



Value-Based Insurance Design for Diagnostics, Devices, and Procedures

A Novel Approach to Better Recognize the
Effectiveness and Value of Medical Technology

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EXECUTIVE SUMMARY

Few reform initiatives simultaneously address the critical issues of cost containment and quality improvement. As a result, *value*—the clinical benefit achieved relative to the money spent—has frequently been neglected during discussions about how to manage healthcare spending.

Value-based insurance design (V-BID) has emerged as a potentially viable approach to promote healthcare value by creating health insurance plans that better reflect scientific evidence about the benefit of medical services. The basic strategy of V-BID is to remove barriers to essential, high-value medical services and providers.

To date, V-BID programs have focused on preventive care and prescription drugs. In this paper, the clinical emphasis is on medical technology, and how using V-BID as a consumer engagement strategy can maximize the patient-centered outcomes achieved from the more efficient use of devices, diagnostics, and procedures.

Given the cost-related underutilization of evidence-based diagnostics, devices, and procedures, the potential clinical gains from the use of a “clinically nuanced” insurance design are substantial. However, since a specific medical technology is often a component of a complex episode of care, the design, implementation, and evaluation of such a V-BID program is more complicated than for prescription drugs. V-BID implementations should be coordinated with innovative healthcare delivery initiatives and payment reform programs.

Value—the clinical benefit achieved relative to the money spent—has frequently been neglected during discussions about how to manage healthcare spending.

Pay-for-performance initiatives and patient-centered medical homes are typically designed to reward providers for achieving quality benchmarks, increasing preventive care, and decreasing overuse of low-value services—all of which constitute evidence-based medicine. This alignment is particularly important in cases where the outcomes of the use of technology-intensive medicine, including invasive procedures and implantable devices, critically depend on provider competence. In these instances, patient incentives and provider payments should be aligned to encourage patients to obtain evidence-based technologies from high-quality providers.

Four basic approaches to V-BID in the pharmaceutical realm have been outlined previously. Given the different attributes of devices, diagnostics, and procedures, an alternative categorization of V-BID approaches is proposed:

Design by Clinical Indication. Waive or reduce copayments for specific groups of patients, when evidence has demonstrated value.

Design by Condition. Waive or reduce copayments or coinsurance for technologies, based on specific clinical conditions with which patients have been diagnosed.

Design by Risk. Waive or reduce copayments or coinsurance for high-risk individuals who are eligible for screening, genetic counseling programs, or treatments.

Design by Provider. An adjuvant to other approaches, this V-BID solution reduces or waives copayments or coinsurance for patients who obtain care from healthcare providers who consistently provide high-quality, high-value services.

By setting patient cost-sharing levels based on clinical value—not price—to ensure access to medical technologies that produce health benefits that exceed their costs, V-BID will produce more health per dollar spent. Such a reorientation of spending toward services with greater potential for achieving patient-centered outcomes is feasible and applicable to devices, diagnostics, and procedures. The use of “clinically nuanced” incentives to direct the use of medical technologies can improve clinical outcomes, enhance patient and provider satisfaction, and encourage innovation, all within a sustainable cost structure.

The basic strategy of V-BID is to remove barriers to essential, high-value medical services and providers.

INTRODUCTION

Addressing Cost Containment and Quality Improvement

The past several decades have produced remarkable technological and therapeutic innovations for the prevention and treatment of disease, resulting in impressive reductions in morbidity and mortality. In the United States, however, the achievement of such enhanced clinical outcomes has coincided with a significant stress on the healthcare system—namely, the burden of ballooning costs of care.

Although slowing the growth rate of healthcare expenditures has been a major goal of many recent U.S. healthcare reform proposals, broadening access to medical services and improving the quality of care have also shared the limelight. Despite unequivocal evidence of clinical benefit, substantial underutilization of high-value services persists across the entire spectrum of clinical care including prevention, diagnosis, and treatment.

Few reform initiatives have simultaneously addressed the critical issues of cost containment and quality improvement. As a result, *value*—the clinical benefit achieved relative to the money spent—has frequently been neglected during discussions about how to manage healthcare spending. Today's ongoing challenge for healthcare stakeholders is to enable innovation in healthcare while containing expenditure growth. Proposed strategies to improve quality while containing costs include:

- Paying physicians for adhering to care processes (guidelines or measures) that enhance health outcomes.
- Educating patients and physicians about the expected benefits and risks of care.
- Involving patients and patient values more fully in care planning (shared decision making).
- Creating health insurance plans that better reflect scientific evidence about the benefit of medical services.

Today's ongoing challenge for healthcare stakeholders is to enable innovation in healthcare while containing expenditure growth.

This final approach—better incorporating scientific evidence into insurance design—is the focus of this paper: Our emphasis is on the clinical application of medical technologies, and how this innovative consumer-engagement strategy can maximize the patient-centered outcomes achieved from the more efficient use of devices, diagnostics, and procedures.

Expanding Role of Health Insurance in Quality and Cost of Care

Historically, insurers have played a limited role in ensuring the quality of medical care received by their beneficiaries. Over time, health plans have gradually become more involved in measurement and research to benchmark the quality of the services provided. But until recently, little attention was paid to how the financial incentives in health plan designs affect the care-seeking behaviors and health outcomes of enrollees.

It is well known that insurance coverage may conceal the true costs of care from beneficiaries, and therefore carries a risk that patients will utilize services for which the total costs outweigh the health-creating benefits. To offset such potential overuse and constrain the growth

of healthcare costs, employers, health plans, and other payers have implemented a variety of mechanisms with varying levels of success. Among the most commonly applied strategies to control healthcare expenditures are cost-shifting to consumers in the form of increased premiums, and cost-sharing at the point of service.

The theory behind cost-shifting and cost-sharing in the form of premiums, deductibles, and copayments is that beneficiaries will use healthcare services most appropriately if they are directly involved in the financial decision-making related to their care choices. By assuming a share of the cost, patients take some responsibility for selecting the services that are of greatest value, based on their personal preferences and medical needs. **Under optimal circumstances, individuals will choose to use only those services for which the clinical benefit is worth the added out-of-pocket cost.**

Nevertheless, consumers' incentives are often misaligned with the goal of seeking evidence-based care. In a typical health plan, patients' copayments are set at the same amount for a certain type of service (e.g., physician visit, laboratory test, drug within a formulary tier) regardless of the relative clinical value of specific interventions within each service type. In such a "one-size-fits-all" system, little consideration is usually given to evidence about the effectiveness of an intervention.

To be optimally effective, higher patient copayments should not discourage the use of all healthcare services, only those known to be of low value. Yet, consumers respond to prices for healthcare services just as they do in other economic sectors. As copayments rise, utilization falls for all services—regardless of their clinical value. Increases in patient cost-sharing result in lower use rates for essential screenings, diagnostic tests, and procedures, leading to worse clinical outcomes and, in some cases, higher aggregate expenditures.

A Roadmap to V-BID Objectives

When it comes to implementing a value-based insurance design program, details are vitally important for encouraging best practices in the selection and use of medical technologies. But it's also a good idea to keep an eye on such big-picture objectives as the following:

- Cost-containment efforts should not be permitted to reduce quality of care.
- V-BID principles can be used to facilitate cost-containment activities. But cost savings should not be the exclusive goal applied to V-BID or other healthcare reform efforts.
- V-BID should be considered as a set of principles that can help guide the healthcare system's inevitable and increasing reliance on cost-containment initiatives.
- Under a V-BID program, barriers to the adoption and use of high-value services should be eliminated or set at a low rate, while higher patient costs should apply to technologies of lesser or uncertain value.
- Consumer engagement initiatives such as V-BID must be aligned with ongoing payment reform and delivery system transformation such as pay-for-performance initiatives, disease management programs, and wellness initiatives.

To be optimally effective, higher patient copayments should not discourage the use of all healthcare services, only those known to be of low value.

While recognizing that constraining healthcare expenditures is an important national fiscal priority, cost-containment efforts should not produce preventable decreases in quality of care. Value-based insurance design (V-BID) was developed to mitigate the negative consequences on utilization of evidence-based services that can occur when levels of patient cost-sharing are increased.¹

V-BID's basic strategy is to remove barriers that inhibit the use of essential, high-value health services. Using a "clinically nuanced" approach, patients assume an out-of-pocket cost proportional to the clinical value—not the price—of a given service. In doing so, V-BID incorporates evidence regarding the clinical benefit of a given intervention, and can be tailored for application to a specific patient or group.

V-BID is innovative in its ability to make highly effective care more attractive by reducing or eliminating barriers to use. Conversely, V-BID programs can also make poorly effective, lower-value care less desirable by increasing patient cost-sharing. By promoting the most effective interventions, V-BID programs increase the quality and value of care patients receive and thus add efficiency to the healthcare system as a whole.

As defined and applied by the University of Michigan's Center for Value-Based Insurance Design, the V-BID concept encompasses several key principles:

- Healthcare services differ in their costs and in the health benefits they produce.
- The value of healthcare interventions depends upon the characteristics and preferences of the individuals who receive them.
- The value of a particular healthcare service is a measure of the clinical benefit it provides to a specific recipient relative to the money spent in performing the service.

Because the notion of *value* incorporates both the amount spent on healthcare services and the amount of health benefit gained by the recipient, assessing the value of a treatment or benefit package requires simultaneous consideration of both the cost and quality of services.

Achieving high value does not necessarily require that a service must be less expensive. Less-costly services may not always generate sufficient health benefits to be considered high value. On the contrary, in some clinical scenarios earlier use of a more expensive clinical intervention leads to better outcomes and lower aggregate costs.

Primer on FDA Regulation of Devices

The Food and Drug Administration (FDA) defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, that does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and is not dependent on being metabolized for the achievement of any of its intended purposes.

In the United States, medical devices are regulated by the FDA Center for Devices and Radiological Health (CDRH), which shapes the regulatory processes for permitting devices to enter the marketplace in accordance with the risk of the device in use. Class I is associated with the lowest risk devices, for which the agency requires compliance with *general controls* that include standards for manufacturing, labeling, postmarket surveillance, and adverse event reporting. This class encompasses a wide range of technologies, including bandages and scalpels. Most Class I devices do not undergo any formal FDA review prior to being marketed.

Class II devices carry potentially higher risk, for which general controls are considered insufficient.

These devices are associated with *special controls*, which may include a declaration of conformity with internationally accepted performance standards. Class II devices also generally require FDA clearance, which is obtained via a premarket notification (510(k)) submission demonstrating the *substantial equivalence* of the new device to a specified predicate device already on the market. The standard of substantial equivalence usually requires only in vitro and animal data, although clinical information is not precluded and is required—at the discretion of the agency—for approximately 30% of 510(k) submissions.

Class III devices are those judged to pose the highest potential risk. Implantable devices, some diagnostic devices, and monitoring devices fall under Class III. These devices may sustain or support life or may carry a high risk of adverse events. The type of controls used for Class I and Class II devices are considered insufficient to demonstrate safety and efficacy; therefore, most Class III devices require FDA premarket approval (PMA) prior to being released. Approval via the PMA pathway typically requires clinical data demonstrating the safety and efficacy of the device for specified clinical applications in its intended patient population.

APPLYING V-BID TO DIAGNOSTICS, DEVICES, AND PROCEDURES

Most published research addressing the clinical impact of changes in patient cost-sharing has focused on preventive care and prescription drugs. The impact of increases in patient cost-sharing on the use of services is fairly intuitive and straightforward. Specifically, a growing body of evidence demonstrates that increased patient cost-sharing leads to decreases in both nonessential and essential care, including cancer screening and ambulatory clinician visits.^{2,3}

As consumer-directed, high-deductible health plans grow in popularity, out-of-pocket costs are likely to rise for diagnostic tests, therapeutic devices, and medical-surgical procedures, likely leading to decreased access to medical technologies that enable the prevention, early diagnosis, or better treatment of clinical conditions.

Given the cost-related underutilization of diagnostics, devices, and procedures, the potential clinical gains from the use of a “clinically nuanced” insurance design are substantial. Because the use of a specific medical technology is often a component of a complex episode of care, however, it is more complicated to design, implement, and evaluate a V-BID program for technologies than for prescription drugs. In the following sections, selected clinical scenarios illustrate the potential opportunities and impediments for V-BID in the medical technology realm.

Screening. In the realm of diagnostic testing, age-appropriate cancer screening lends itself well to the application of V-BID. Reducing barriers to targeted cancer screening improves compliance with recommended testing, which in turn identifies cancers at an earlier stage and saves years of life.

Although lung cancer is one of the most lethal cancers, responsible for 150,000 deaths in the United States

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each year, the U.S. Preventive Services Task Force does not recommend screening. In 2011, the National Lung Screening Trial published the results of a longitudinal study showing that the use of serial lung cancer screening with low-dose computed tomography (CT) is more effective than chest x-rays in selected patients, resulting in a 20% relative reduction in lung cancer mortality.⁴ Further, actuarial analysis of similar data suggests that annual low-dose CT screening of 50–64-year-old current and former heavy smokers results in a cost per year of life saved comparable to colon cancer screening.⁵

A V-BID program that reduces the copayments of the targeted population of smokers for indicated screening tests would likely enhance compliance with this clinically beneficial and cost-effective intervention.

Therapeutic Devices. Many technologies and therapies provide high value for a select subset of patients. Such highly targeted interventions result in lower overall costs to the V-BID program, because few individuals are eligible for reduced copayments.

CASE STUDY

Integration of Devices and Drugs in a Tiered Chronic Disease Management Program

Use of a Predictive Model to Identify Opportunity

Pitney Bowes commissioned an analysis to determine what caused its diabetic health plan participants to incur increased costs. A program was developed that used an artificial intelligence model to link employee variables to increased costs, and included the indirect costs related to absenteeism and disability.

The Plan. The main benefit structure moved several tier 2 and tier 3 drugs to tier 1. Additionally, any glucose test strips that were in tier 2 or tier 3 (e.g., Accu-Chek, OneTouch Ultra) were shifted to tier 1.

In parallel with these benefit changes, the company increased its diabetes disease management and wellness efforts, supplying glucometers free of charge.

Results. Patient costs for a 30-day refill dropped by 50%. Under the new 10% tier 1 copayment, many patients pay 80% less than their previous drug costs.

The percentage of members with suboptimal adherence to insulin therapy decreased by more than 65%, while the percentage using fixed-combination oral hypoglycemic agents increased from 9 to 22%.

Finally, among insulin-dependent diabetic plan participants, the shift to the newer brands of test strips in tier 1 was associated with a doubling in the usage rate of these test strips on glucometers (from 28% usage to 55% usage).

Healthcare utilization and costs for participants with diabetes also decreased. The rate of emergency department visits dropped by 26%, likely due to improved adherence with the oral hypoglycemia medications. The hospitalization rate increased slightly for participants with diabetes, but remained below the demographically adjusted benchmark rates derived from the Medstat database.

Overall, the per-patient cost of care for Pitney Bowes plan participants with diabetes decreased by 6% from 2001 to 2003.

Given the cost-related underutilization of diagnostics, devices, and procedures, the potential clinical gains from the use of a “clinically nuanced” insurance design are substantial.

An example of such a targeted V-BID approach would be to incentivize the use of high-value technologies, such as implantable cardioverter-defibrillators for patients with a cardiac ejection fraction $\leq 35\%$ and medically optimized New York Heart Association Class 2 or 3 congestive heart failure (CHF).

A similar example would be to lower copayments for percutaneous coronary intervention (PCI) for patients with persistent Canadian Cardiovascular Society Class 3 or 4 angina despite maximal anti-anginal therapy.

Conversely, higher copayments would be appropriate for patients with chronic stable angina undergoing PCI who had not been treated with optimal medical care. Those increased copayments would not be applied to patients who had persistent angina in spite of optimal medical therapy.

Molecular Diagnostics and Targeted Therapy.

Another opportunity for V-BID lies in genetic tests to determine epidermal growth factor receptor (EGFR) tumor expression, and the subsequent development of EGFR tyrosine-kinase inhibitors, for the treatment

of non-small-cell lung cancer. EGFR tyrosine-kinase inhibitors have been shown to be more effective than a standard chemotherapy regimen in treating EGFR-positive lung cancer, and have demonstrated greater clinical benefit for women, non-smokers, and certain ethnic groups.

Since V-BID seeks to remove barriers and provide incentives for therapies with high potential for clinical benefit, one can imagine a scenario of varying copayments for treatment with tyrosine-kinase inhibitors dependent upon EGFR expression and other factors that predict clinical benefit. In this scenario, V-BID would encourage the performance of genetic testing to quantify EGFR expression and determine potential clinical benefit, as well as to establish the patient's share of treatment costs.

High Performing Providers. V-BID principles may be extended by providing incentives for patients to receive care at high-performing diagnostic and treatment centers. By reducing copayments for using clinicians and healthcare systems that have demonstrated their ability to deliver high-quality care, payers can use V-BID principles to guide patient choices, and potentially influence physician practice.

For example, Blue Shield of California's “Blue Groove” program uses lower copayments for clinician visits and evidence-based services as an incentive to steer patients with chronic diseases such as CHF, hypertension, and diabetes toward a designated team of clinicians that provide high-quality, evidence-based care. Similarly, a program for employees of Lowe's Companies offers reduced out-of-pocket costs when they select the Cleveland Clinic for invasive heart procedures, illustrating how guidance toward high-performing providers can be applied to devices and procedures.

CASE STUDY

Incorporating Molecular Diagnostics

Advanced Technologies for Determining Prognosis or Predicting Response or Toxicity to Therapy

The adoption rate of new markers to inform treatment decisions for cancer patients has been slow, and very few such markers are employed in clinical practice. Although full information in this rapidly evolving area of clinical medicine is elusive, the field is highly appropriate for the application of V-BID programs.

Prognostic biomarkers are indicators of the natural history of disease and the pathological process, and can enable clinicians to estimate the probability of recurrence. Predictive markers are distinct from prognostic markers in that they provide an estimate of the patient's probable response to therapy.

Examples of Successful Predictive Markers.

Recently, several anticancer therapies, including immunotherapy and targeted therapies, have provided alternative treatment options for cancer patients.

Vemurafenib, a signaling pathway inhibitor that targets the mutated BRAF gene, has conferred improved overall and progression-free survival for patients with advanced melanoma compared to standard chemotherapy, but only in those patients whose tumors harbor the mutated BRAF gene.

Based on these results, FDA approved Vemurafenib for the treatment of patients whose metastatic melanoma carries the BRAF V600E mutation, as determined by an FDA-approved test.

The introduction of epidermal growth factor receptor (EGFR) inhibitors in the clinic has led to the identification of molecular markers for predicting the success of cancer therapies. EGFR-activating mutations are used in patients with non-small-cell lung carcinoma (NSCLC), and gene amplification methods are used in patients with colorectal carcinoma, to predict sensitivity to EGFR inhibitors. FDA recently approved Crizotinib to treat a small subset of NSCLC patients who have the EML4-ALK fusion gene resulting in the activated ALK kinase this drug targets.

Potential V-BID Design. Given such results, it would be appropriate to reduce or eliminate copayments for many molecular diagnostic tests that produce information to guide therapy. Alternatively, copayments may be increased for treatments used in specific patient populations for whom they are less likely to be effective based on the test results.

CASE STUDY

Bariatric Surgery

Addressing Obesity Is the “Right Thing to Do”

MGM is one of the world’s leading hospitality companies, operating a portfolio of destination resort brands. The company determined to create a surgical weight-loss option as part of its self-administered benefit plan to help improve employee quality of life while reducing obesity-related healthcare costs.

Implementation Details. When implemented in 2010, the sponsor’s bariatric and metabolic program for employees and dependents included:

- Bariatric surgery coverage at a designated center of excellence.
 - Six-month medically supervised weight-loss program.
 - Reimbursement of \$5000 out-of-pocket surgical copayment if employee reaches a predetermined weight-loss goal (at two years).
 - Incentive of \$5000 toward cosmetic procedures to remove excess skin (at four years).
 - Stop-loss benefit to minimize plan exposure for expenses related to complications.
 - Coverage of expenses related to reversal procedures when deemed medically necessary.
- During the first eight months of the program, 41 surgeries were performed (39 sleeve, 1 bypass, 1 band), on patients whose average preoperative body mass index was 47.5.
 - During the medically supervised weight-loss program prior to surgery, average weight loss was 18 lbs.
 - Measured at six months after surgery, average weight loss was 45 lbs, with a top loss of 100 lbs.
 - During the first six months of the program, observed postsurgical benefits included:
 - 70.8% reduction in medications taken (before surgery, 39 patients were taking a total of 113 medications).
 - 88.3% reduction in comorbidities (before surgery, 39 patients had 128 comorbidities).

Benefit Plan Design Results. Although MGM is in the early stages of implementation, the results have been positive. The company says that its health plan has experienced reduced direct claims costs, indirect costs, and prescription drug costs, while its employees have experienced improved quality of life. Measurable outcomes of the program include the following.

Change in Culture. For MGM, this V-BID program addressed the issue of obesity and assisted its members in losing and maintaining weight. For those members in need of an effective intervention to treat a higher BMI, the program also provided a bariatric surgery option. Although the clinical outcomes and ROI data were positive, MGM implemented the program because it was “the right thing to do.”

Today, development of equivalent programs is under way at other MGM facilities, including two in Mississippi and another in Michigan. Additional employers in the West are evaluating implementation of a similar benefit package.

FINANCIAL IMPACT OF V-BID

A key goal of the value movement is to shift the focus of health plan sponsors from saving money to maximizing the clinical outcomes produced by the plan's expenditures. Given the shared goal of health creation and cost containment, V-BID program sponsors may be disappointed if they seek an immediate monetary return on investment through reductions in short-term direct medical expenditures. The V-BID proposition implies full consideration of all benefits that come from improvements in health, which includes factors beyond the amounts spent on healthcare.

The economic impact of V-BID implementations depends largely on the details of each program. Since most high-value clinical services do not reduce direct medical costs in the short-term, immediate reductions in medical expenditures are usually related to the decreased use of medical interventions that do not produce value. The net benefit of a V-BID program on direct medical spending improves if:

- The underlying risk of an adverse outcome is high.
- The cost of that adverse outcome is high.
- An available intervention is effective at preventing the adverse outcome.
- Consumers are responsive to the incentive of lower copayments.

Savings versus Utilization. V-BID acknowledges the important role that cost-sharing can play in containing costs, but challenges the notion that achieving short-term savings through decreased utilization is always an appropriate endpoint. Lowering medical expenditures without regard to health effects may not be a desirable goal.

A key goal of the value movement is to shift the focus of health plan sponsors from saving money to maximizing the clinical outcomes produced by the plan's expenditures.

Because disease-specific healthcare costs often encompass multiple components, reduced short-term spending on specific high-value services does not necessarily result in lower overall spending on healthcare. Incremental expenditures on certain evidence-based services may play an important role in keeping patients healthy. In such cases, suboptimal use of recommended services may ultimately lead to worse healthcare outcomes and higher utilization of expensive services, including hospitalization and emergency care.

For example, V-BID plans may reduce barriers to such recommended care activities as monitoring the clotting time of patients taking anticoagulant medications, providing spirometers for individuals with asthma, implanting pacemakers in patients with symptomatic bradycardia, and performing total joint replacement for those with debilitating pain after recommended courses of pharmacotherapy and physiotherapy.

Effects on Direct Healthcare Spending. The financial impact of a V-BID program on direct healthcare spending depends on the precision of the plan's clinical targeting, the extent of the plan's changes in copayments, and beneficiary responses to those changes. Although increased use of high-value products and services will often add short-term costs to a V-BID plan, these may be offset by savings achieved through reductions in future adverse events due to better clinical outcomes.

For example, the increased direct costs resulting from lower copayments for appropriately targeted technologies (e.g., upper esophageal endoscopy for those at high risk for Barrett's esophagus, PET scanning to assess response to chemotherapy, minimally invasive surgery) would be offset, at least in part, by savings achieved through earlier diagnosis and less-expensive treatment of disease.

Lowering medical expenditures without regard to health effects may not be a desirable goal.

Effects on Healthcare Purchasers. As in the case of direct healthcare spending, the financial impact of a V-BID program on the aggregate finances of the sponsoring organization depends very much on the specific elements of the program. If an organization chooses to implement a V-BID plan, evidence shows that financial gain may occur in two related areas:

- Improved health outcomes, leading to a reduction in the number of costly complications and resulting in direct medical cost offsets.
- Enhanced productivity, lower disability, and other performance improvements among beneficiaries that accrue outside of the sponsor's medical spending.

The available evidence suggests that by incorporating value assessment into benefit design, V-BID produces a more-strategic allocation of health expenditures, improves employee health, and enhances employee productivity—all of which may positively contribute to an organization's bottom line.⁶

The potential for the purchasing organization to achieve a positive return on its investment increases when V-BID implementation incorporates the following characteristics:

- Adopts highly targeted incentives.
- Uses disincentives for low-value care to offset incentives for high-value care.
- Accounts for higher beneficiary productivity.
- Improves uptake by communicating with employees about the benefits available to them.
- Integrates the V-BID program with ongoing complementary efforts to improve health.

ALIGNING V-BID WITH HEALTH REFORM INITIATIVES

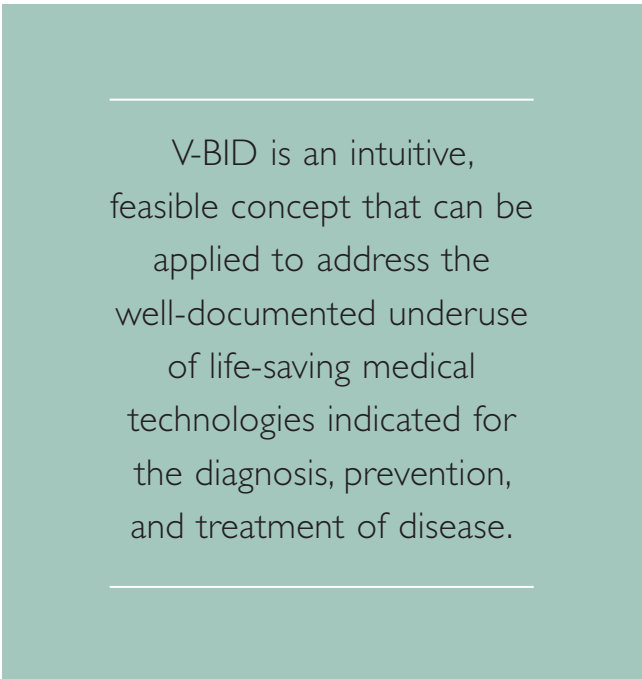
V-BID is a distinct concept that can be implemented independently. Yet it is complementary to many other healthcare reform initiatives such as wellness programs, health information technology, accountable care organizations, patient-centered medical homes, and value-based purchasing programs. These approaches shift financial risks and incentives for quality and efficiency to health systems and providers.

However, such supply-side strategies often do not explicitly address consumer incentives, the demand-side of this complex system. Alignment of clinical and financial policies for providers and patients—rather than just providers—will likely expedite the process of maximizing healthcare quality while restraining cost growth.

V-BID implementations should be coordinated with existing physician payment reform programs. Pay-for-performance and patient-centered medical home initiatives are typically designed to reward providers for achieving quality benchmarks, increasing preventive care, and decreasing overuse of services—all of which constitute evidence-based medicine.

Alignment with such initiatives is particularly important in cases where the outcomes of the use of high-technology medicine—such as invasive procedures and implantable devices—critically depend on provider competence. In these instances, patient incentives and provider payments should be aligned to encourage patients to obtain these devices from providers who have demonstrated high-quality practice.

Many health reform proposals that focus primarily on cost-containment will be directed by non-clinicians who may have a limited understanding of the important effects of clinical nuance on quality metrics. To ensure



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that patient-centered outcomes remain a critical policy priority, clinicians will be required to have understanding of the quality and value of their services, and be adept at communicating that value to policymakers and healthcare payers.

Novel approaches that imbed clinical nuance in payment and benefit designs have the advantage of inherently directing care toward efficient and effective interventions without requiring undue physician administrative efforts or internecine budgetary conflicts among providers.

V-BID is an intuitive, feasible concept that can be applied to address the well-documented underuse of life-saving medical technologies indicated for the diagnosis, prevention, and treatment of disease.

ENHANCING EFFICIENCY IN MEDICAL TECHNOLOGY UTILIZATION

There is growing concern that the efficiency of our healthcare delivery system is being adversely affected by the rapid adoption of technology-intensive clinical services before there is sufficient evidence of their efficacy.

We know much more about how regulatory and market forces interact in the adoption of prescription drugs than in the areas of devices, diagnostic testing, and procedures. This is in part due to the distinctive characteristics of the regulatory processes that govern market access for devices, and the fact that FDA and other device regulatory agencies are expressly prohibited from regulating the practice of medicine—even for procedures directly related to the use of medical technologies.

Determining clinical outcomes for devices and diagnostics requires significantly different evaluation processes from those used for pharmaceuticals.

Factors related to these differences include:

- Interaction with physician decision-making (in the case of how diagnostic test results are used).
- Relationship with other technologies (a specific device is often a single element in a complicated episode of clinical care).
- User interface requirements (physician skill in procedural technologies).
- Short product cycles and low profitability, often resulting in reduced investment in research and development for new devices.

Evidence-Based V-BID Program Evaluation

As employers seek to become more prudent purchasers of healthcare, they need value-based measurement tools to help assess the total value of their expenditures. Employers often lack reliable ways to evaluate the value of the pharmacy benefits they purchase.

This knowledge deficit is likely more profound when considering medical technologies, where the evidence base is more limited and methodological challenges make it difficult to identify the value of using alternative devices, diagnostic approaches, and procedures.

An essential, yet underestimated component of the V-BID agenda is rigorous evaluations of both the clinical and economic aspects of these innovative programs. An ideal evaluation should:

- Measure patient-reported clinical outcomes as well as process metrics that predict high-quality care.
- Use appropriate control groups. Controls make it possible to determine the extent to which observed clinical and economic changes are due to the characteristics of the V-BID program.
- Incorporate long-term follow-up to more effectively reveal the clinical gains of high-value services.
- Measure the nonmedical benefits of health improvement, such as effects on productivity and disability.

Determining clinical outcomes for devices and diagnostics requires significantly different evaluation processes from those used for pharmaceuticals.

Because of these and other attributes unique to medical technologies, there is concern that nonclinical factors are driving the adoption and use of new devices and procedures.

Since the production of high-quality evidence for devices and procedures is suboptimal, technological innovations that reduce spending are underutilized, while the use of devices, diagnostic tests, and procedures of unknown value is perceived to be widespread.

These factors contribute to a slow production rate for high-quality comparative effectiveness evidence about medical technologies.

Further, because of the complexity involved in determining at what stage of development it is appropriate to assess device technologies—“the moving target”—and difficulties in accounting appropriately for the physician learning curve, current efforts at health technology assessment may actually hamper the adoption of innovative devices.

ROLE OF V-BID IN DIRECTING APPROPRIATE ADOPTION OF MEDICAL TECHNOLOGY

The optimal benefit design of a V-BID program for devices, diagnostics, and procedures is likely to require reduced cost-sharing for high-value, evidence-based technologies; and increased cost-sharing for technologies that do not contribute value to quality of life or other patient-reported outcomes, and whose clinical effectiveness is not supported by evidence.

The easiest approach would be to reduce cost-sharing for the use of well-known, guideline-recommended technologies within appropriate patient groups (e.g., eye examinations and glucose monitors for diabetics, human papillomavirus testing after an abnormal cervical cancer screening test), and to increase cost-sharing for all other services, thereby offsetting the added expense attributable to increased use of subsidized services. While this approach may impose barriers to the use of some services that provide high value, it would represent an improvement over the common practice of increased cost-sharing across all services, regardless of clinical value.⁷

There are few instances where the use of a specific diagnostic test or procedure is always appropriate or inappropriate.

An alternative would be to use an evidence-based approach to identify selected low-value diagnostic and therapeutic interventions and to increase copayments for those services.

The Oregon Health Leadership Task Force has adopted such an approach as the basis for a V-BID plan that incorporates both “carrots” and “sticks.”⁸ The group’s current three-tiered system reduces copayments below standard levels for guideline-based services, but increases copayments for “health services that are nationally recognized as overused and driven by provider preference or supply rather than evidence-based need.” Standard cost-sharing rates are applied to all other services and technologies.

Since there are few instances where the use of a specific diagnostic test or procedure is always appropriate or inappropriate, it is likely that V-BID programs for many devices, diagnostics, and procedures will require more-complex and sophisticated programs than those for prescription drugs.

The “Choosing Wisely” campaign coordinated by the American Board of Internal Medicine (ABIM) Foundation is another example of the momentum behind the establishment of “stick” V-BID programs that explicitly identify services of low or unproven value.⁹ The ABIM Foundation partnered with *Consumer Reports* and several other medical specialty societies to launch the campaign. Each of the societies was challenged to identify five commonly used tests or procedures of questionable necessity in their field. Imaging tests make up a majority of the services included on the initial list.

APPROACHES TO V-BID FOR DEVICES, DIAGNOSTICS, AND PROCEDURES

A combination of financial incentives and patient education may be sufficient to improve treatment compliance or to steer patients toward high-value services and providers. However, other elements of program design will likely become important as we move into the broader landscape of healthcare technologies.

Program design elements of importance might include management of referral programs, incentives for physician training in more-effective modalities, and better methodologies for identifying both more-effective technologies and the most-effective physicians and systems for delivering those technologies. In many instances, V-BID programs will need to be coordinated with systems where physicians are operating under a pay-for-performance structure, rather than traditional fee-for-service reimbursement.

The entire spectrum of V-BID—from evidence supporting the selection of high-value technologies to program design and implementation—is likely to be more complex for devices and procedures than for prescription drugs. This distinction is germane since many important medical technologies are imbedded in multifaceted episodes of care, and therefore may not be explicitly singled out in a V-BID program.

There are some exceptions: for example, specific imaging tests, stand-alone devices, and laboratory studies that have unique reimbursement codes. Hence, the potential for quality improvement and return on investment is equally high. Knowing what is working will require well-designed evaluations across the spectrum of patients, providers, and technologies.

Because the use of V-BID in the realm of devices, diagnostics, and procedures is relatively new, information about its economic impact and effects on clinical outcomes is sparse.

Four basic approaches to V-BID in the pharmaceutical realm have been outlined previously.¹⁰ Given the role that medical technology plays in an episode of care, V-BID for devices and diagnostics need not be implemented separately from programs targeting optimal pharmaceutical use. However, given the different attributes of devices, diagnostics, and procedures, an alternative categorization of V-BID approaches is proposed, as described below.

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Because the use of V-BID in the realm of devices, diagnostics, and procedures is relatively new, information about its economic impact and effects on clinical outcomes is sparse.

Design by Clinical Indication. Waive or reduce copayments for the use of a test, device, or procedure, when evidence has demonstrated the value of making those services and technologies available for consumers with a specific clinical indication. This approach would be suitable for implementing the U.S. Preventive Services Task Force recommendations for primary prevention interventions, such as immunizations and certain cancer screening tests.

Design by Condition. Waive or reduce copayments or coinsurance for technologies, based on specific clinical conditions with which patients have been diagnosed. This approach would reduce copayments in order to incentivize the use of high-value services, such as a program to steer patients to clinically appropriate laparoscopic procedures.

Design by Risk. Waive or reduce copayments or coinsurance for high-risk individuals who are eligible for screening, genetic counseling programs, or treatments. Examples for this type of V-BID program include the use of molecular diagnostic tests for patients with appropriate risk profiles, such as BRCA1 testing for women at risk for breast cancer; or HPV testing for women at high risk for cervical cancer.

Treatment examples might include providing continuous positive airway pressure (CPAP) machines to patients diagnosed with severe sleep apnea, or incentivizing percutaneous coronary intervention for patients with persistent symptoms of angina (Canadian Cardiovascular Society Class 3 or Class 4) despite maximal anti-anginal pharmacotherapy.

Design by Provider. An adjunct to other approaches, this V-BID solution reduces or waives copayments or coinsurance for patients who obtain care from healthcare providers who consistently provide high-quality, high-value services.

This approach has been implemented by Lowe's Companies, which offers its employees reduced out-of-pocket costs when they select the Cleveland Clinic for invasive heart procedures. Similarly, employers are using V-BID programs to steer patients to centers of excellence for organ transplants and minimally invasive procedures.

IMPLEMENTATION ISSUES

How employers and other V-BID implementers communicate about V-BID will affect the program's level of public acceptance. Focus groups completed in 2012 addressed the question of how employers can best present V-BID to participating employees.¹¹ Among other recommendations, employers should:

- Focus communications efforts on actionable ideas to improve health and control costs. For example, provide sample questions for consumers to ask their doctors. When possible, draw on real, in-house success stories to make communications efforts more impactful.
- Describe a comprehensive health enhancement program. When using health questionnaires and assessments, communicate screenings as the first phase in a journey to be healthier.
- Consistently communicate about the benefit design and coverage options for all types of medical services (e.g., visits, diagnostics, drugs), and provide concrete examples.
- When encouraging employees to seek care from certain providers, offer detailed information about the organizations that are rating providers and the criteria used.
- Show employees how the new designs differ from current offerings (e.g., in- and out-of-network costs).

A deliberate, carefully executed communications strategy can help consumers and employers obtain maximum benefit from V-BID.

Effective communication with consumers is essential for promoting engagement, optimizing participation, and avoiding unexpected negative consumer experiences.

However, many employees are unfamiliar with basic cost-sharing terminology, and the clinical nuances of a V-BID program may not be immediately intuitive. Therefore, a deliberate, carefully executed communications strategy can help consumers and employers obtain maximum benefit from V-BID.

Potential Barriers to V-BID

Despite growing implementation of V-BID programs, uptake remains gradual, indicating that there are some barriers to implementation. Recognizing such potential obstacles is part of the solution to overcoming them.

Short-Term Increases in Utilization and Cost.

Reducing beneficiary costs for targeted services may increase short-term utilization of those services, resulting in an aggregate increase in system costs. However, the intention and expectation is that greater use of such targeted services will result in better health and fewer adverse complications, eventually lowering aggregate costs. Nevertheless, there remains some concern that when copayments are reduced and aggregate costs rise, benefits may accrue too far “downstream,” to offset the upfront costs associated with increased use of targeted high-value services.

Sophisticated Data Systems. Implementing V-BID may require data systems to identify high-value services, the specific patient groups using them, and their compliance with prescribed therapies. Detailed, accurate, and comprehensive clinical data are the key to both identifying opportunities for V-BID’s effectiveness, and integrating V-BID into existing and emerging health information systems and disease management programs.

Copayment Variance. V-BID programs may initially generate negative reactions from plan members whose copayments are higher than those of other members for the same medical service. V-BID programs that target specific diagnoses or high-risk patients may encounter this problem, but clear communication of V-BID objectives can engender a positive response from employees.

Privacy Issues. The transfer of data and communications efforts must comply with the Health Insurance Portability and Accountability Act (HIPAA)—the same issue that arises with disease-management programs.

Return on Investment (ROI). How to quantify a V-BID program’s clinical and economic ROI remains an area of controversy. Although there is an ongoing debate about whether V-BID strategies produce a short-term positive ROI, expanded use and improved compliance with beneficial diagnostic and treatment strategies hold the prospect of improved health outcomes, lower costs, and healthier, more-productive employees.

Measuring Outcomes. There are few studies on the impact of decreasing copayments on utilization of clinically sensitive healthcare services, especially outside of pharmaceutical treatments. However, it is critical to measure outcomes—especially increased utilization—along with appropriate downstream clinical outcomes associated with changes in the use of a targeted service.

Adverse Selection. A health plan instituting V-BID may attract a disproportionate number of enrollees with chronic conditions or conditions benefitting from low copayments for higher cost technology by targeting those patients or the services they use. Such “adverse selection” will be less of an issue when the plan’s population is relatively stable.

Measuring the Value of Services. Accurately determining value requires a blend of clinical judgment, health economics, and actuarial techniques; setting copayments appropriately takes robust actuarial analysis as well as continuous monitoring and adjustment.¹ V-BID programs become easier to create and optimize as we learn more about high-value services through comparative effectiveness research.²

Potential for Fraud. V-BID programs may have difficulty in differentiating between patients who qualify for lower copayments and those who do not, encouraging some providers and patients to misreport information in order to qualify for the reduced copayment. Third-party information sources that accurately identify and classify patients could prevent this type of fraud.

CLOSING THOUGHTS

Concerns regarding escalating healthcare budgets have led to the implementation of cost-containment mechanisms that lead to the underuse of evidence-based, health-producing medical technologies across the entire continuum of clinical care. An opportunity exists for a cost-saving reallocation of healthcare expenditures within any health budget, through increasing the use of high-value interventions and simultaneously reducing the use of interventions that offer little or no benefit relative to their cost.

By setting patient cost-sharing levels based on clinical value—not price—to ensure access to medical technologies that produce health benefits that exceed their costs, V-BID will produce more health per dollar spent. Such a reorientation of spending toward services with greater potential for achieving patient-centered outcomes is feasible and applicable to devices, diagnostics, and procedures.

The use of “clinically nuanced” incentives (and disincentives) to encourage (and discourage) the use of medical technologies can improve clinical outcomes, enhance patient and provider satisfaction, and encourage innovation—all within a sustainable cost structure.

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The University of Michigan Center for Value-Based Insurance Design is a leader in research, development, and advocacy for innovative health benefit plans. Since its inception in 2005, the center has led efforts to promote the development, implementation, and evaluation of innovative health benefit designs balancing cost and quality. A multidisciplinary team of faculty first published and named the V-BID concept, and has guided this approach from early principles to widespread adoption in the private and public sectors. The center played a key role in the inclusion of V-BID in national healthcare reform legislation, as well as in numerous state initiatives.



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