Third-Party Reimbursement for Diabetes Care, Self-Management Education, and Supplies

AMERICAN DIABETES ASSOCIATION

Diabetes is a chronic disease that affects nearly 26 million Americans (1) and is characterized by serious, costly, and often fatal complications. The total cost of diagnosed diabetes in the U.S. in 2007 was estimated to be \$174 billion (2). To prevent or delay costly diabetes complications and to enable people with diabetes to lead healthy, productive lives, appropriate medical care based on current standards of practice, self-management education, and medication and supplies must be available to everyone with diabetes. This paper is based on technical reviews titled "Diabetes Self-Management Education" (3) and "National Standards for Diabetes Self-Management Education Programs" (4).

The goal of medical care for people with diabetes is to optimize glycemic control and minimize complications. The Diabetes Control and Complications Trial (DCCT) demonstrated that treatment that maintains blood glucose levels near normal in type 1 diabetes delays the onset and reduces the progression of microvascular complications. The U.K. Prospective Diabetes Study (UKPDS) documented that optimal glycemic control can also benefit most individuals with type 2 diabetes. To achieve optimal glucose control, the person with diabetes must be able to access health care providers who have expertise in the field of diabetes. Treatment plans must also include self-management training and tools, regular and timely laboratory evaluations, medical nutrition therapy, appropriately prescribed medication(s), and regular self-monitoring of blood glucose levels. The American Diabetes Association position statement "Standards of Medical Care in Diabetes"

outlines appropriate medical care for people with diabetes (5).

An integral component of diabetes care is self-management education (inpatient and/or outpatient) delivered by an interdisciplinary team. Self-management training helps people with diabetes adjust their daily regimen to improve glycemic control. Diabetes self-management education teaches individuals with diabetes to assess the interplay among medical nutrition therapy, physical activity, emotional/physical stress, and medications, and then to respond appropriately and continually to those factors to achieve and maintain optimal glucose control.

Today, self-management education is understood to be such a critical part of diabetes care that medical treatment of diabetes without systematic self-management education is regarded as inadequate. The "National Standards for Diabetes Self-Management Education" establish specific criteria against which diabetes education programs can be measured, and a quality assurance program has been developed and subsequently revised (6).

Treatments and therapies that improve glycemic control and reduce the complications of diabetes will also significantly reduce health care costs (7,8). Numerous studies have demonstrated that self-management education leads to reductions in the costs associated with all types of diabetes. Participants in self-management education programs have been found to have decreased lower-extremity amputation rates, reduced medication costs, and fewer emergency room visits and hospitalizations.

To achieve optimal glycemic control, thus achieving long-term reduction in

health care costs, individuals with diabetes must have access to the integral components of diabetes care, such as health care visits, diabetes supplies, self-management education, and diabetes medications. As such, insurers must reimburse for diabetes-related medical treatment as well as for self-management education programs that have met accepted standards, such as the American Diabetes Association's National Standards for Diabetes Self-Management Education. Furthermore, third-party payers must also reimburse for medications and supplies related to the daily care of diabetes. These same standards should also apply to organizations that purchase health care benefits for their members or employees, as well as managed care organizations that provide services to participants.

It is recognized that the use of formularies, prior authorization, competitive bidding, and related provisions (hereafter referred to as "controls") can manage provider practices and costs to the potential benefit of payors and patients. Social Security Act Title XIX, section 1927, states that excluded medications should not have "a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcomes of such treatment of such population." A variety of laws, regulations, and executive orders also provide guidance on the use of such controls to oversee the purchase and use of durable medical equipment (hereafter referred to as "equipment") and single-use medical supplies (hereafter referred to as "supplies") associated with the management of diabetes.

Certain principles should guide the creation and enforcement of controls in order to insure that they meet the comprehensive medical needs of people living with diabetes. A wide array of medications and supplies are correlated with improved glycemic outcomes and a reduction in the risk of diabetes-related complications. Because no single diabetes treatment regimen is appropriate for all people with diabetes, providers and patients should have access to a broad array of medications and supplies to develop an effective treatment modality.

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The recommendations in this paper are based on the evidence reviewed in the following publications: Diabetes self-management education (Technical Review). *Diabetes Care* 18:1204–1214, 1995; and National standards for diabetes self-management education. *Diabetes Care* 33:S89–S96, 2010.

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However, the Association also recognizes that there may be a number of medications and/or supplies within any given class. As such, any controls should ensure that all classes of antidiabetic agents with unique mechanisms of action are available to facilitate achieving glycemic goals to reduce the risk of complications. Similar issues operate in the management of lipid disorders, hypertension, and other cardiovascular risk factors, as well as for other diabetes complications. Furthermore, any controls should ensure that all classes of equipment and supplies designed for use with such equipment are available to facilitate achieving glycemic goals to reduce the risk of complications. It is important to note that medical advances are rapidly changing the landscape of diabetes medications and supplies. To ensure that patients with diabetes have access to beneficial updates in treatment modalities, systems of controls must employ efficient mechanisms through which to introduce and approve new products.

Though it can seem appropriate for controls to restrict certain items in chronic disease management, particularly with a complex disorder such as diabetes, it should be recognized that adherence is a major barrier to achieving targets. Any controls should take into account the huge mental and physical burden that intensive disease management exerts upon patients with diabetes. Protections should

ensure that patients with diabetes can readily comply with therapy in the widely variable circumstances encountered in daily life. These protections should guarantee access to an acceptable range and all classes of antidiabetic medications, equipment, and supplies. Furthermore, fair and reasonable appeals processes should ensure that diabetic patients and their medical care practitioners can obtain medications, equipment, and supplies that are not contained within existent controls.

Diabetes management needs individualization in order for patients to reach glycemic targets. Because there is diversity in the manifestations of the disease and in the impact of other medical conditions upon diabetes, it is common that practitioners will need to uniquely tailor treatment for their patients. To reach diabetes treatment goals, practitioners should have access to all classes of antidiabetic medications, equipment, and supplies without undue controls. Without appropriate safeguards, these controls could constitute an obstruction of effective care.

The value of self-management education and provision of diabetes supplies has been acknowledged by the passage of the Balanced Budget Act of 1997 (9) and by stated medical policy on both diabetes education and medical nutrition therapy.

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