

**October 2, 2007**

## Value Based Payment for Medical Technologies

Over the past four decades, health care spending has exceeded economic growth by 2.5 percentage points annually. The Congressional Budget Office projects that if this trend continues for another four decades, Medicare and Medicaid spending would rise to 20 percent of the nation's gross domestic product (GDP); the same percentage attributable to the entire federal budget today. Many economists identify medical technology as the major factor driving the real growth in health care spending. New medical technologies bring substantial clinical benefits for patients. At the same time, inappropriate use of medical technologies results in excess costs and unnecessary risks for patients. Overuse of expensive technologies is influenced by manufacturer marketing, demand from price-insensitive patients, and financial incentives for providers to prescribe services that may have only limited clinical benefits regardless of cost.

In response, policy-makers are beginning to develop "value-based" payment strategies based on the clinical and economic benefit of specific products and services. Among these techniques are "pay-for-performance" programs that reward providers for complying with clinical best practices like regular diabetic eye exams or beta blocker use following heart attacks. Some payers are exploring reimbursement and consumer cost sharing strategies designed to reward providers and patients who use cost effective medical technologies and discourage them from using technologies with limited or unproven benefits. These efforts are limited by the current lack of research examining the comparative effectiveness of alternative medical technologies, though there is growing consensus about the need for greater US investment in this type of research. As new information becomes available, policymakers will need to determine how they can use it to support more effective health care payment systems.

On October 2, 2007, The Health Industry Forum hosted a conference of leading academics, industry executives, and healthcare practitioners to discuss strategies for purchasing medical technologies that would reflect clinical "value." The purpose of this meeting was to begin discussing key principals and challenges for value-based payment and to articulate future needs for research and policy development.

### KEY THEMES

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- *Widespread use of fee-for-service reimbursement creates economic incentives for using expensive medical services even when costs far exceed potential benefits. In this system, Manufacturers price products to maximize return on investment.*
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Under fee-for-service reimbursement, providers who do more are paid more. Clinicians are eager to adopt new therapies and frequently lobby insurers to cover them quickly. Patients with health insurance generally view most medical services as valuable since they are responsible for only a fraction of the cost. Under such conditions, medical technology firms sell into markets where the end users - consumers and physicians - are price-insensitive.

Like any rational business, pharmaceutical, biotechnology, and medical device companies price their products to maximize return on investment. Pricing dynamics affect future investment, risk-taking, and resource allocation. While companies frequently claim that prices reflect research and development costs, prices are usually based on what manufacturers believe purchasers are willing to pay. Pricing also depends on external factors including the targeted disease, size of patient population, product performance, and availability of alternative treatments. Even when manufacturers point to clinical improvements over existing

products to justify prices, comparison product prices may well have been based on “willingness to pay” rather than any objective measure of clinical value.

Device manufacturers sell products directly to hospitals and other providers who make purchasing decisions within the context of how they are reimbursed by third party payers. Medicare and private payers reimburse differently based on the site of care and generally pay more in high-intensity settings. Device manufacturers have strong incentives to introduce products into the most intensive settings to help justify a higher launch price - even if the product would be equally effective in a lower-cost setting.

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- *Employers and health plans support a shift towards value-based payment, but need better clinical evidence to support paying more for high-value care and less for marginally useful care.*
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Employers and other purchasers want to improve clinical and economic outcomes per dollar of health care spending. Forward-thinking insurers and their customers are promoting changes in payment policy, benefit design, and provider/patient education that encourage high-value care. To do so effectively, however, purchasers need better information about the comparative effectiveness of alternative treatments. Although manufacturers are required to collect safety and efficacy evidence for FDA approval, insurers often believe these data are insufficient to justify coverage of high-cost products. Payers want information about the cost and effectiveness of therapies across likely patients (versus highly-selected clinical trial volunteers), in actual practice settings (versus idealized conditions), and compared to relevant treatments (versus only against a placebo).

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- *Expanded evidence requirements are costly and can delay product sales, but purchasers can create financial incentives for evidence development.*
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The ability to assess a product’s value evolves over time. Insurers frequently have to make coverage decisions for new products based on limited information. For example, evidence based on early clinical trial results may not accurately reflect long term outcomes or utilization patterns. If payers deny coverage for early stage products, they may limit diffusion of an innovation with substantial long term value. On the other hand, once technologies have diffused into widespread use, payers have great difficulty scaling back coverage even for expensive technologies that are later proven to be only marginally effective.

Payers and manufacturers frequently disagree over whether new studies are necessary and “how much evidence is enough.” Some have questioned the value of long term outcome studies for technologies like medical devices, where rapid product improvement cycles may make the studies obsolete before they are completed. Conflicts also occur over requests for data about patient subgroups. Payers frequently want more detailed information to refine coverage policy, while manufacturers argue that physicians should determine the appropriate treatment on a patient by patient basis.

One approach to addressing these challenges is linking coverage to ongoing data collection, similar to Medicare’s new coverage with evidence development (CED) policy. While appealing, the CED initiative has many unresolved issues including: funding for data collection; responsibility for collecting and analyzing data, whether observational data will be sufficient for refining coverage policy, and how much data will ultimately be enough.

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- *Third party payers have to accommodate differing patient responses to therapies, making value-based payment systems complex to administer.*
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Almost every new product will likely prove cost-effective for certain classes of patients, but determining which sub-populations and indications are cost effective requires considerable data and analysis. Payers are unlikely to be able to deny treatments that are highly effective for some patients. Because determining "value" will rely heavily on patient-specific factors, payers will face an unprecedented need for medical review. Reviews that require human intervention are economically infeasible for all but the most expensive technologies. Therefore more widespread application of value-based payment principals will require very sophisticated claims and benefits systems. The complexity of establishing new coverage rules and computerized benefits-management technologies is another factor limiting the rate of value-based payment system adoption in the immediate future.

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- *Payers are experimenting with value-based purchasing strategies including risk sharing with manufacturers and value-based benefit design.*
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Payers are exploring new ways of rewarding high value services while discouraging lower value care. One approach is explicitly linking reimbursement to patient outcomes through risk-sharing with providers or manufacturers. For example, Britain's National Health Service has a new arrangement with Johnson and Johnson in which the company has agreed to refund the cost of its Velcade cancer treatment when the treatment is not effective. A complex issue facing the negotiators of this arrangement was defining when treatment would be considered "effective." Payers are also considering new benefit designs that encourage patients to select high value services or providers. This approach essentially expands the "tiered" drug formulary concept to other medical services. Rather than making controversial coverage decisions for services that may benefit certain patients, value-based benefit design increases cost sharing for technologies that have not been proven cost-effective and shifts financial risk to the end users who are arguably the best arbiter of value.

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- *Value-based purchasing has both risks and benefits for manufacturers. One area for collaboration with payers is promoting appropriate use of their products.*
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In today's healthcare market, medical products and services are both over- and under-priced. A shift towards value based purchasing would reward manufacturers that produce innovative products and reward providers that treat patients effectively. Diminishing unnecessary use of medical technologies would reduce manufacturer revenues. However, the US healthcare system is also plagued with substantial under-utilization of effective services. New programs to promote "appropriate" utilization that simultaneously address both over- and under- use could provide a basis for collaboration between payers and manufacturers.

Any new health care payment structure poses financial risk for participants. Shifting towards a value-based system will be adversarial; progress will require a framework for setting goals and evaluating the performance of new arrangements. More work is needed to set the "ground rules" for value-based payment system so that data collection and analysis can be conducted as a partnership. In reality, evidence evaluation is imperfect. Deciding when to restrict coverage or limit reimbursement for inefficient or ineffective therapies requires strong resolve from employers, elected representatives, and society. Without resolve, progress will be gradual.

*This policy brief was prepared by Robert Mechanic and Darren Zinner of Brandeis University  
Conference presentations and a more detailed proceedings document are available at [www.healthindustryforum.org](http://www.healthindustryforum.org)*

**The Health Industry Forum** is based at Brandeis University and chaired by Professor Stuart Altman. The Forum brings together public policy experts and senior executives from leading healthcare organizations to address challenging health policy issues. The Forum conducts independent, objective policy analysis and provides neutral venues where stakeholders work together to develop practical, actionable strategies to improve the quality and value of the US healthcare system.

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