

## Diabetes Benefit Management: Evolving Strategies for Payers

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### Abstract

Over the next quarter century, the burden of type 2 diabetes mellitus (T2DM) is expected to at least double. Currently, 1 in every 10 healthcare dollars is spent on diabetes management; by 2050, it has been projected that the annual costs of managing T2DM will rise to \$336 billion. Without substantial, systemic changes, T2DM management costs will lead to a potentially untenable strain on the healthcare system. However, the appropriate management of diabetes can reduce associated mortality and delay comorbidities. In addition, adequate glycemic control can improve patient outcomes and significantly reduce diabetes-related complications. This article provides an overview of key concepts associated with a value-based insurance design (VBID) approach to T2DM coverage. By promoting the use of services or treatments that provide high benefits relative to cost, and by alternatively discouraging patients from utilizing services whose benefits do not justify their cost, VBID improves the quality of healthcare while simultaneously reinvesting in spending. VBID initiatives tend to focus on chronic disease management and generally target prescription drug use. However, some programs have expanded their scope by incorporating services traditionally offered by wellness and disease management programs. The concept of VBID is growing, and it is increasingly being implemented by a diverse and growing number of public and private entities, including pharmacy benefit managers, health plans, and employers. This article provides key background on VBID strategies, with a focus on T2DM management. It also provides a road map for health plans seeking to implement VBID as part of their programs.

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**D**iabetes mellitus, a group of metabolic disorders associated with hyperglycemia, currently affects an estimated 25.8 million individuals, or 8.3% of the entire US population.<sup>1</sup> The underlying etiology differs according to diabetes type, but recognized risk factors include obesity, sedentary lifestyle, genetic predisposition, and environmental factors.<sup>2</sup>

Type 2 diabetes mellitus (T2DM) accounts for the vast majority of diagnosed diabetes in the United States; about 18.8 million US residents have been diagnosed with T2DM, and an estimated 7.0 million adults have undiagnosed diabetes. Furthermore, nearly 79 million adults have prediabetes, a T2DM precursor marked by elevated glucose levels.<sup>1,2</sup> Given the chronic, progressive nature of T2DM, as well as its multiple associated comorbidities, it is not surprising that the economic burden associated with this disease is substantial. Adults with T2DM have nearly 3 times the annual number of physician office visits compared with otherwise healthy individuals,<sup>2</sup> and their medical expenditures are 2.3 times greater than for those without the disease.<sup>3</sup>

In 2007, it was estimated that medical costs and reduced work productivity associated with diabetes totaled \$218 billion,<sup>2</sup> with an average annual cost (including both medical and nonmedical costs) per patient of \$9975 for individuals with diagnosed T2DM and \$2864 for undiagnosed individuals (defined as unknowingly having an elevated glucose level that meets the criteria for diabetes, based on data obtained from the National Health and Nutrition Examination Survey).<sup>2,4</sup>

Put another way, more than 1 out of every 10 dollars spent in the United States on healthcare can be directly attributed to diabetes management.<sup>5</sup> Specific expenditures include hospital inpatient stays (\$40.3 billion), nursing home care (\$13.9 billion), and physician office visits (\$10 billion). In addition, in 2002, the annual cost of oral agents to lower blood glucose, insulin, and insulin-related supplies was estimated at approximately \$12 billion.<sup>6</sup>

Over the coming quarter century, the population-level burden of diabetes is expected to at least double. This increase is related directly to an aging population and changes in the racial/ethnic composition of the United States. Within the next 25 years, it

has been projected that the number of Americans with diagnosed and undiagnosed diabetes will reach 44.1 million, with related costs increasing to \$336 billion.<sup>7</sup>

Without substantial and systemic changes in T2DM management, associated costs will lead to a pronounced and potentially untenable strain on an already overburdened healthcare system. This article will explain key concepts associated with a value-based approach to T2DM managed care coverage. It will discuss how several organizations have implemented value-based insurance design (VBID) in T2DM, as well as provide a framework for implementing a VBID approach for health plan members with T2DM. Last, it will forecast potential next steps in the development of value-based health plans.

### Appropriate T2DM Management Reduces Morbidity and Cost

The appropriate management of diabetes can reduce associated mortality and delay comorbidities. Available literature shows that adequate glycemic control can improve patient outcomes and significantly reduce diabetes-related complications. In response to this evidence, national organizations such as the American Diabetes Association and the National Committee on Quality Assurance advocate for early T2DM diagnosis and optimal glycemic control (glycosylated hemoglobin [A1C]  $\leq 7\%$ ).<sup>8</sup> To achieve and maintain this target, however, patients typically require a progressively increasing number of medications.<sup>9,10</sup>

Improved glycemic control can also reduce both the direct and indirect costs related to diabetes.<sup>5</sup> For example, Shetty et al reported that higher A1C levels were associated with increased costs. In this 1-year, retrospective database analysis, 3121 patients with T2DM (46%) were identified as being at target A1C levels, while 3659 patients (54%) were above target A1C levels. After controlling for confounders, the authors found that patients with T2DM who remained continuously at A1C levels of 7% or less had significantly lower total diabetes-related costs compared with patients whose levels climbed above target. The annual predicted diabetes-related costs for above-target patients were \$1540 per patient; this was nearly one-third higher (32%) than costs incurred by the group who remained at target (\$1171).<sup>11</sup>

Although evidence for the benefit of improved glycemic control in T2DM is fairly straightforward, treatment decision making and management can be complex. In 1995, the only therapeutic agents available to treat T2DM were insulin and sulfonylureas. However, during the past decade, 9 additional new classes of oral antidiabetic medications have been approved for use.<sup>8</sup> Additionally, in recent years, clinical research has directed attention to the elevated cardiovascular

(CV) risk faced by patients with T2DM.<sup>12,13</sup> Alongside this, the number and quality of medications known to effectively manage low-density lipoprotein (LDL) cholesterol and hypertension, and to prevent negative CV outcomes in patients with T2DM, has increased substantially.<sup>14</sup> This has led to an increased recognition of the value of early, ongoing, multifactorial treatment of the glycemic, CV, and other complications of T2DM.<sup>10,15,16</sup>

National, population-level data show overall improvements among US adults in terms of maintaining recommended A1C levels, blood pressure, and cholesterol levels.<sup>17</sup> However, for many individuals, diabetes care is far from ideal. An estimated 2.2 million individuals with diabetes, or 1 in 5, continue to have poor glycemic control (defined as an A1C level  $>9.0\%$ ). About 3.6 million, or 2 in 5 individuals with diabetes, have poor control of their LDL cholesterol levels, and 3.5 million, or 1 in 3, have suboptimal blood pressure control.<sup>18</sup>

Improving patient outcomes has proved to be a challenging task, as a number of barriers to care exist. Two of the most important barriers are patient adherence to pharmacotherapy and lifestyle modification, and provider adherence to guideline recommendations.<sup>5</sup>

### Patient Adherence

Multiple factors contribute to poor blood glucose control in T2DM,<sup>5</sup> but failure to adhere to medication regimens is a well-documented cause, and provides an appropriate target for health plans seeking to improve patient outcomes.

Estimates of patient adherence with oral antidiabetic agents vary substantially, and have been reported to range from 36% to 93%. Adherence to insulin therapy may be even lower in patients with T2DM, in the range of 62% to 64%.<sup>19</sup> A recent analysis of published glycemic control studies reported that, in the majority of cases, improved medication adherence was associated with better glycemic control.<sup>20</sup> Pharmacologic adherence in T2DM is also associated with a lower use of healthcare resources, including reduced hospitalization rates, while optimal adherence to therapeutic regimens has been shown to substantially reduce both costs and complications related to diabetes.<sup>5,21</sup>

A number of factors affect patient adherence to a treatment regimen, and the underlying reasons for nonadherence may be complex and multifaceted. Cost of care has been identified as one key cause of medication underuse. A study of adults with T2DM taking oral medications found that higher copays and coinsurance were associated with lower levels of refill compliance.<sup>22</sup>

As a means of controlling prescription drug costs, some health insurance plans and employers have increased drug cost sharing via strategies such as multitiered formularies,

■ **Table 1.** Four Approaches to VBID<sup>23</sup>

**1. Design by service.** This strategy reduces copayments or coinsurance for selected high-value clinical services or prescriptions, without regard to individual patient profiles. It may also waive or lower copayments/coinsurance for certain pharmaceuticals or services, regardless of individual patient characteristics.

**2. Design by condition.** This approach is data-driven, and waives or reduces copayments/coinsurance for high-value services only among patients with a specific diagnosis (for example, patients with T2DM or CV disease).

**3. Design by condition severity.** This strategy waives or reduces copayments/coinsurance for plan members who are both high-risk and eligible for inclusion in a disease management program.

**4. Design by disease management participation.** This approach is an extension of option 3, as it provides reduced or waived copayments/coinsurance to high-risk members who are active participants in a disease management program.

CV indicates cardiovascular; T2DM, type 2 diabetes mellitus; VBID, value-based insurance design.

prior authorization, step therapy, and higher copayments and/or coinsurance. Although cost sharing often achieves its desired purpose of encouraging the use of generics and steering patients to preferred brand-name drugs, it can also have negative consequences.<sup>22</sup> Cost sharing has been associated with treatment disruptions in patients with chronic illnesses<sup>22</sup> and with poorer adherence.<sup>23</sup> Cost sharing can also have a detrimental impact on the use of essential drugs, as patients may reduce the amount of drugs taken and/or skip doses in order to stretch out a refill.<sup>22</sup>

### Value-Based Insurance Design

The need to contain costs while simultaneously improving quality of care and overall population health has proved to be a formidable challenge. A goal of increased patient cost sharing was to discourage the use of low-value care. For this to be achieved, it had to be assumed that patients could distinguish between high- and low-value care. However, a large and increasing body of evidence shows that, in response to higher out-of-pocket costs, patients tend to reduce their use of both high- and low-value services.<sup>23,24</sup>

VBID is a strategy developed to improve the quality of healthcare while simultaneously reining in spending. The University of Michigan's Center for Value-Based Insurance Design has defined "value" as being the amount of health gained per dollar spent on healthcare services or benefits.<sup>23</sup> VBID argues that, when examining the value of a drug or benefit package, both the cost and quality of services need to be considered. From this perspective, an approach that is considered "value based" is not necessarily less expensive, and it is recognized that lower cost benefits or treatments do not always culminate in health benefits that are of value.

VBID programs are intended to promote the use of services or treatments that provide high benefits relative to cost

and, alternatively, discourage patients from utilizing services whose benefits do not justify their cost. While the design and implementation of these programs can vary, the basic goal is to reduce patient cost sharing for services associated with important clinical benefits. In the case of T2DM, it was suspected that there may be both health and cost saving benefits associated with removing financial restrictions limiting access to care.<sup>25</sup>

VBID initiatives in general tend to focus on chronic disease management and generally target prescription drugs.<sup>25</sup> However, some programs have expanded their scope by incorporating services traditionally offered by other types of wellness and disease management programs. In a program initiated by UnitedHealthcare for patients with T2DM, for example, participants are given free access to online monitoring and education tools.<sup>23</sup> The specifics of VBID programs will vary based on the insurance program type and populations served.<sup>25</sup> Although programs differ, there are 4 basic approaches to VBID, which are shown in [Table 1](#).<sup>23</sup>

Several groups have merged and mixed these approaches, primarily for members with chronic conditions. In Asheville, North Carolina, a program was initiated to reduce copayments for employees with diabetes. Known as the Asheville Project, this pharmacist-driven program was implemented for the City of Asheville (a self-insured employer) in 1996. As a follow-up, the City started the Hickory Project, which combined a community pharmacist-led coaching program with reduced copayments for employees with diabetes.<sup>26</sup>

In another case, Healthcare Alliance Medical Plans, Inc created a fourth copayment tier, which made certain drugs available at reduced cost. Last, the Service Employees International Union Health Care Access Trust coupled its VBID efforts with participation in a disease management program. In this setting, office visit copayments were absorbed for participating employees.<sup>27</sup>

The concept of VBID is growing, and it is increasingly implemented by a diverse and growing number of both public and private entities, including pharmacy benefit managers, health plans, and employers. Private employers with self-funded insurance programs were the first leaders in large-scale VBID implementation and, because of their greater organizational flexibility, continue to drive innovation. Results of a

## Case Studies: VBID in T2DM

### **Pitney Bowes**

Pitney Bowes can be considered the “poster child” of VBID, as it is perhaps the most well-known pioneer of the concept. This Stamford, Connecticut-based manufacturer of software, hardware, and services that integrate physical and digital communications employs 35,000 individuals worldwide. An internal analysis showed that the burden of illness and ensuing costs among employees was driven primarily by a lack of pharmaceutical adherence. Among patients with diabetes, those who were only refilling their oral medications or insulin about two-thirds of the time were most likely to eventually become the costliest patients.<sup>28</sup>

For their VBID strategy, Pitney Bowes shifted all diabetes and hypertension drugs and devices from tier 2 or tier 3 formulary status to tier 1. All insulin and oral agents were included, along with glucose monitoring test strips. These formulary changes led to an immediate financial impact for members, as the cost for filling a 30-day prescription declined by approximately 50%. However, the most important impact was on medication adherence. The percentage of patients with suboptimal adherence to their insulin regimen declined by two-thirds, while the percentage of individuals consistently using fixed-combination oral antidiabetic agents increased from 9% to 22%. Adherence was considerably greater among patients using combination therapies.<sup>28</sup>

In the 2- to 3-year period following pharmacy benefit changes, it was found that increased medication adherence appeared to be having the desired effect. Even though the company's total pharmacy costs increased, pharmacy costs for patients with diabetes declined by 7%. This was hypothesized to be due to reduced rates of complications (which would trigger the need for more expensive drugs). Medical utilization and costs also declined, and the rate of emergency department visits dropped by 26%. Overall, Pitney Bowes found that between 2001 and 2003, per-patient costs decreased by 6% for individuals with diabetes.<sup>28</sup>

### **University of Michigan**

At the University of Michigan (UM), the cost of employee healthcare was increasing at a rate of 10% to 12% per year, substantially higher than the mean 8% national growth rate. Concerned about this trend, UM looked at VBID as a possible means to trim costs while improving care.<sup>29</sup>

Using Pitney Bowes as a model, UM further modified this system by stratifying payment schemes based on patient disease status.<sup>29</sup> UM also sought to improve existing programs. For example, UM had a diabetes disease management program already in place. They were able to draw on that program's database to identify persons within the system who had diabetes. The new VBID program was implemented on July 1, 2006, and was made available to the 2200 UM employees and dependents with a diagnosis of diabetes mellitus.<sup>24,29</sup>

UM reduced certain oral drug copayments for the targeted population, as well as payments for specific interventions that were judged to be highly beneficial, based on medical evidence. These included drugs targeting blood pressure, cholesterol, and depression, which are known to help reduce or prevent known long-term complications of diabetes. In addition, copayments for annual eye exams were also reduced.<sup>24</sup>

Prior to its implementation, a 3-tiered formulary was in place. Although the pricing structure remained unchanged, all tiers implemented a reduction in copay price for VBID program participants. For the targeted medications, tier 1 copays were lowered by 100% (from \$7 to \$0); tier 2 copays by 50% (from \$14 to \$7); and tier 3 copays by 25% (from \$24 to \$18).<sup>24,29</sup>

The program has received overwhelming employee support. The pilot program was initially supposed to run for 2 years, but in 2008 was extended for an additional 3 years. Outcomes measures on changes in adherence and institutional costs are expected to be published in 2011.<sup>29</sup>

recent survey show that an estimated 20% to 30% of large employers currently use some form of VBID.<sup>27</sup>

## Road Map for Implementing a VBID Approach to T2DM

Value-based design can take multiple forms and continues to evolve. Any plan considering VBID implementation for patients with T2DM must first recognize that cost savings should not be the exclusive goal. Instead, VBID strategies should be considered as steps that will ultimately lead to cost savings or cost neutrality based on reduced use of other care areas over time.<sup>23</sup> Because of this, VBID may not be the best solution for a plan looking for immediate short-term savings. Instead, VBID should be viewed as a long-term investment with the goal of trimming costs over time by improving member health.<sup>23</sup> For the program to be successful, plans need to seize opportunities to restructure health benefits, with a focus on obtaining the greatest long-term positive health impact from the expense outlay.

When implementing a “road map” for VBID development, plans should consider the 4-step process known as “Data, Design, Delivery, and Dividends.” Developed by Nayer and colleagues, this approach can help clarify goals and build confidence among health management team members, providers, and the work force.<sup>30</sup>

### **Data**

As a first step, because an adequate health information technology (HIT) system is an essential requirement for VBID rollout, any plan considering implementing VBID for patients with T2DM should conduct an assessment of its current clinical data systems.<sup>27</sup> The system needs to be able to identify and target patients with specific diagnoses, and all clinical sites need to have access to this information. In addition, it is important to ascertain how much flexibility exists in the system

■ **Table 2.** Three Key Levers Useful to Prompt Change in VBID<sup>30</sup>

**Condition management.** Typically, plans undertaking condition management examine which conditions are the most costly, and assess how that cost can be quickly reduced. The solution usually lies in a total health management approach; this demands a long-term strategy to improve costs. Specific actions that might be taken include reducing the high cost of rescue treatments and levels of comorbid conditions (for example, hypertension in patients with diabetes). Typical solutions include providing improved access (for example, is the copay too high?).

**Provider guidance.** Three main issues drive the levers that can alter the trend of higher cost: access (are there enough primary care doctors?); avoidance (I don't need to go to my doctor); and relevance (my doctor didn't tell me to get the test). The use of incentives to link providers and patients is extremely important to improve both patient health and organizational financial outcomes. By removing avoidance barriers and lowering costs, and at the same time improving provider reimbursement for time spent with the most complex patients, an aligned strategy is developed that encourages the patient to undertake better health management.

**Health/competency.** Personal health competency and individual responsibility are imperative to creating optimal health management and reducing risk. Plans must evaluate the wellness, prevention, and lifestyle behaviors of their members in order to decide what new skills are needed for improvement, and which skills no longer work.

VBID indicates value-based insurance design.

to segment and analyze patient data. Compared with regional organizations, payers operating within an integrated systems-delivery framework are much more likely to be fully engaged with electronic medical records (EMRs).

However, this does not mean that other payers cannot implement computerized networks and health information exchanges. With the adoption of the Health Information Technology for Economic and Clinical Health Act, for example, eligible providers who demonstrate meaningful use of certified EMR approaches will receive financial incentives.<sup>31</sup>

### Design

The second step is to design a plan strategy, and decide what levers you will utilize to prompt change. First, decide if levers should be preventive, which may prevent or delay disease and/or reduce financial risk to the organization. Next, determine if levers should be sequenced. If sequencing is used, decide on the highest priority area for intervention and work from there. Next is a process of segmenting and titration. If levers are segmented, certain services will be provided to 1 subset of the population (ie, flu shots to older persons with T2DM). Alternately, levers can be titrated, for example, by providing flu shots to elderly patients with T2DM, but then increasing the eligible population to all patients with diabetes and continuing to expand until a downward financial trend is observed. Plans may also be clinician inclusive; this means that healthcare providers are incented to participate by sharing in any financial rewards achieved. This may be a useful approach in cases where redesign would require providers to offer more member services.<sup>30</sup>

### Delivery

The next step is to decide how to best implement the levers and address key questions. For example, in what setting are the levers most likely to have the greatest impact?

Alternately, what outcomes is the plan willing to risk<sup>30</sup>—for example, what effort does it take to change the type of food available in vending machines, or to create awards for goal achievement?

### Dividend

The final step is the desired dividend, an understanding of which will help determine which levers to utilize. Ideally, the outcomes should define acceptable levels of investment risk, and they should be measurable for all stakeholders.<sup>30</sup>

A VBID program should also seek to establish synergy with initiatives that correspond to key aspects of US healthcare reform. In addition to HIT, other tools that can be incorporated into VBID design and/or assessment include consumer-directed health plans (CDHPs), pay-for-performance, comparative effectiveness research, and patient-centered medical homes. Plans also need to evaluate the potential barriers to implementing a VBID. One is the very real likelihood of a short-term increase in both service utilization and costs.<sup>23</sup>

It is also important for plans to address 3 specific levers of change. The first is “condition management,” in which the goal is to create persistency for care management over time; the second is “provider guidance,” where the goal is to create meaningful, timely, and actionable interactions with appropriate providers; the third is “individual health competency,” where the goal is to create accountability for personal and organizational health (this is where incentives tie in to CDHPs).<sup>30</sup> **Table 2** provides more detailed descriptions of these tools to leverage change.

Last, it is important to recognize when an intervention is not working and should be discontinued. For example, when targeting improved compliance, the plan must consider which benefits need to be provided to patients, and at what cost to the plan. At the same time, line items need to be

identified, as well as the time frame after which anticipated cost savings should become evident. A stop date needs to be established for interventions that are not working.

## Conclusion

While still a form of cost sharing, VBID acknowledges that services may vary in their value based on underlying patient health. Value can be increased if targeted cost sharing is permitted for different services among specific patient groups. This can be accomplished without eliminating the role of systemic cost sharing.<sup>24</sup>

Thus far, field experience suggests that VBID approaches are both feasible and acceptable to all vested stakeholders, and in general, are very well received by health plan members. VBID can also work synergistically with other initiatives, such as disease-management programs and pay-for-performance systems, and the VBID design can help remove barriers and provide incentives to encourage behavioral changes.<sup>23</sup> VBID programs should become easier to develop as HIT use becomes more widespread, and as ongoing research sheds light on which services are truly high value for certain populations.

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