

Medicare Competitive Bidding Program Blood Glucose Monitoring Systems

The American Association of Diabetes Educators, because of our members commitment to quality diabetes care, urges the Centers for Medicare and Medicaid Services to include several critically important provisions if blood glucose monitoring systems are to be included in the competitive bidding program established by the Medicare Modernization Act of 2003 (MMA).

Consistent self-monitoring of blood glucose levels by patients is central to the effective care and management of diabetes and to avoiding serious and costly complications. Patients with diabetes are in control of their own care regimen, in which they rely on self-monitoring of blood glucose systems to maintain control of their glucose levels.

It is important that if blood glucose monitoring systems are included in the Medicare competitive bidding program, patient care will not be undermined and no barriers are placed between beneficiaries and their preferred treatment practices. Specifically, AADE urges that the following provisions be considered:

Access to High-Quality Products: Coverage must ensure access to products such that the medical needs of beneficiaries are adequately addressed. Furthermore, coverage must be limited only to blood glucose meters and associated products that have been approved by the Food and Drug Administration (FDA) for testing blood glucose in people with diabetes.

Appropriate Exemption and Appeals Process: There must be a fair, expedient, and appropriate appeals and exemption process which allows beneficiaries to utilize meters with specific modifications and/or features based on medical necessity. Such a process should be initiated by any members of diabetes care teams, including physicians, beneficiaries, other health care professionals, as well as other caregivers (including family of beneficiaries). In all appeals, appropriate medical documentation should be required.

Full-Time Access to Supplies: In order to properly protect beneficiaries in the event of emergency situations, beneficiaries must be able to access to all components of blood glucose monitoring systems including, but not necessarily limited to, a meter, testing strips, testing lancets, and a lancet-delivery device -at all times.

Inclusion of Diabetes Management Experts in Decision-Making Bodies and Processes: Diabetes management experts -physicians, Certified Diabetes Educators (CDEs), other health professionals, and laypersons with diabetes -must be included in policy determination and implementation processes associated with the competitive bidding program. Similarly, diabetes management experts must be included as part of the appeals and exemption processes for beneficiaries with diabetes.

Technology Review Procedures: The program should include periodic technology and contract reviews to ensure that beneficiaries have access to appropriate supplies. Such reviews should lead to alterations in contracts and/or monitor availability when evidence demonstrates that

technological upgrades lead to improved diabetes care. Furthermore, in order to ensure that new technologies are fully considered, contracts should not be awarded for an overly extensive period of time.

Evaluation Systems: CMS should endeavor to collect and analyze data to study the health outcomes of beneficiaries with diabetes to ensure that all have proper access to blood glucose monitoring systems and supplies. Because no competitive bidding pilot program was conducted for blood glucose monitoring systems, the analysis should focus on the effects of the competitive bidding program itself to ensure that it is not causing undue harm to people with diabetes.

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