ACP
American College of Physicians
INTERNAL MEDICINE | *Doctors for Adults*

September 12, 2006

Amy Bassano
Director, Division of Ambulatory Services
Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Bassano:

The American College of Physicians, representing more than 120,000 physicians and medical students would like to offer our comments on the payment determination for a Current Procedural Terminology (CPT) code 83037 that describes "Hemoglobin; glycated (A1C) by device cleared by FDA for home use." ACP asks that CMS consider these comments in the payment determination process for this new CPT code.

This CPT code was approved by the American Medical Association's CPT Editorial Panel on February 12, 2005. The explicit purpose of this code was to create a new payment amount for A1C when this test is run in physician offices or other point-of-care locations where diabetes patients are treated and managed. In doing so, the CPT Editorial Panel acknowledged the distinction between the resource requirements for A1C methods used in the laboratory and the slightly higher resource requirements for A1C methods designed for use in the physician office. The code description "cleared by FDA for home use" was used only to distinguish new self-contained A1C devices for point-of-care testing from conventional laboratory and physician office methods, which are designed for high volume use and require expensive instrumentation and capital investment.

The necessity for access to real-time A1C results during physician visits is well established in the medical literature and supported by medical thought-leaders and national physician organizations. Unfortunately, despite the fact that regular A1C monitoring is a long accepted standard of care, it remains one of the most underutilized tests in the country. A recent study published in the *New England Journal of Medicine* (June 23, 2003) showed that fewer than 24% of patients with diabetes have their A1C monitored according to established medical guidelines. This same study was cited by CMS as an indication of the need to improve quality of care by providing "actionable evidence at the point-of-care." A1C is one of the best examples of such actionable evidence.

The existing code, 83036(QW) currently used for conventional A1C test methods, is adequate for clinical laboratories and physician practices that see a high volume of patients with diabetes. This is because high test volumes result in a low per-test cost. These economics are not available to the majority of physicians in primary care, even though 85% of patients with diabetes are treated by this physician group.

Self-contained A1C systems enable broader access to real-time A1C monitoring because they do not require the same capital investments required for large analyzers. Generally, investments in bench-top instruments can only be economically justified by diabetes specialists who perform a large number of A1C tests each year. As a result, only a small minority of patients receives real-time A1C monitoring and is tested in accordance with the standards of care established by both the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE). Self-contained A1C systems eliminate the need for capital investment by miniaturizing the reagent and detection technology into a single-use device. These systems make it possible for any physician to incorporate real-time A1C testing into their practice. Self-contained A1C systems have a slightly higher per unit cost (consistent with other hand-held glycemic control systems), which needs to be reflected in the practice expense for this unique test.

Both glycated protein (CPT 82985) and glycated hemoglobin (CPT 83036) measure long term glycemic control and are provided for in the same Medicare National Coverage Determination (CMS document 190.21). As the table below indicates, evaluating payment methodology for this new code results in the same payment of about $21 using two different approaches. Thus, we recommend a crosswalk to code 82985.

Approach *(Similar to…)*	**Market Comparison** *(Cross-Walking)*	**Building Blocks**
Rationale	**Glycated Protein**: Measures glycemic control over 2-4 weeks 82985-QW reimbursed @$21.06	**Costs Components/Test:** Wholesale price $12.95 + Shipping/handling 1.50 + Blood collection 3.00 + Physician overhead 3.70 Total Cost $21.15
Estimated Payment (If applied to physician office A1C)	$21.06/test	$21.15/test

We understand that CMS is now in the process of determining a National Limiting Amount (NLA) for this code based on an analysis of the gap-filled amounts that are reported by Medicare Part B carriers. We do not believe that this method would be appropriate in this case because the carriers do not have the ability to properly analyze the costs of providing the test in a physician's office and many set the price by cross-walking to the reference laboratory test.

ACP encourages CMS to do a full review of the data available to them to ensure that this test is properly reimbursed when performed in a physician's office. ACP believes that the reimbursement for the office-based test should truly reflect the costs of performing the test in the office and not the cost of performing the test in a larger clinical laboratory.

Thank you for your time and consideration of our comments. If you have any questions about this matter, please contact Brian Whitman, Senior Analyst for Regulatory and Insurer Affairs, by phone at (202) 261-4544 or by e-mail at bwhitman@acponline.org.

Sincerely,

Joseph W. Stubbs, MD
Chair, Medical Service Committee