medicare Part D regulations.⁶⁴ If a pharma company "lowers price to a commercial customer, they also must lower price to the government programs."⁶⁵

It is unclear how value-based pricing agreements would affect the "buy-and-bill" system used for high-cost specialty pharmaceuticals – by which specialty providers acquire pharmaceuticals from pharma companies and distributors, use them for in-office treatments, and then obtain reimbursements from payers for out-of-pocket expenses. Unless payers require prescribers to purchase specialty pharmaceuticals through specialty pharmacies, value-based pricing agreements could be challenging for these pharmaceuticals.⁶⁶

There could be provider opposition to a push towards mandating certain pharmaceuticals over others or over other procedures (as imposed by the payer, who has entered into an agreement with a pharma company). For example, physicians might lose personal revenue due to a mandated switch from surgery to medication. There could be consumer opposition if some pharmaceuticals which have been shown to be safe and effective are not paid for by health insurance plans, because their value is not justified; 59 percent of consumers state that they oppose the idea of this occurring.⁶⁷ Additionally, if a payer is paid for a pharmaceutical that fails, consumers could perceive this negatively. Payers getting paid for success could provide a more positive consumer-perception.

There could be negative free-rider effects where competitors (companies or payers) benefit from agreements or health information exchange (HIE)/health information technologies (IT) developed by the first-mover, but do not incur any of the costs. (This cuts into profits of the first-mover, because imitation costs are lower than innovation costs.)⁶⁸ Finally, pharma companies that do not achieve value metrics and who are ineligible for higher prices/rewards will have “fixed operating costs that could challenge the viability”⁶⁹ of the company – “if the manufacturer cannot have some degree of a margin on the medication, they simply do not stay in the market.”⁷⁰

Possible benefits of value-based pricing for pharmaceuticals

If implementation and administration challenges are overcome, value-based pricing could provide a better distribution of risk between payers and pharma companies as well as greater transparency of the medication’s value contribution to the consumer.

Pharma companies, aware of which “product features were valued and rewarded,”⁷¹ could derive potential benefit from directing resources and research efforts towards developing pharmaceuticals most likely to achieve higher price/reward (away from unrewarded areas).⁷² Also, widespread electronic exchange of health information, that would allow pharma companies to gain access to broader datasets to monitor user outcomes, could:⁷³

- Guide product development and ensure a competitive advantage at launch by better predicting the effectiveness of new pharmaceuticals.
- Provide important insights into commercial strategy.
- Facilitate and expedite clinical trial recruitment (including the simulation of clinical trials to eliminate some in-vivo trials).
- Provide a stronger foundation for outcomes research.

Pharma companies could differentiate their pharmaceuticals against competitors through higher value achievement.⁷⁴ Costs for postmarket surveillance could decrease (safety-based, postmarket research could be combined with activities supporting postmarket value assertions, thereby saving considerable expense), while quality of surveillance could increase because data standards, infrastructure, and robustness could be improved due to a value-based pricing system. Documenting and analyzing product safety data during value assertion activities could identify potential safety signals, if they exist, earlier; bringing data with a safety

study design to policy makers/regulatory agencies could allow pharma companies to potentially avoid having a particular design imposed by regulators.⁷⁵

Payers could benefit from value-based pricing because they would pay premium pricing only for high-value pharmaceuticals (versus the possibility today of paying premium pricing for low-value pharmaceuticals). Value-based pricing could reduce the risk of paying too high a price for a pharmaceutical that may ultimately have low-value in the real-world.⁷⁶ Payers could, therefore, better allocate resources towards consumers likely to receive the most benefit.^{77,78}

The more integrated providers become, the more aligned their incentives are expected to become. In addition, payer implementation of performance metrics will reward these integrated providers for achieving, or penalize for not achieving, consumer outcomes. Payers could align provider performance goals with the performance/value metrics as specified in value-based pricing agreements.

Consumers could have access to new tools/programs (that assist with value metric attainment and analysis), such as reminders for taking prescriptions or getting lab work done, that could help them better understand and follow their treatment plans.

Better outcomes achieved by consumers (due to receiving targeted, high-value pharmaceuticals) could translate into greater provider satisfaction, possibly reducing the risk that consumers switch providers. Providers could also potentially benefit further from value-based pricing if the payer provides shared savings models. Under such models, the provider would be financially rewarded for selecting the correct high-value pharmaceutical at the right time for the consumer; monitoring, collecting, and submitting consumer value attribute data; and assessing and addressing drivers and obstacles to consumer compliance with pharmaceuticals.

Successful, widespread implementation of a value-based pricing system is dependent on several key actions such as developing and adopting useful and workable value metrics, providing adequate reward for value, and establishing electronic exchange of health information to capture data from the entire consumer experience. All stakeholders must collaboratively work together to help ensure these key actions are achieved (Figure 8).

Figure 8: Key actions that can facilitate successful value-based pricing

Actions	Details	Action Leaders
Develop useful and workable value metrics	Hold discussions (early and often) and collaborate to determine what is of value to each stakeholder.	Pharma companies and payers
	Develop formal, well-defined, consensus-driven value metrics composed of individually weighted value attributes. For example, a value metric could comprise the following attributes (each with a unique weight): mechanism of action (MOA), safety, risk-benefit, cost-effectiveness, BOI, and QoL.	
	Obtain consensus on a common set of principles, policies, and technical methods for the data collection program.	
Provide appropriate rewards for value	Detail and obtain stakeholder consensus on structuring how a higher pricing threshold (highest price/reward and lowest price/penalty) is set and satisfied.	Pharma companies and payers
	Obtain consensus on the payment or reimbursement mechanism. For example, free initial therapy might be preferable to later penalties if a value metric is not reached (determined during periodic postmarket assessments). ^{79,80}	
	Consider payer-provider shared savings models, which could encourage, through the potential to earn rewards, providers to select high-value pharmaceuticals for consumers, as well as collect consumer value attribute data and help consumers achieve compliance with pharmaceuticals.	Payers
Create advanced, large-scale HIEs to collect data from entire consumer experience	Develop the statistical analysis plan ⁸¹ for value metric assessment early. It is critical to determine data standards and interoperability, including data content, definitions/characteristics of raw data, “transport, vocabulary, and terminology standards needed for exchange of health information across settings and a timeline for their evaluation and adoption.” ⁸²	Federal government in collaboration with pharma companies, payers, and private companies
	Leverage the standardized technical specifications, testing resources, legal agreements, and operating policies and procedures of the Nationwide Health Information Network (NwHIN) to enable secure health information exchange across diverse entities over the Internet. This network must allow data/input from a wide range of sources, including clinicians, hospitals, privacy advocates, payers, regulators and policy makers, and consumers (via consumer applications/tools such as mobile health [mHealth] apps). Consumer protected data must be available to pharma companies for review and analysis.	
	Develop standardized data reporting plans for providers to help ensure accurate capture and timely submission of consumer-level value attribute data by providers.	
	Develop, make widely available, and continually improve the usability of innovative consumer applications/tools (that capture and transmit health information into HIE). Educate consumers about the benefits of tools/apps and how to use them.	Pharma companies, payers, and private companies
	Before conducting a value metric assessment, verify that a large enough sample size exists (according to <i>a priori</i> power analysis) ⁸³ so that value metric assessment is not conducted without adequate power, and all data variables are gathered in a realistic time period. Convert aggregated data using a decision rule (examples are provided in the Appendix, Figure A1). Conduct the value metric assessment using health information data from exchange network according to the statistical analysis plan.	Payers in collaboration with pharma companies

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Considerations for stakeholders

Pharma companies

- In the near-term, consider more aggressive and proactive value-based pricing agreements or pilot programs (e.g., with small regional plans) in some therapeutic areas and geographies.
 - Determine which pharmaceuticals work best with value-based pricing agreements, such as when there is a simple method for measuring the treatment effect (e.g., decreased blood pressure or biomarker available); where there is an unreasonably shorter time frame to achieving value performance, if required for access, in competitive disease areas; or to get pharmaceuticals on the market at the desired price points (e.g., expensive oncology biologics).
- Change cultures to promote and reward value.
- Coordinate R&D and commercial functions to focus product development in areas of greatest value.
 - Develop a value-conscious process for selecting and developing compounds based on value determination (e.g., via modeling) in comparison to alternatives.⁸⁴
- Consider developing pharmaceuticals with companion diagnostics to identify the correct patient for the medication. During ongoing treatment, diagnostics could also measure a medication's effects on consumer's disease/condition and assist with treatment and compliance management.
- Identify relevant stakeholders and understand the roles they play in the decision-making process. Initiate discussions early to gain insights and understanding of stakeholders' value perceptions and needs (e.g., key value drivers, economics, unmet needs, and evidence requirements).⁸⁵
- Realize that: "Product differentiation and value story development will need to occur throughout the product lifecycle, from discovery to launch."⁸⁶
- Develop molecular diagnostic capabilities and provide companion diagnostics, when possible, to allow for targeted uses of pharmaceuticals. "Currently, companion tests are being developed in conjunction with biologic therapies for solid and blood cancers, cystic fibrosis, multiple sclerosis, and Alzheimer's disease."⁸⁷
- Compile important safety data while undertaking activities supporting postmarket value assertions.
- Build entirely new value networks through partnerships between different stakeholders who are working together

to solve specific challenges in value-based pricing.

- Diversify and provide non-traditional, customer-focused market offerings/programs that increase total value, such as:⁸⁸
 - Consumer support programs, consumer-centric health management plans, reminders for taking prescriptions or getting lab work done, social media/online communities, on-demand live call center support, click-to-chat support through websites, mobile sites and applications, or consumer monitoring devices.
- Focus on gaining greater compliance within a subgroup of consumers who are most likely to respond to specific pharmaceuticals (versus achieving average compliance across a larger consumer population).⁸⁹
- Communicate how pharmaceuticals impact and fulfill stakeholders' needs. A robust value communication strategy will need to be implemented. To do so, companies should develop an active value communication strategy after assessing how to communicate effectively with stakeholders and determining what tools are needed to demonstrate value to them (e.g., tailored pharmaceutical dossiers not only for clinicians, payers, regulators, and policy makers, but also for consumers).⁹⁰

Health plans (private and public)

- In the near-term, determine which pharmaceuticals work best with value-based pricing agreements, such as when there is high unmet need, high cost and/or high volume, variable treatment duration, uncertain outcomes, or no companion diagnostics. Pilot value-based pricing agreements with pharma companies.
- Verify that pharmacy and medical benefits are not misaligned and link data between the two in order to evaluate cost and outcomes across the entire health-care spectrum, not just through the lens of pharmacy. Consider moving pharmaceuticals covered under the medical benefit to the pharmacy benefit, if feasible.
 - Pharmaceutical management activities should supplement health management interventions, specifically to lower total health care costs.
- Identify and place consumers into disease management programs or wellness programs.
- Communicate in a standardized manner with regulators.
- Align provider and PBM performance goals with the performance/value metrics as specified in value-based pricing agreements.

- As quality metrics are introduced and providers become more integrated, value-based pricing agreements may be more aligned with payer-provider goals.
- Conduct research to understand how consumers impact outcomes and effectively engage with the consumers.
- Conduct research to improve the understanding of barriers to enhance consumers' compliance with pharmaceuticals and incorporate the findings into future initiatives, such as formulary listing considerations⁹¹ and consumer incentives that induce improved compliance.

Employers

- Verify that pharmacy and medical benefits are not misaligned and link data between the two in order to evaluate cost and outcomes across the entire health-care spectrum, not just through the lens of pharmacy. Consider moving pharmaceuticals covered under the medical benefit to the pharmacy benefit, if feasible.
- Align incentives with PBMs.
- Facilitate the right incentives to induce consumers' medication compliance, such as using value-based insurance design.

PBMs

- Understand and monitor each consumer's response and gaps to pharmaceuticals and gaps in care.
- Effectively identify and direct consumers to receive targeted pharmaceuticals (the right/most appropriate treatment for the right person at the right time) so that they are most likely to respond (avoid potential non-responders). Targeting could be done using simulation modeling, predictive analytics,^{92,93} and/or utilizing companion diagnostics or pharmacogenomics.⁹⁴ This action could also improve the way that consumers who most need treatment are found.
 - This action could be best managed by PBMs, because "prescription drug insurance benefit services are typically purchased from a PBM, usually by the underlying health insurer or as a 'carve-out' policy by a large employer."⁹⁵
 - If, however, a PBM is not retained, or when the pharmaceutical is covered under the medical versus pharmacy benefit (e.g., certain specialty pharmaceuticals),⁹⁶ the health plan could manage the targeting of consumers to correct pharmaceuticals.
- Input into data systems (e.g., electronic health records [EHRs]) the targeted medication(s) that were identified for each consumer so that other stakeholders have and can use this information.

- Facilitate consumers' use of high-value pharmaceuticals through reduced cost-sharing amounts.
- Facilitate consumers' greater medication compliance by focusing on the right incentives to induce compliance.

Prescribers/health care providers

- Leverage information technologies to make better decisions in targeting correct pharmaceuticals to consumers.⁹⁷
- Help consumers understand the benefits of high-value pharmaceuticals (versus low-value pharmaceuticals).⁹⁸
- Use information technologies, such as e-prescribing, to reduce errors when prescribing pharmaceuticals; avoidable hospital admissions/re-admissions due to prescribing errors could be reduced.
- Conduct accurate monitoring, collecting, and submitting of consumer value attribute data.
- Assess and address drivers and obstacles to consumer compliance.
- As providers become integrated, have performance-based incentives, and bear risk, value-based pricing agreements could align with provider goals.

Consumers

- Develop strategies to help ensure that consumers understand the need for compliance with pharmaceuticals.
- Educate consumers about the benefits of being compliant with medications and evaluating outcomes.
- Educate consumers on how to use tools/apps that capture and transmit health information into HIE.
- Provide the right incentives (e.g., positive and/or negative reinforcement mechanisms) to drive intended compliance behavior.
- Determine value attributes important to consumers (i.e., consumer-reported outcomes).
- Increase consumer engagement in their health care decision-making process through use of value-based insurance design plans.

Policy-makers: State and Federal government

- U.S. Food and Drug Administration (FDA):
 - Strengthen scientific base/oversight: update Prescription Medication User Fee Act (PDUFA).
 - Bring together regulation and health technology assessments (HTA)/CER⁹⁹ as part of medication approvals.¹⁰⁰
 - Include more consumer-reported outcomes in pharmaceuticals' labeling claims.¹⁰¹
 - Clarify which mHealth apps will require FDA approval.
- Office of the National Coordinator for Health Information Technology (ONC):
 - Direct the next phase of meaningful use and related standards and certification programs to support more robust exchange of standards-based data across multiple settings.¹⁰²
 - Collaborate with industry and consumer stakeholders to develop and implement a national strategy for better matching individuals to their health information.¹⁰³
 - "Issue consistent, comprehensive, and clear guidance on federal privacy and security laws covering personal health information and calls for consistent protection of personal health information."¹⁰⁴
- Health and Human Services (HHS):
 - Facilitate the public sharing of lessons related to HIE that have emerged from federal grantees and contractors – including those participating in the ONC programs identified above, as well as the State Medicaid Program and Center for Medicare and Medicaid Innovation (CMMI) initiative pilots – to support public and private sector efforts to accelerate HIE.
- Cross-agency collaboration:
 - Continue and increase collaboration efforts between agencies (e.g., FDA, CMS, Agency for Healthcare Research and Quality [AHRQ], HHS), such as: FDA-CMS parallel product review (currently, only a pilot program for medical devices); CMS' sharing of part D data with FDA to help identify possible postmarket adverse events; and HHS' new analytics team that ensures the quality of analysis across agencies.

Final thoughts

The quest for value in health care is a global trend that could result in unprecedented impact. The health systems of the world are facing challenges including the need to implement delivery systems that can demonstrate efficiency and effectiveness, establish payment systems that reward desired performance, and have users – consumers – who are actively engaged in appropriate self-care and adhere to evidence-based practices.

Pharma companies are in the eye of this storm. The status quo is not an option. Pursuit of a pivotal role in the quest for value supports the need for change such as implementing value-based pricing as a core strategy.

About this research

Value-based Pricing for Pharmaceuticals: Implications of the shift from volume to value was prepared by the Deloitte Center for Health Solutions and Deloitte Consulting under the direction of Paul H. Keckley (Executive Director, Deloitte Center for Health Solutions) and Glenn H. Snyder (Principal, Life Sciences, Deloitte Consulting).

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Figure A1: Representative approaches to the aggregation of overall value, some of the issues and merits of each, and potential implications for the identification of the value-based price

Aggregation approach	How is value aggregated?	Key issues specific to this approach	Key merits of this approach	Issues common to all approaches
Net benefit	As the sum of the benefits, each assessed in monetary terms.	Challenges estimating the value in monetary terms of each type of value.	Arguably, a better grounding in economic theory. Facilitates the comparison of value and value for money across health and other sectors.	A consensus on the perspective (NHS, government, or societal) from which value is assessed is required, regardless of which approach is used. The metrics by which aspects of value other than health are measured needs to be defined, as a prior step to valuing them.
Multiple criteria decision analysis (MCDA)	As the sum of the points assigned to each aspect of value.	The cost effectiveness threshold would need to be re-assessed in terms of the cost per incremental "point"	A pragmatic approach, widely used in the UK public sector. A more transparent (than a weighted QALY, or deliberative process alone) means of addressing multiple criteria. MCDA is used in local NHS commissioning – potential to develop a consistent priority-setting framework for both new and existing health care technologies.	
Weighted quality-adjusted life years (QALYs)	By QALYs gained, uprated or down-rated by one or multiple weights to represent the magnitudes of other aspects of value.	Assumes that all other sources of value are proportional to the number of QALYs gained Implications for the threshold. If the value of new technologies is assessed in terms of a range of criteria, then opportunity cost has also to be considered in the same terms, not just QALYs foregone. Even if a simple social weighting or QALYs is applied, the opportunity cost will change.	QALY comprises both length and quality-of-life (QoL, which incorporates value (utilities) assessment based on stated preferences).	

Source: Sussex J, et al. *Operationalising Value Based Pricing of Medicines: A Taxonomy of Approaches*. Office of Health Economics. London, UK: Research Paper 11/04;2011 Aug.

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- 60 Established by the Affordable Care Act (section 6301), PCORI (non-profit, non-government entity) develops and carries out a research agenda, including systematic reviews and assessments of existing and future research; primary research (such as randomized clinical trials, molecularly informed trials, and observational studies); and any other methodologies recommended by the methodology committee. PCORI is prohibited from calculating explicit cost-effectiveness metrics or determining explicit cost-effectiveness thresholds.

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