Value-based insurance design (VBID) programs have focused on reducing consumer cost sharing in health insurance for preventive tests and chronic care medications. But value principles need to be extended to expensive services and ones for which the evidence is limited in order to have a strong economic impact.

This Issue Brief presents highlights from a paper in *Health Affairs* that applies VBID principles to self-administered and office-administered specialty drugs, implantable medical devices, advanced imaging modalities, and major surgical procedures.

This Issue Brief is based on an article published in the journal *Health Affairs* ["Applying Value-Based Insurance Design to High-Cost Health Services." 29(11) 2010: 2009–2016].
Applying Value-Based Insurance Design to High-Cost Health Services

Rising health care costs are leading to significant increases in cost sharing for patients, as purchasers seek to moderate the rise in insurance premiums. Cost sharing promotes social value to the extent it reduces patients’ use of unproven and clinically ineffective services but undermines value to the extent it reduces use of proven and effective services. Value-based insurance design (VBID) embodies the principle that cost sharing should be structured to encourage use of the most effective services and discourage the use of ineffective services.

Large corporate sponsors of health benefits have embraced VBID principles by reducing copayments for medications that treat chronic illness such as diabetes. Given the clinical and economic importance of high-cost health services such as biopharmaceuticals, implantable medical devices, and advanced imaging modalities, it is important that cost sharing for these services reflect VBID principles and, conversely, that VBID principles be extended and beyond low-cost chronic care drugs.

IDENTIFYING HIGH-VALUE SERVICES FOR LOWER COST SHARING

VBID discussions to date have focused on services where value is not controversial, such as medications to manage blood sugar for diabetics. In the domain of high-cost services, however, the evidence of effectiveness and value often is incomplete. Most drugs, devices, and tests are used for patients with the appropriate indication, but some are not targeted at the appropriate patient subpopulation, used at the appropriate dose or frequency, combined appropriately with other needed services, administered by adequately trained and skilled practitioners, linked to patient shared decision-making, or used with quality measurement and reporting. There is a pressing need for criteria that define these services as high value and to differentiate them from low value services or low value applications of otherwise effective services.

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 or service indications.

► For some drugs and devices, value could be defined with respect to use in accordance with FDA label, a recognized drug compendium (e.g., National Comprehensive Care Network), or an authoritative, evidence-based care pathway.
► For drugs whose effectiveness varies according to disease severity or patient genotype, value
could defined using a diagnostic test of susceptibility (*ex ante* evidence of value), or biomarker indicator of response (*ex post* evidence of value).

► For devices and drugs with incomplete evidence of effectiveness, value could be defined with respect to use within the context of evidence development (e.g., patient enrollment in clinical trial or data registry).

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

**BENEFIT DESIGN FOR SPECIFIC TYPES OF HIGH-COST SERVICES**

**Self-Administered Specialty Drugs**

Most drugs typically are purchased by the patient at a pharmacy or through pharmacy mail order and is covered by insurance through a “three-tier” formulary. Typically, the insurer pays drug manufacturers low prices for generic drugs, higher prices for preferred brand drugs, and the highest prices for non-preferred brand drugs. The consumer's cost sharing responsibility is structured analogously, e.g., $10 for generics in Tier 1, $25 for preferred brand drugs in Tier 2, and $50 for non-preferred brand drugs in Tier 3.

As high-cost ‘specialty’ drugs have become more prevalent in the pharmacy benefit, employers and insurers have moved towards 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. Examples include oral cancer drugs and self-injected drugs for rheumatoid arthritis. The consumer is charged either a high dollar copayment (e.g., $500 per month) or, increasingly, a percentage known as coinsurance (e.g., 25-50 percent). With the cost of these drugs extending into the 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 the patient's 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, over three-quarters require coinsurance payment for specialty drugs, with the most common design requiring 33 percent be paid by the consumer.

The pharmacy benefit design, with a coinsurance-based fourth tier for specialty drugs, poses the most immediate challenge to principles of value-based insurance design because they are the domain where cost sharing burdens are most onerous for patients with severe illnesses. 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, non-discretionary therapies. Some outpatient specialty drugs replace more expensive office-administered drugs and thereby reduce the overall cost of care. However, the clinical value of specialty drugs varies considerably, depending on characteristics of the patient (e.g., clinical indication, disease severity, co-morbidities) and characteristics of the practice setting (e.g., physician specialty, care coordination, patient education services).

VBID 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 (e.g., $25) in contrast to the coinsurance requirement in Tier 4 (e.g., 25 percent). Alternatively, the tier structure could be expanded from four to five, extending the "preferred" versus "non-preferred" distinction made for non-specialty drugs (Tier 2 versus Tier 3) to the specialty drug domain.

Office-Administered Specialty Drugs

Some drugs and vaccines traditionally have been administered to the patient during the course of a physician visit or hospital admission, either by injection or infusion. Considered accessory to the professional practice of medicine, they have been covered under the medical rather than 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.

The typical PPO product imposes a deductible, then coinsurance (often 20 percent) up to an annual maximum (if any) for services used by the patient through the medical benefit. The typical HMO product does not include a deductible and imposes fixed dollar copayments (e.g., $20) per visit rather than percentage coinsurance. The HMO enrollee thus does not pay anything for the office-administered drug, while the PPO patient pays a percentage of the cost. Medicare covers office-administered specialty drugs under 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.

Value-based benefit design 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 (e.g., Tier 5). As outlined above, one design option would be to retain the current specialty drug coinsurance rate (e.g., 35 percent) for Tier 5 while offering a lower rate (e.g., 10 percent) for high-value drugs in Tier 4.

Implantable Medical Devices

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 within 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 protection of the patient from direct cost sharing for medical devices is under re-evaluation. 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, and these relationships appear to be conducive to the surgeon’s brand loyalty and use of the newest and most expensive variants. Consumers increasingly are involved in the choice of device, with their preferences influenced by direct-to-consumer advertisements.

A value-based insurance design for implantable devices would offer consumers the opportunity to reduce their financial exposure to the extent they cooperate with efforts to ensure the appropriateness and efficiency of the care they receive. Some cost differences across devices are due to differences in functional level (e.g., for knee replacement and cardiac rhythm management devices). Here the VBID 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 is 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, enforced through the prior authorization mechanism.

The structure of cost sharing would again be in the form of two tiers, with basic-function devices in Tier 1 with low coinsurance or generous reference price support (e.g., insurer pays 90 percent); other devices would be relegated to a Tier 2 and subjected to higher cost sharing. To the extent cost differences are due to 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. 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
Rising technical capabilities for advanced imaging testing procedures such as CT and 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. Imaging tests are used for patients with confirmed illness 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.

Advanced imaging procedures have been embraced by advocates of value based insurance design to the extent 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. However, these early detection uses of advanced imaging have been subject to considerable debate as to appropriateness within particular sub-populations, e.g., depending on age and history of disease. While policy 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 the unit prices across neighboring hospitals, ambulatory diagnostic facilities, and physician offices, often based on their degree of market power.

**Application of VBID 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.

**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 while many services that lack evidence of effectiveness receive generous coverage. Incomplete information and perverse
Incentives foster over-consumption of low-value services and under-consumption 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, VBID initiatives have focused on low-cost preventive tests and chronic care medications. This proof-of-concept has been important but has left untouched the major drivers of health care costs. Surgical procedures, office-administered and self-administered specialty drugs, implantable medical devices, and advanced imaging modalities are more expensive and often more controversial than the services VBID initiatives have addressed to date. They constitute the new frontier for insurance benefit design.

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