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Applying Value-Based Insurance Design To High-Cost Health Services

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ABSTRACT Value-based insurance design programs have focused on reducing consumer cost sharing in health insurance for preventive tests and medications for chronic diseases. But for value-based design principles to have a stronger clinical and economic impact, they should be extended to expensive services and to those for which the evidence is limited or controversial. This paper proposes applying value-based insurance design principles to self-administered and office-administered specialty drugs, implantable medical devices, advanced imaging modalities, and major surgical procedures.

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ising health care costs are leading to major increases in cost sharing for patients, as purchasers seek to moderate the rise in insurance premiums. Cost sharing promotes social value to the extent that it reduces patients' use of unproven and clinically ineffective services. At the same time, cost sharing undermines value to the extent that it reduces the use of proven and effective services.

The current trend toward increased copayments, coinsurance, and deductibles reflects purchasers' urgency in moderating cost inflation. Unfortunately, the trend does not seek to differentiate between high- and low-value health services.

Value-based insurance design has emerged as a tool to partially correct this indiscriminate approach, by reducing cost sharing for services when the clinical and cost-effectiveness are uncontroversial. As observed by Peter Neumann and colleagues, current applications of value-based insurance design focus on reducing cost sharing for high-value services and ignore increasing cost sharing for low-value services.¹

Another important limitation of existing value-based insurance design initiatives is that they focus on low-cost drugs, whereas the greatest financial burdens to patients come from biopharmaceuticals, devices, imaging, and surgical

procedures. Some of these services lack evidence of effectiveness, and many are used for conditions other than those for which evidence has been developed. Consumer cost sharing is rising for these services, but purchasers and health plans are not seeking to differentiate between high- and low-value applications.

Resurgence Of Consumer Cost Sharing

The recent increase in consumer cost sharing is reigniting fears about disincentives for consumers to use effective care services. Early studies of cost sharing and service utilization, such as the RAND Health Insurance Experiment in the 1970s, had not reported adverse health effects of consumer cost sharing,² a finding frequently cited by those advocating new high-deductible "consumer-driven health plan" designs.

Some recent studies, however, have documented reductions in the use of preventive tests, such as mammograms, and primary care treatments, such as chronic care medications.³⁻⁵ A few studies have reported that cost sharing for basic services was associated with higher expenditures for specialty services, such as hospitalization and emergency department visits.⁶⁻⁸

None of the recent studies contradicts the general finding, however, that consumer cost shar-

ing reduces health care spending in most contexts. The robust nature of this association underlies the continued interest among employers and insurers in increasing consumer cost sharing. It is important to recognize that consumer cost sharing increases the overall value of the health care system by reducing overconsumption of low-value services. Comprehensive, first-dollar insurance coverage of all health services, regardless of clinical and cost-effectiveness, cannot be the goal of benefit design.

As developed by Michael Chernew and colleagues, value-based insurance design embodies the principle that cost sharing should be structured to encourage use of the most effective services and discourage the use of ineffective services. Deductibles and copayments reduce the propensity of some consumers to use even the most valuable services, despite their benefits for individuals and society.

Large corporate sponsors of health benefits have embraced value-based insurance design principles by reducing copayments for medications that treat chronic illnesses such as diabetes. One "consumer-driven health plans" exempt a defined list of preventive tests and therapies—such as mammograms and vaccines—from the deductible requirements.

Given the clinical and economic importance of high-cost health services such as biopharmaceuticals, implantable medical devices, advanced imaging modalities, and specialized surgical procedures, it is important that cost sharing reflect value-based insurance design principles and, conversely, that these principles be extended beyond low-cost chronic care drugs.

Benefit Designs For High-Cost Health Services

The most important contemporary developments in health insurance design, spurred by the continuing escalation in health care costs, are percentage coinsurance and reference pricing. In contrast with dollar copayments and deductibles, which disproportionately affect low-cost preventive and primary care services, coinsurance and reference pricing disproportionately affect high-cost specialty services.

If structured appropriately, these incentive mechanisms have the potential to increase the value of the health care system by channeling patients to the most effective procedures, providers, and products. If structured inappropriately, however, each has the potential to reduce value by imposing onerous financial burdens on patients who need expensive but effective services.

Percentage coinsurance requires the patient to

pay a fixed percentage—such as 20 percent—of the total charge, rather than a fixed-dollar copayment—for example, \$20. For high-cost services, the difference between coinsurance and copayment can be substantial. Under reference pricing, the insurer pays a defined amount toward the cost of a health-related product or service and the patient pays the remainder. This contrasts with a deductible, where the patient pays a defined amount toward the total cost and the insurer pays the remainder. For high-cost health services, the choice of who pays the remainder, which often is very large, is very important.

An obvious liability of coinsurance and reference pricing as incentive mechanisms for promoting value in health care, ironically, derives from their simplicity. Uniform coinsurance and reference pricing are inherently cost-based rather than value-based incentive mechanisms. Consumers are obligated to pay more for products and services that cost more, regardless of whether those therapies will have a major or minor impact on their health. They are not given signals to help distinguish between very effective, partially effective, and totally ineffective treatments.

Also, some patients pay more than they can afford and end up in medical bankruptcy or forgo care to avoid burdening their families with unmanageable expenses. If value-based insurance design principles are to take hold in the domain of high-cost services, the coinsurance rate must be set lower and the reference price must be set higher for high-value than for low-value alternatives.

Identifying High-Value Services For Lower Cost Sharing

Value-based insurance design discussions to date have focused on services where value is not controversial, such as medications to manage blood sugar for patients with diabetes. In the domain of high-cost services, however, the evidence of effectiveness and value often is incomplete.

Some procedures, drugs, devices, and tests are not targeted at the appropriate patient subpopulation. They might not be used at the appropriate dose or frequency or combined appropriately with other needed services. In addition, they might not be administered by adequately trained and skilled practitioners, linked to patient education and shared decision making, priced at competitive levels, or used with quality measurement and reporting.

On the other hand, many products and procedures are used for appropriately selected pa-

There are numerous criteria according to which the value of a clinical product could be judged.

tients and administered in an effective and costeffective manner. There is a pressing need for criteria that define these as high-value services to be protected from onerous cost sharing.

There are numerous criteria according to which the value of a clinical product could be judged, and different criteria could be used for different services, settings, or patient subpopulations. All are plagued by data gaps and controversies. The available evidence cannot support a complete classification of products and procedures, but it can be used to protect some particularly high-value services.

For some drugs and devices, value could be defined with respect to use in accordance with the Food and Drug Administration (FDA) label; ^{12,13} a recognized drug compendium, such as the National Comprehensive Care Network; ¹⁴ or an authoritative, evidence-based care pathway.

For drugs whose effectiveness varies according to disease severity or patient genotype, value could be defined by using a diagnostic test of susceptibility (ex ante evidence of value)^{15,16} or a biomarker indicator of response (ex post evidence of value).¹⁷

For devices and drugs with incomplete evidence of effectiveness, value could be defined with respect to use within the context of evidence development, such as patient enrollment in a clinical trial or data registry.¹⁸

For services or products where patient selfcare and regimen compliance are salient, value could be defined in terms of use within a shared decision-making or care-management program.¹⁹

For surgical procedures that have substantial variability in cost and quality across provider organizations, high-value providers could be identified with criteria similar to those used to identify centers of excellence, which are hospitals or other delivery organizations that are able to provide outstanding quality statistics and documented adherence to evidence-based processes of care.

Specific Types Of High-Cost Services SELF-ADMINISTERED SPECIALTY DRUGS

► CONTEMPORARY BENEFIT DESIGNS: Historically, outpatient drugs that are prescribed by a physician and obtained by the patient from a retail pharmacy or mail-order service have been carved out of the general "medical" component of health insurance. Instead, they have been covered under a distinct "pharmacy" benefit, with different cost-sharing provisions.

This separation facilitated point-of-service data gathering for such things as drug brand, dose, price, and copayment, and allowed plans to structure cost sharing to encourage the use of low-cost generic and discounted brand-name options. The structure of pharmaceutical services within the overall insurance benefit design offers important lessons for efforts to promote more efficient use of other clinical inputs that have remained within the medical benefit, such as office-administered specialty pharmaceuticals, imaging tests, and implantable devices.

The three-tier drug formulary for pharmacy benefits is a partial example of reference pricing in health insurance design. Typically, the insurer pays drug manufacturers low prices for generic drugs, higher prices for preferred brand-name drugs, and the highest prices for nonpreferred brand-name drugs. The consumer's cost-sharing responsibility is structured analogously; for example, a consumer may have to pay \$10 for generic drugs in tier 1, \$25 for preferred brand drugs in tier 2, and \$50 for nonpreferred brand drugs in tier 3.²⁰

As high-cost "specialty" drugs have become more prevalent in the pharmacy benefit, employers and insurers have moved toward adding a fourth tier to the cost-sharing structure. Specialty drugs, which include biopharmaceuticals, vaccines, and other medications that are expensive and require special handling, are assigned to this fourth tier. ^{21,22} Examples include oral cancer drugs and self-injected drugs for rheumatoid arthritis.

For these drugs, the consumer is charged either a high-dollar copayment, such as \$500 per month or, increasingly, a coinsurance percentage such as 25–50 percent. With the cost of these drugs extending into six figures per patient per year, this specialty tier and its coinsurance structure shift considerable financial exposure to the patient.

The burden of cost sharing is moderated by annual out-of-pocket payment maximums and by the willingness of some pharmaceutical firms to subsidize patients' cost sharing. However, not all insurance designs include maximums, and not all patients are eligible for pharmaceutical subsidies. Medicare Part D plans vary in their

levels of cost sharing for beneficiaries. Among stand-alone plans, more than three-quarters require coinsurance payment for specialty drugs; the most common design requires that 33 percent be paid by the consumer.²¹

▶ APPLICATION OF VALUE-BASED INSURANCE DESIGN PRINCIPLES: Many specialty drugs are disability-reducing and even life-saving, when used appropriately, and insurance principles would declare that coverage be comprehensive for high-cost, nondiscretionary therapies.²⁴ Some outpatient specialty drugs replace more expensive office-administered drugs and thereby reduce the overall cost of care.²⁵

However, the clinical value of specialty drugs varies considerably, depending on characteristics of the patient. These characteristics include clinical indication, disease severity, and comorbidities. Characteristics of the practice setting may also vary, such as physician specialty, the presence of care coordination, and patient education services. Value-based insurance design therefore would need to distinguish between low- and high-value drugs and, more importantly, between low- and high-value uses of the same drug.

In the four-tier formulary structure, which features generic drugs in tier 1, preferred brandname drugs in tier 2, nonpreferred brand-name drugs in tier 3, and specialty drugs in tier 4, value-based insurance design principles could be applied in one of two ways.

Specialty drugs and uses identified as high value could be moved from tier 4 to tier 2, which typically imposes a modest copayment, such as \$25, in contrast to the coinsurance requirement in tier 4 of, perhaps, 25 percent. Alternatively, the tier structure could be expanded from four to five, extending the "preferred" versus "nonpreferred" distinction made for nonspecialty drugs (tier 2 versus tier 3) to the specialty drug domain.

For example, if the conventional four-tier design imposes 25 percent coinsurance in tier 4, the value-based insurance design could create tier 5 for most specialty drugs, retaining the 25 percent coinsurance there. Tier 4 would be designated for preferred, high-value specialty drugs and would be associated with a lower coinsurance rate, such as 10 percent.

This approach would not solve an additional complication: that some specialty drugs are effective—and high value—for some patients, but are ineffective for other patients suffering from the same illness. Value-based insurance design principles ultimately need to be applied to products and patients, not just to products without regard to which patients use them. Tailoring benefit design to differences among patients will depend on the development of reliable diagnos-

The clinical value of specialty drugs varies considerably, depending on characteristics of the patient.

tic tests that can identify ex ante which products will be effective for which patients.

OFFICE-ADMINISTERED SPECIALTY DRUGS

▶ CONTEMPORARY BENEFIT DESIGNS: Some drugs and vaccines traditionally have been administered to the patient during the course of a physician visit or hospital admission, by either injection or infusion. Considered accessory to the professional practice of medicine, they have been covered under the medical rather than the pharmacy benefit. As components of the medical benefit, these specialty drugs are subject to whichever form of cost sharing is applied to physician services, rather than to the tiered formulary design used with the pharmacy benefit.

The cost sharing required of the patient receiving an office-administered specialty drug depends on the level of the deductible, coinsurance, and annual payment maximum, if any. For services used by the patient through the medical benefit, preferred provider organization (PPO) insurance imposes a deductible, then coinsurance (typically, 20 percent) up to an annual maximum, if any.

The typical health maintenance organization (HMO) does not include a deductible and imposes fixed-dollar copayments, such as \$20, per visit, rather than a coinsurance percentage. The HMO enrollee thus does not pay anything for the office-administered drug, while the PPO patient pays a percentage of the cost.

Office-administered specialty drugs are covered under Medicare Part B, which is subject to a \$155 annual deductible and 20 percent coinsurance. There is no out-of-pocket payment maximum under Part B.

▶ APPLICATION OF VALUE-BASED INSURANCE DESIGN PRINCIPLES: There is no justification for imposing different levels of consumer cost sharing on specialty drugs depending on whether they are administered in the office by a physician or self-administered at home by the patient. Differential cost sharing distorts a decision that

should be based on clinical criteria, on the preferences of the patient, and on the total cost of each product.

Cost sharing for office-administered specialty drugs could be structured in a manner identical to that for self-administered specialty drugs. There could be a two-tier specialty drug formulary, with preferred (high-value) medications on the lower tier (tier 4 in the above discussion of the pharmacy benefit design) and the remainder of medications on the second tier (for example, tier 5). As outlined above, one design option would be to retain the current specialty drug coinsurance rate, such as 35 percent, for tier 5 while offering a lower rate, such as 10 percent, for high-value drugs in tier 4.

IMPLANTABLE MEDICAL DEVICES

▶ CONTEMPORARY BENEFIT DESIGNS: Implantable medical devices, such as artificial joints, spine surgery components, vascular stents, and pacemakers, traditionally have not faced consumer cost-sharing requirements separate from those of the surgical procedure during which they are used. Neither physicians nor patients typically take cost sharing into consideration when selecting the brand and type of medical implant because the consumer exceeds the deductible and out-of-pocket maximum regardless of which implant is chosen.

The traditional patient protection from direct cost sharing for medical devices is under reevaluation. The cost of implants varies widely across brands and functional level, often without corresponding variation in clinical effectiveness.

Many surgeons engage in collaborative activities with device manufacturers, for which they receive extensive financial remuneration. These relationships appear to be conducive to the surgeon's brand loyalty and use of the newest and most expensive variants. ²⁶⁻²⁸

Patients increasingly are involved in the choice of devices, and their preferences are influenced by direct-to-consumer advertisements. The prices actually paid by particular hospitals and ambulatory surgery centers depend on the extent of collaboration among the staff physicians and between physicians and the hospital management. Collaborative systems are able to extract lower prices and better service commitments.

▶ APPLICATION OF VALUE-BASED INSURANCE DESIGN PRINCIPLES: A value-based insurance design for implantable devices would offer consumers the opportunity to reduce their financial exposure to the extent that they cooperate with efforts to ensure the appropriateness and efficiency of their care. Some cost differences across devices are a result of differences in functional levels, such as devices for knee replacement and cardiac rhythm management.

Here the value-based insurance design approach would be to cover the basic-function device, leaving the patient to buy up to a higher-function alternative—unless the higher-function device were known to offer a clinically better outcome to this particular type of patient. The question of whether a higher-function device is appropriate—and hence subject to low cost sharing—for a particular patient would be adjudicated by the health plan's medical management professionals in consultation with the patient's physician. That process would be enforced through the prior authorization mechanism.

The structure of cost sharing would again be in the form of two tiers. Basic-function devices would be in tier 1 and have low coinsurance or generous reference-price support, such as the insurer's paying 90 percent. Other devices would be relegated to tier 2 and subjected to higher cost sharing.

To the extent that cost differences are a result of price differences across brands for functionally equivalent devices, the patient could be required to pay the full difference between the lowest available price and the price of the device chosen (another example of reference pricing). Physicians would then have the incentive to discuss device alternatives with the patients and justify the choice of a device with a price higher than the minimum.

ADVANCED IMAGING TESTS

▶ CONTEMPORARY BENEFIT DESIGNS: Rising technical capabilities for advanced imaging procedures such as computed tomography (CT) and magnetic resonance imaging (MRI), combined with the financial remuneration that accrues to facility owners, has led to a rapid increase in the number of testing facilities, patients tested, and tests per patient. ²⁹ Imaging tests are used for patients with confirmed illnesses but also increasingly for healthy populations, such as screenings for cancer. There is considerable debate concerning how to define, measure, and foster high-value applications while limiting applications that offer low value to the patient. ³⁰

Advanced imaging procedures have been embraced by advocates of value-based insurance design to the extent that the tests offer cost-effective warnings of latent cancer or other serious illness. For example, mammography has been shown to be discouraged by consumer cost sharing and therefore has been exempted from the deductible in many high-deductible health plans.⁵

However, these early-detection uses of advanced imaging have been subject to considerable debate about their appropriateness within particular subpopulations (for example, depend-

ing on age and history of disease). 32,33 Although policy makers' attention has focused on the rate at which diagnostic imaging is applied to patient populations, insurers are also concerned with the prices that are charged for each test. There is substantial variation in unit prices across neighboring hospitals, ambulatory diagnostic facilities, and physicians' offices, often based on their degree of market power.

▶ APPLICATION OF VALUE-BASED INSURANCE DESIGN PRINCIPLES: Prior authorization embodies a benefit design component in that it specifies that the insurer will pay all (complete coverage) or part (coverage with consumer cost sharing) if the test is done according to accepted guidelines. Reference-pricing principles can be applied to the related issue of what rate should be paid by the insurer for the test and, by extension, what degree of cost sharing should be expected of the patient choosing among alternative providers.

Under reference pricing, the insurer would specify a maximum benefit for a test within a specified geographic market. Enrollees would be free to choose their own providers but would pay the difference if their provider charged more than the insurer's benefit limit.

An example of reference pricing can be found in the health benefits program for Safeway, a self-insured grocer that employs a large number of people in Northern California, where its corporate headquarters is located (personal communication, Ann Marie Giusto, Safeway, October 2009). Safeway developed an insurance benefit pilot in 2009 for preventive colonoscopy in the effort to encourage early cancer detection.

The benefit features no copayment, and the deductible does not apply to this preventive screening test. However, claims data revealed a significant variation in procedure costs within the larger San Francisco metropolitan area (including professional and facility components). The corporation therefore established a reference-price limit of \$1,500 for screening colonoscopy. Safeway enrollees receive information on which providers charge this amount or less.

Enrollees who choose an in-network provider charging more than the reference amount must pay the entire difference. These additional payments do not count toward their annual out-of-pocket maximums. Patients who require more than a routine screening colonoscopy, such as biopsy at the time of a procedure, are not subject to the reference price. Their test is reimbursed at the standard rate, and standard coinsurance applies.

HIGH-COST SURGICAL PROCEDURES

► CONTEMPORARY BENEFIT DESIGNS: Most health care services are reimbursed through fees

Fragmented provider payment fosters fragmented and incoherent consumer cost sharing.

for individual visits, tests, and drugs rather than for entire procedures or episodes of care. This approach undermines efforts at care coordination and furthers the misalignment of incentives among participants in each patient's course of care. Most important for this discussion, fragmented provider payment fosters fragmented and incoherent consumer cost sharing.

In order for consumers to effectively compare and choose among high-cost health services, the individual components should be bundled together into episodes of care.³⁴ This bundling of clinical components is central to their value, as individual tests, drugs, and procedures often rely on previous or subsequent interventions to ensure appropriate selection, sequencing, and follow-up.

From an economic perspective, the bundling of components is analogous to the creation of "products" that can be evaluated, priced, and compared to alternative treatments. Provider reimbursement can be made as a single payment that covers the entire case or episode, thereby giving all participants a financial common interest in efficiency.

This bundling is especially important for complex and high-cost health services for which consumers experience difficulty in evaluating quality and price. Consumer cost sharing then can be applied in a straightforward manner.

It is more meaningful to apply coinsurance to a case rate for knee replacement surgery, for example, than to require cost sharing for each individual component of care, as is now commonly the case. These include requiring the patient to share payment for presurgical tests as part of a deductible; to pay a portion of the hospital charge as part of an admission copayment; to share physicians' fees as part of coinsurance under the medical benefit; to bear some of the cost of postdischarge medications as part of a tiered formulary under the pharmacy benefit; and to share the expense of postdischarge physical therapy on the basis of office visit copayments.

▶ APPLICATION OF VALUE-BASED INSURANCE DESIGN PRINCIPLES: One starting point for value-based insurance design would be to structure coinsurance for high-cost procedures in two tiers. The standard coinsurance requirement would be 20 percent—similar to the dominant contemporary PPO design; coinsurance for procedures in the high-value tier could be reduced to 10 percent.

Reference-pricing principles could be used to provide an even stronger economic incentive to choose high-value providers. Here the health plan could set its contribution based on the price charged by the average or low-cost provider in the relevant geographic area, with the consumer paying the difference between that contribution and the price charged by the provider chosen.

Reference-pricing principles already are evident in "high performance" network designs. These set a low copayment level for primary care physician visits, a higher copayment for specialty care visits, and an even higher copayment for visits to physicians who do not meet criteria for inclusion in the network.³⁵

Reference-pricing principles are evident in insurance benefit designs that include centers of excellence for organ transplantation, which are hospitals with documented superior performance. In these insurance designs, the consumer's cost sharing is reduced if care is received from a center of excellence.

This principle could readily be extended to more common surgical procedures such as knee replacement. Here the insurer could specify a contribution that it would make, with the contribution based on the payment rate for the most efficient provider team in the local market. The patient would be assigned responsibility for paying the extra costs incurred if a higher-price provider team is chosen.

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Conclusion

Contemporary health insurance designs are byzantine in their complexity and make little effort to differentially cover services according to their effectiveness. Consumer cost sharing often is applied most heavily to high-cost services, regardless of the benefit they offer. By the same token, many services that lack evidence of effectiveness receive generous coverage. Incomplete information and perverse incentives foster overconsumption of low-value services and underconsumption of high-value services.

Value-based insurance design emerged as an effort to protect the most valuable clinical services from consumer cost sharing. Continued cost increases, coupled with the stresses of economic recession, are accelerating the imposition of deductibles, coinsurance, and reference pricing into benefit design.

To date, value-based insurance design initiatives have focused on low-cost preventive tests and chronic care medications, and in this regard have established proof of concept—the design works. But at the same time, current modes of value-based insurance design have left untouched the major drivers of health care costs.

Surgical procedures, office-administered and self-administered specialty drugs, implantable medical devices, and advanced imaging services are more expensive and often more controversial than the services that value-based insurance design initiatives have addressed to date. They constitute the new frontier for insurance design and require that value principles be applied to coinsurance and reference pricing, multiple interventions be bundled into episodes of care for payment purposes, and value-based cost-sharing incentives directed at consumers be coordinated with value-based payment incentives directed at physicians.

NOTES

- 1 Neumann PJ, Auerbach HR, Cohen JT, Greenberg D. Low-value services in value-based insurance design. Am J Manag Care. 2010;16:280–6.
- 2 Newhouse JP, Insurance Experiment Group. Free for all? Lessons from the RAND Health Insurance Experiment. Cambridge (MA): Harvard University Press; 1993.
- **3** Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. JAMA. 2007;298:61–9.
- **4** Trivedi AN, Swaminathan S, Mor V. Insurance parity and the use of outpatient mental health care following a psychiatric hospitalization. JAMA. 2008;300:2879–85.
- 5 Trivedi AN, Rakowski W, Ayanian JZ. Effect of cost sharing on screening mammography in Medicare health plans. N Engl J Med. 2008;358:375–83.
- 6 Hsu J, Price M, Huang J, Brand R, Fung V, Hui R, et al. Unintended consequences of caps on Medicare drug benefits. N Engl J Med. 2006; 354:2349-59.
- **7** Trivedi AN, Maloo H, Mor V. Increased ambulatory care copayments and hospitalizations in the elderly. N Engl J Med. 2010;362:320–8.
- 8 Chernew ME, Juster IA, Shah I, Wegh A, Rosenburg S, Rosen AB, et al. Evidence that value-based insurance can be effective. Health Aff (Millwood). 2010;29(3):530-6.
- **9** Chernew ME, Rosen AB, Fendrick AM. Value-based insurance design. Health Aff (Millwood). 2007;26(2): w195–203.
- 10 Fendrick AM. Value-based insurance design landscape digest. Washington (DC): National Pharmaceutical Council; 2009.
- 11 Robinson JC. Consumer-directed health insurance: the next generation. Health Aff (Millwood). 2005;24(6):w5-583–90. DOI:10.1377/hlthaff.W5.583.
- 12 Stafford RS. Regulating off-label drug use: rethinking the role of the FDA. N Engl J Med. 2008;358: 1427–30.
- **13** Gazarian M, Kelly M, McPhee JR, Graudins LV, Ward RL, Campbell TJ.

- Off-label use of medicines: consensus recommendations for evaluating appropriateness. Med J Aust. 2006; 185:544–8.
- 14 National Comprehensive Cancer Network. Managed care and medical oncology: 'cancer is now on the table' [Internet]. Fort Washington (PA): The Network; 2009 [cited 2010 Sep 29]. Available from: http:// www.nccn.org/network/business_ insights/oncology_trends/manged_ care.asp
- 15 Phillips KA, Vennstra DL, Ramsey SD, Van Bebber SL, Sakowski J. Genetic testing and pharmacogenomics: issues for determining the impact to healthcare delivery and costs. Am J Manag Care. 2004; 10:425–32.
- **16** Lee SC, Bernhardt BA, Helzsouer KJ. Utilization of BRCA1/2 genetic testing in the clinical setting: report from a single institution. Cancer. 2002;94:1876–85.
- 17 Garber AM, McClellan MB. Satisfaction guaranteed: payment by results for biologic agents. N Engl J Med. 2007;357:1575–7.
- 18 Tunis SR, Pearson SD. Coverage options for promising technologies: Medicare's "coverage with evidence development." Health Aff (Millwood). 2006;25(5):1218–30.
- 19 Weinstein JN, Clay K, Morgan TS. Informed patient choice: patientcentered valuing of surgical risks and benefits. Health Aff (Millwood). 2007;26(3):726–30.
- 20 Kaiser Family Foundation, Health Research and Educational Trust. Employer health benefits: 2009 annual survey [Internet]. Menlo Park (CA): KFF; 2009 Sep [cited 2009 Dec 1]. Available from: http:// www.kff.org/insurance/7936/ index.cfm
- 21 US Government Accountability Office. Medicare Part D: spending, beneficiary cost sharing, and cost-containment efforts for high-cost drugs eligible for a specialty tier [Internet]. Washington (DC): GAO; 2010 Jan [cited 2010 Sep 29]. Available from: http://www.gao.gov/products/GAO-10-242
- 22 Lee TH, Emanuel EJ. Tier 4 drugs

- and the fraying of the social compact. N Engl J Med. 2008;359:333–5.
- 24 Goldman DP, Joyce GF, Lawless G, Crown WH, Willey V. Benefit design and specialty drug use. Health Aff (Millwood). 2006;25(5):1319–31.
- Wu E, Chen L, Birnbaum H, Yang E, Cifaldi M. Cost of care for patients with rheumatoid arthritis receiving TNF-antagonist therapy using claims data. Curr Med Res Opin. 2007;23: 1749–59.
- **26** Robinson JC. Value-based purchasing for medical devices. Health Aff (Millwood). 2008;27(6):1523–31.
- 27 Montgomery K, Schneller ES. Hospitals' strategies for orchestrating selection of physician preference items. Milbank Q. 2007;85:307–35.
- 28 Wilson NA, Schneller ES, Montgomery K, Bozic KJ. Hip and knee implants: current trends and policy considerations. Health Aff (Millwood). 2008;27(6):1587–98.
- 29 Baker LC, Atlas SW, Afendulis CC. Expanded use of imaging technology and the challenge of measuring value. Health Aff (Millwood). 2008; 27(6):1467-78.
- **30** Levin DC, Bree RL, Rao VM, Johnson J. A prior authorization program of a radiology benefits management company and how it has affected utilization of advanced diagnostic imaging. J Am Coll Radiol. 2010; 7:33–8.
- **32** Redberg RF, Walsh J. Pay now, benefits may follow: the case of cardiac computed tomographic angiography. N Engl J Med. 2008;359:2309–11.
- **33** Pearson SD, Knudsen AB, Scherer RW, Weissberg J, Gazelle GS. Assessing the comparative effectiveness of a diagnostic technology: CT colonoscopy. Health Aff (Millwood). 2008;27(6):1503–14.
- 34 Hackbarth G, Reischauer R, Mutti A. Collective accountability for medical care: toward bundled Medicare payments. N Engl J Med. 2008;359:3-6.
- **35** Robinson JC. Hospital tiers in health insurance: balancing consumer choice with financial incentives. Health Aff (Millwood). 2003;22(3): w3-35–46. DOI:10.1377/hlthaff .w3.135.