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

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iabetes is a chronic disease that affects nearly 17 million Americans,1 with over 10 million cases diagnosed, and is characterized by serious, costly, and potentially fatal complications. The total cost of diagnosed cases of diabetes in the U.S. in 2002 was estimated to be \$92 billion.1 To prevent or delay the costly 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"² and "National Standards for Diabetes Self-

Management Education Programs."3

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 include self-management training, regular and timely laboratory evaluations, medical nutrition therapy, appropriately prescribed medication(s), and regular self-monitoring of blood glucose

(SMBG) levels. The American Diabetes Association position statement "Standards of Medical Care for Patients with Diabetes Mellitus" outlines appropriate medical care for people with diabetes.⁴

An integral component of the DCCT was self-management education (inpatient and/or outpatient) delivered by an interdisciplinary team. Self-management training also helps people with type 2 diabetes adjust their daily regimen to improve glycemic control. Diabetes selfmanagement education is the process of providing the person with diabetes with the knowledge and skills to perform selfcare on a day-to-day basis. Self-management education teaches the person with diabetes to assess the relationships among medical nutrition therapy, activity level, emotional and physical status, and medications and then respond appropriately and continually to those factors to achieve and maintain optimal glucose

Today, self-management education is a critical part of the medical plan for people with diabetes, such that medical treatment of diabetes without systematic self-management education cannot be regarded as acceptable care. The National Standards for Diabetes Self-Management Education Programs establish specific criteria against which diabetes education programs can be measured, and a quality assurance program has been developed and subsequently revised.5

Treatments and therapies that improve glycemic control and reduce the complications of diabetes will also significantly reduce health care costs.^{6,7} Numerous studies have demonstrated

that self-management education leads to reductions in the costs associated with all types of diabetes. Participants in selfmanagement education programs have been found to have decreased lowerextremity amputation rates, reduced medication costs, and fewer emergency room visits and hospitalizations.

Access to the integral components of diabetes care, such as health care visits, diabetes supplies and medications, and self-management education, is essential. The American Diabetes Association believes insurers must reimburse for medical treatment and also for self-management education programs that have met accepted standards, such as the American Diabetes Association's National Standards for Self-Management Education Programs. All medications and supplies, such as syringes, strips, and meters, related to the daily care of diabetes must also be reimbursed by third-party payers. Organizations that purchase health care benefits for their members or employees should insist that self-management education, medications, and supplies should be included in the services provided, and managed care organizations should include these services and supplies in the basic plan available to all participants.

It is recognized that the use of formularies, prior authorization, and related provisions (hereafter referred to as "controls"), such as competitive bidding, can manage provider practices as well as costs to the potential benefit of payers and patients. Social Security Act Title XIX, section 1927, states that excluded agents 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 singleuse medical supplies (hereafter referred to as "supplies") associated with the management of diabetes. Consideration of certain principles should occur in creating and enforcing these controls that impact comprehensive medical needs of people living with type 1, type 2, or gestational diabetes.

Reductions in hemoglobin A_{1c} to ≤7% have been associated with improved outcomes and a reduction in the risk of diabetes-related complications. Outcome data are only available for animal source insulins, sulfonylureas, and metformin. Newer medications, blood glucose monitors, blood glucose test strips, insulin pumps, and related supplies, as well as other equipment and supplies associated with the use of these items, are expected to similarly reduce the risk of diabetic complications in proportion to glucose lowering. More than one agent is typically required to achieve glycemic targets, and the effect of multiple agents used in combination is additive. A variety of equipment and supplies are also necessary to manage diabetes and reach glycemic targets. Thus, 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.

The major limitation to achieving stringent glycemic targets is treatment-emergent hypoglycemia, which can be a significant safety issue limiting effectiveness of care and can on occasion result in serious morbidity and mortality. In patients with severe or frequent hypoglycemia or certain diabetes complications, some antidiabetic agents, equipment, and supplies are associated with lower risks of hypoglycemia at similar levels of overall control and should be available to special populations.

Though it can seem appropriate for controls to restrict perceived items of convenience 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 burden of intensive insulin management on patients, particularly in the management of type 1 diabetes. Protections should ensure that patients with diabetes can 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 anti-diabetic 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 1997⁸ and by stated medical policy on both diabetes education⁹ and medical nutrition therapy.¹⁰

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