

Optimizing Diabetes Management: Managed Care Strategies

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Diabetes mellitus (DM) is a term used to describe a group of metabolic diseases of multiple etiologies. The condition results from defects in insulin secretion, insulin action, or both, and it is characterized by hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism.^{1,2} Approximately 90% to 95% of patients with DM have type 2 DM (T2DM), a form of DM associated with a continuum ranging from insulin resistance with relative insulin deficiency to a predominantly insulin secretory defect with or without insulin resistance.^{1,2} In 2008, the Centers for Disease Control and Prevention estimated that 23.6 million Americans (7.8% of the population) had DM and another 57 million had prediabetes, a condition marked by levels of blood glucose or glycated hemoglobin (A1C) that are above normal ranges, but not high enough to be classified as T2DM.³ By 2010, that number had increased to 25.8 million Americans (8.3% of the population) with DM.⁴ Those numbers represent increases of at least 50% in 42 states and of 100% or more in 18 states.⁵ Furthermore, the prevalence of DM is projected to continue to increase. One study projected that between 2009 and 2034, the number of people with diagnosed and undiagnosed DM will increase from 23.7 million to 44.1 million and that the DM population within the Medicare-eligible population will increase from 8.2 million in 2009 to 14.6 million in 2034.⁶ Not surprisingly, the economic burden associated with DM is substantial and is also projected to increase. Between 2009 and 2034, annual DM-related spending is projected to increase from \$113 billion to \$336 billion (2007 dollars) and associated spending in the DM population within the Medicare-eligible population is projected to increase from \$45 billion to \$171 billion.⁶ The authors of this projection study astutely pointed out that without significant changes in public or private strategies, this population and cost growth will place a significant strain on an already overburdened healthcare system.⁶

Utilizing Treatment Guidelines and Other Evidence to Develop and Implement Medical Policies Relative to the Management of DM

There are 3 primary DM management goals for payers. One of these goals is to optimize resource management through unit cost management and rebate contracting. A second goal of improving clinical management is achieved through fostering adherence and

Abstract

Both the prevalence of type 2 diabetes mellitus (DM) and its associated costs have been rising over time and are projected to continue to escalate. Therefore, type 2 DM (T2DM) management costs represent a potentially untenable strain on the healthcare system unless substantial, systemic changes are made. Managed care organizations (MCOs) are uniquely positioned to attempt to make the changes necessary to reduce the burdens associated with T2DM by developing policies that align with evidence-based DM management guidelines and other resources. For example, MCOs can encourage members to implement healthy lifestyle choices, which have been shown to reduce DM-associated mortality and delay comorbidities. In addition, MCOs are exploring the strengths and weaknesses of several different benefit plan designs. Value-based insurance designs, sometimes referred to as value-based benefit designs, use both direct and indirect data to invest in incentives that change behaviors through health information technologies, communications, and services to improve health, productivity, quality, and financial trends. Provider incentive programs, sometimes referred to as “pay for performance,” represent a payment/delivery paradigm that places emphasis on rewarding value instead of volume to align financial incentives and quality of care. Accountable care organizations emphasize an alignment between reimbursement and implementation of best practices through the use of disease management and/or clinical pathways and health information technologies. Consumer-directed health plans, or high-deductible health plans, combine lower premiums with high annual deductibles to encourage members to seek better value for health expenditures. Studies conducted to date on these different designs have produced mixed results.

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■ **Table 1.** Example of a Medical Coverage Policy⁸

Bydureon (exenatide, extended release), Byetta (exenatide), Victoza (liraglutide)

GLP-1 analogues may be considered medically necessary when the following criteria are met for the following indication:

- Improvement of glycemic control in members with type 2 diabetes mellitus

The member has had previous treatment with, contraindication, or intolerance to at least 1 of the following therapies: biguanide (ie, metformin), sulfonylurea, or thiazolidinedione.

The recommended dose of Byetta is 5 mcg per dose administered via subcutaneous injection twice a day at any time within the 60-minute period before the morning and evening meals. Exenatide should not be administered after a meal. Based on clinical response, the dose of exenatide can be increased to 10 mcg twice a day after 1 month of therapy.

Victoza is administered via subcutaneous injection once daily at any time of day, independent of meals. Victoza should be initiated with a dose of 0.6 mg per day for 1 week. The 0.6-mg dose is a starting dose intended to reduce GI symptoms during initial titration, and is not effective for glycemic control. After 1 week at 0.6 mg per day, the dose should be increased to 1.2 mg. If the 1.2-mg dose does not result in acceptable glycemic control, the dose can be increased to 1.8 mg.

Bydureon is administered via subcutaneous injection once every 7 days (ie, weekly). The recommended dose is 2 mg given any time of day with or without meals.

Quantity limits:

- Byetta: 1 prefilled pen per 30 days
- Victoza: 3 prefilled pens per 30 days
- Bydureon: 4 vials per 28 days

GLP-1 analogues will be approved for plan year duration or as deemed appropriate by clinical review.

GLP-1 indicates glucagon-like peptide-1.

persistence to treatment, providing patient care services and therapy case management, and ensuring demonstrated outcomes. The third goal is to ensure appropriate use of treatments through adherence to clinical guidelines and treatment algorithms, use of formulary/preferred products, and proper use of prior authorizations and step edits. Through the use of clinical guidelines and treatment algorithms, such as the most recent American Diabetes Association/European Association for the Study of Diabetes (ADA/EASD) management guideline,⁷ managed care organizations (MCOs) can make decisions regarding appropriate use of treatments. For example, the information in **Table 1**, drawn from an MCO pharmacy coverage policy,⁸ reflects the ADA/EASD recommendations for the use of glucagon-like peptide-1 (GLP-1) analogues. It is important to note that MCOs rely on guidelines and treatment algorithms rather than just US Food and Drug Administration (FDA) indications, as GLP-1 analogues are FDA approved as monotherapy without the precondition of patient failure on other pharmacotherapies.⁹⁻¹¹ As guidelines and treatment algorithms are updated based on evidence-based data, MCOs update their pharmacy coverage policies to reflect new treatment recommendations.

Impact of Disease Management Programs

In general, DM disease management programs consist of 3 principal elements: target identification and outreach, engagement and education along with incentives, and lifestyle modification and follow-through. These programs are designed to limit the medical and economic burden of DM by

attempting to detect the disease early and initiate treatment to prevent advancement of prediabetes to DM and worsening of newly diagnosed DM. Results from a study published in 2002¹² provided excellent evidence that either a lifestyle-intervention program or the administration of metformin could prevent or delay the development of DM. Importantly, the beneficial effects of the lifestyle intervention were apparent regardless of sex, age, ethnicity, or body mass index (BMI). Study results also revealed that the efficacy of the lifestyle intervention relative to metformin was greater in older persons and in those with a lower BMI (<30 kg/m²) and that the efficacy of metformin relative to placebo was greater in those with a BMI of 30 kg/m² or higher.¹² These data provide MCOs with an excellent approach to managing DM, as they demonstrate the power of prevention. Therefore, MCOs are very interested in incentivizing patients to live the healthiest possible lifestyles in order to keep DM at bay. As a hypothetical example of an MCO-initiated, healthy lifestyle-based incentive program, members could enroll in the program and log on via computer, select an assessment tool such as a pedometer, engage in a healthy activity that is monitored by the tool and results in reward points, utilize an in-office measurement device, and redeem points for rewards at a reward center. Essentially, the goal is to foster healthy lifestyle choices and incentivize them. Such programs are focused on prevention and physical activity; provide tools and incentives to motivate members to get moving and stay moving; launch engagement and ongoing communications to help members boost activation and participation; are

comprehensive, engaging, and customizable; and hold members accountable. Incentive programs theoretically hold great promise, as the data from the aforementioned study showed that members in the lifestyle intervention group had the lowest incidence of DM (number of cases/100 person years after 2.8-year follow-up: 4.8 vs 7.8 for those in the metformin group, and 11 in the placebo group), the greatest reduction in incidence of DM compared with placebo (58% vs 31% for those in the metformin group), and a lower number needed to treat to prevent 1 case in 3 years (6.9 vs 13.9 persons to prevent 1 case in the metformin group).¹²

In practice, the results of such initiatives have been mixed and several factors that account for barriers to progress have been identified. One study examined the business case for improved DM care from the perspective of a single health plan (HealthPartners of Minnesota).¹³ Investigators determined that potential benefits from DM disease management attributed to a health plan included medical care cost savings and higher premiums, and that potential costs were accrued from disease management program costs and adverse selections. Overall, it was determined that the implementation of DM disease management coincided with large health improvements and that medical care cost savings over several years were small in the closed panel medical group representing a defined population of DM patients but moderate for the health plan. Conversely, adverse selection and the timing of cost and benefits worsened the health plan business case. The business case was found to be further weakened by the very weak connection between payment systems, from purchaser to health plan and health plan to provider, to the quality of DM care. Additionally, the authors found that overlapping provider networks limited the health plan's ability to privately capture the benefits from its investments. The study authors concluded that improved DM care was associated not only with economic benefits to health plans, but also with quality of life benefits for adults with DM.¹³ Regarding the difficulties in establishing MCO DM disease management programs, the results of 1 study indicated that health literacy may be an important factor for predicting who will benefit from such programs.¹⁴ Another important factor to consider is whether members will elect to participate in such programs and the implications of that decision. In a study that compared healthcare costs for patients who fulfilled health employer data and information set (HEDIS) criteria for DM and were in a health maintenance organization–sponsored disease management program with costs for those not in the disease management program, the study authors found an association between providing an opt-in disease management program and reductions in healthcare costs and

other measures of healthcare use. Additional study findings demonstrated improvements in HEDIS quality of care measures.¹⁵ Lastly, cultural issues may play a role in the success or failure of MCO DM disease management programs. In a study that examined the incidence of DM-related lower-extremity complications in a cohort of patients enrolled in a DM disease management program, the study authors found that although rates of ulceration, infection, vascular disease, and lower-extremity bypass were similar to those of non-Hispanic whites, Mexican Americans had a higher incidence of amputation.¹⁶

Implications and Impact of Various Benefit Plan Designs

When considering the tenets of benefit plan design, it is important to recognize that, while there are still traditional designs, newer plans are evolving as well. The traditional benefit plan design entailed managing costs through restriction of resource utilization. In traditional plans, medical and pharmacy designs were usually independent and cost sharing was used to influence utilization patterns such that the patient cost share was related to the acquisition cost of services or products. Importantly, this design assumed inelastic demand or willingness to pay. In contrast, evolving benefit management strategies focus on the overall long-term value of treatment versus drug costs. The scope and structure of such programs vary widely; however, all attempt to strike a balance between the interests of payers, patients, and physicians. Therefore, evolving strategies include an increased emphasis on influencing the behavior of plan participants and minimizing the effects of out-of-pocket expenses. The results of 1 study that estimated the effects of a large employer's value-based insurance initiative designed to improve adherence to recommended treatment regimens have already shown this to be an effective strategy in general. In the study, an intervention to reduce copayments for 5 chronic medication classes in the context of a disease management program was initiated and resulted in reduced nonadherence rates of 7% to 14% for 4 of the 5 medication classes compared with a control employer that did not use the intervention, but used the same disease management program.¹⁷ The study authors concluded that reducing copayments could increase adherence to medications even in the context of existing disease management programs.

Value-based insurance design, sometimes referred to as value-based benefit design, is an engagement tool for consumers, plan sponsors, and providers that uses both direct and indirect data to invest in incentives that change behaviors through health information technologies, communications,

■ **Figure. Value-Based Insurance Design**¹⁸



This diagram shows the key features of a value-based insurance design. Adapted from Center for Health Value Innovation. Leveraging the value of health: a decision matrix for value-based designs. www.vbhealth.org/wp-content/uploads/CHV_Report-11-24WEB-FINAL.pdf. Accessed April 2, 2013.

and services to improve health, productivity, quality, and financial trends (Figure).¹⁸ Recently, a 2-year study from United Healthcare followed 620 people with DM in a DM health plan to examine their compliance with 6 key DM treatment and testing requirements, including regular primary care visits and screening tests for blood sugar, cholesterol, cancer, kidney function, and eye disease.¹⁹ Results from the study revealed that incentives, including offering some DM supplies and DM-related prescription drugs at no charge, increased adherence to treatment guidelines and improved participants' health. In addition, on average, study participants achieved compliance with 75% of the key requirements, whereas participants with DM not enrolled in the plan achieved compliance with 61% of the key requirements. Furthermore, the compliance rate of plan participants increased by 6% over the 2-year study period. Lastly, results indicated that 21% of the study participants had reduced health risk scores, which are used to measure expected healthcare costs for an individual or a population, and that healthcare costs grew at a 4% slower pace for participants than for employees with DM who were not enrolled in the plan.¹⁹

Provider incentive programs, sometimes referred to as "pay for performance," represent a payment/delivery paradigm that places emphasis on rewarding value instead of volume, with the goal of improving the quality, efficiency, and overall value of healthcare. Various strategies are employed, including value-based purchasing, shared savings, gain-sharing, bundled payments, and capitation. These arrangements provide financial incentives to hospitals, physicians, and other healthcare providers to carry out such improvements and achieve optimal outcomes for patients and are being implemented to align financial incentives and quality of care. It is interesting to note that in a survey of 1500 managed care medical directors and pharmacists, almost half (46.3%) responded that their organization had no pay for performance programs (Table 2).²⁰ In theory, paying providers for achieving better outcomes for patients should improve those outcomes; however, in actuality, studies of these programs have

shown mixed results. One study described the results of the implementation of a pay for performance program based on meeting targets for the quality of clinical care to family practices in England in 2004.²¹ Study results revealed an increased rate of improvement in the quality of care for asthma and DM ($P < .001$) but not for heart disease between 2003 and 2005; and the results also showed that the rate of improvement slowed for all 3 conditions by 2007 ($P < .001$). Improvement rates were unchanged for asthma or DM and were reduced for heart disease ($P = .02$) compared with the period before the pay for performance program was introduced, and the level of the continuity of care was reduced immediately after the introduction of the pay for performance program ($P < .001$).²¹ More recently, a study was conducted to evaluate an online disease management system supporting patients with uncontrolled T2DM.²² A 12-month parallel randomized controlled trial of 415 patients with T2DM with baseline A1C values 7.5% or higher from primary care sites sharing an electronic health record used A1C as the primary outcome measure and examined 7 interventions that collectively represented a personalized healthcare program. At 6 months, the 193 patients in the intervention group had significantly reduced A1C compared with the 189 patients receiving usual care (-1.32% vs -0.66% ; $P < .001$); however, this result became insignificant at 12 months (-1.14% vs -0.95% ; $P = .133$).²²

Accountable care organizations (ACOs) represent another form of benefit plan design that emphasizes an alignment between reimbursement and implementation of best practices through the use of disease management and/or clinical pathways and health information technologies. Furthermore, ACOs involve shared objectives for MCOs and provider systems whereby financial success is tied to the outcomes of a defined population. The specific function of ACOs involves redesigning healthcare delivery to result in more units of health per unit of cost. Toward this end, ACOs typically have 4 components, each attached to a goal. For example, the goals of the Access, Service, Quality, and Value components refer to access to all sites and providers

who deliver appropriate, high patient satisfaction across the entire experience, consistent utilization of best practices, and optimal resource use, respectively. Some encouraging results—increased utilization of clinical laboratory tests and improved patient outcomes—were found after 1 year of a recently initiated pilot ACO project.²³ It should be noted that the results disclosed by the Norton/Humana ACO pilot only cover a short period of time; however, these results demonstrated that testing for patients with DM rose from 87.7% in the baseline year to 93.4% after the first year and that cholesterol management for patients with DM increased to 91.8% from a baseline of 83.9%. Of course, it would be incumbent on physicians to conduct and analyze appropriate laboratory tests to guide patient management.²³ Another study used a simulation model to analyze the effects of the Medicare Shared Savings Program, which was created under the Affordable Care Act. This study evaluated the impact of quality measures and performance targets on Medicare costs in a simulated population of patients aged 65 to 75 years with T2DM.²⁵ Study results suggested that an improvement in performance on DM quality measures of 10% would reduce Medicare costs by only up to approximately 1%, and that costs of performance improvement, such as additional tests or visits, would decrease savings or increase costs. Therefore, the study authors concluded that ACOs would have to lower costs by other means, such as through improved use of information technology and care coordination, in order to achieve greater savings.²⁴

Consumer-directed health plans, sometimes referred to as high-deductible health plans, represent an additional benefit design plan. According to a recent report by the Robert Wood Johnson Foundation that compared expenditures between families enrolling in consumer-directed health plans for the first time in 2005 and families enrolled in conventional plans, those enrolled in consumer-directed health plans spent 14% less.²⁵ The report also revealed that the benefit designs of consumer-directed health plans almost always affected vulnerable (chronically ill or lower-income) populations to the same extent as non-vulnerable populations and that enrollment in consumer-directed health plans was associated with moderate reductions in the use of preventive care, despite the fact that these plans waived the deductible for preventive care for both non-vulnerable and vulnerable populations. A breakdown of cost drivers found that approximately two-thirds of cost savings from enrollment in a consumer-directed health plan were attributable to reductions in the number of episodes of care and that the remaining one-third of the savings were derived from reductions in costs per episode. The report also stated that an immediate increase from 12.4%

■ **Table 2.** Results From a Survey of Managed Care Medical and Pharmacy Directors Regarding Availability of Pay-for-Performance Programs²¹

Response	Percentage of Respondents
Yes	37. w 9 %
No	46.3%
Don't know	9.5%
Planning to in the future	6.3%

When asked if their organizations had any pay-for-performance programs, results from a survey of 1500 managed care medical directors and pharmacists revealed that almost half responded “no,” more than one-third responded “yes,” almost 1 in 10 did not know, and approximately 6% indicated that their organizations planned to develop such programs in the future.

to 50% of the nonelderly population enrolled through their employer in a consumer-directed health plan would result in savings in personal healthcare expenditures of \$57.1 billion nationwide over a 10-year period, an impressive finding.²⁵ A recent publication described the rationale for and design of a planned pre-post, longitudinal, quasi-experimental study to determine the effect of high-deductible health plans on DM quality of care, outcomes, and disparities using a 13-year rolling sample (2001-2013) of members of a high-deductible health plan and members of a control group.²⁶ The study will measure rates of monthly A1C, lipid, and albuminuria testing; availability of blood glucose test strips; and rates of retinal examinations. Annual rates of high-severity emergency department visits, preventable hospitalizations, and inpatient hospital days will also be measured. The study authors explained that their results could be used to design health plan features that promote high-quality care and better outcomes among people who have DM.²⁶

Summary

The prevalence and costs of T2DM are projected to rise dramatically and place enormous strain on an already overburdened healthcare system. Therefore, it is imperative to find ways to manage this disease more effectively to ease the burden of human suffering with the added benefit of reduced costs. MCOs can play a significant role in promoting these goals by using evidence-based guidelines to develop their policies. Additionally, MCOs are exploring several types of benefit plan designs, although it is still unclear which, if any, would be most effective in reducing DM-related costs.

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