

Statement of Novo Nordisk Inc.

to the

Centers for Medicare and Medicaid Services (CMS)

Federal Register: June 23, 2006 (Volume 71, Number 121)] [Notices] [Page 36099-36100]: Information Collection: Expanded Coverage for Diabetes Outpatient Self-Management

Due August 22, 2006

Novo Nordisk Inc. ("Novo Nordisk") is pleased to provide these comments on expanded coverage for diabetes outpatient self-management training to the Centers for Medicare and Medicaid Services ("CMS") information collection announcement referenced in the Federal Register on June 23, 2006.

Diabetes and Prevention

Diabetes is a chronic disease that has no cure. Type 1 diabetes is an autoimmune disease characterized by insulin deficiency. It is more likely to occur in children and young adults with a family history of type 1 diabetes. In type 2 diabetes, the body either does not make enough insulin, has become insensitive to the insulin produced, or both.

Patient and physician awareness and education coupled with professional guidance for people 65 and older at risk for developing diabetes can have a tremendous effect on improving quality of life and health outcomes.

Diabetes Impact in the Medicare Population

Of the estimated 35 million Medicare beneficiaries age 65 or older, 61 percent or 21 million have diabetes or pre-diabetes. Between two and three and a half million Medicare beneficiaries with diabetes are undiagnosed while virtually all of the 14 million Medicare beneficiaries with pre-diabetes are undiagnosed. Diabetes-related medical expenses and lost productivity cost an estimated \$132 billion in the U.S. in 2002. The diabetes screening provisions passed by Congress in the Medicare Modernization Act offer a real opportunity to reduce the staggering costs of diabetes by identifying those with undiagnosed diabetes and pre diabetes.¹ However, a recent National Health and Nutrition Examination Survey (NHANES) reported that undiagnosed diabetes constitutes one-third of total diabetes in U.S. adults.² And it is reasonable to assume that the vast majority of people with pre-diabetes are also undiagnosed.

Need for Expanded Coverage for Diabetes Outpatient Self-Management

¹ *Diabetes Care*. Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population. June 2006.

² Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion: Data and trends: National Diabetes Surveillance System: Prevalence of diabetes. Available from <http://www.cdc.gov/diabetes/statstics/prev/national/figage.htm>. Accessed January 2006.

Undiagnosed diabetes has serious health consequences and growing prevalence demonstrates the need for increased utilization and access to the Medicare diabetes screening benefit. More than half of health expenditures for diabetes are provided to people 65 years or older and the need to increase access through the Medicare diabetes screening benefit is critical to closing the prevention and treatment gap in this population.³ Before beneficiaries can avail themselves of the limited diabetes self-management training benefit offered by Medicare, beneficiaries must first learn that they suffer from diabetes in order to access this benefit and seek proper care.

Since diabetes requires self-monitoring, lifestyle modification, and medication adherence, diabetes self-management training is an essential element in ensuring that people with diabetes can manage their condition. In the case of a chronic disorder like diabetes, optimal management of the disease emphasizes total care - including medical, psychosocial and family support. Patient awareness, education, and professional guidance coupled with comprehensive educational materials developed for people with diabetes and their caregivers can have a tremendous effect on improving the quality of life for everyone who suffers with diabetes.

Indeed, diabetes is widely recognized as a disease that requires tremendous self-management on the part of the patient. Yet, many people do not know even the simplest steps that must be taken upon the diagnosis of diabetes. Diabetes disease management, both for those newly diagnosed and those who are challenged to manage this complicated disease over many years, is often best learned over time through diabetes self-management training. As more complex treatment is required, or as new medical options become available, further patient education is often required. All of this takes time.

Accordingly, Novo Nordisk has two recommendations to make.

First, access to diabetes outpatient self-management must be improved. CMS should undertake to review the current barriers to accessing this important benefit and make changes that can dramatically improve access.

Second, reimbursement for diabetes outpatient self-management should be reviewed and increased. Currently, Medicare payment rates for individual and group diabetes self-management training (DSMT) are low, with individual DSMT receiving \$31.83 per 30 minutes and group DSMT receiving \$18.57 per 30 minutes.⁴ Novo Nordisk is extremely concerned with this level of payment for DSMT services. It is vital that beneficiaries with diabetes have full access to the education they need to manage their illness; the low payment rates for DSMT could serve as a barrier to access. We ask that CMS take steps to increase payment for DSMT as part of the agency's overall commitment to improving care and outcomes for Medicare beneficiaries with diabetes.

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³ *Diabetes Care*. Economic Costs of Diabetes in the U.S. in 2002. March 2003.

⁴ 2006 Medicare national average allowable amounts.