

January 4, 2007

Steven Phurrough, M.D, M.P.A.  
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Coverage and Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
MS C1-09-06, Room C1-13-18  
7500 Security Boulevard  
Baltimore, MD 21244

Re: **Update to Clinical Lab Coverage Determination – 190.21 – Glycated Hemoglobin**

Dear Dr. Phurrough:

This letter respectfully requests that the Centers for Medicare & Medicaid Services (CMS) update its clinical laboratory national coverage decision by adding a related CPT code that has been created by the American Medical Association (AMA).

The current coverage policy – 190.21 – Glycated hemoglobin/glycated protein includes the following HCPCS/CPT Codes:

82985	Glycated protein
83036	Hemoglobin; glycated

Please note that the AMA has revised the descriptor for 83036 which now reads:

Hemoglobin; glycosylated (A1c)

The AMA created another code in this family of codes which should be added to the CMS policy:

83037	Hemoglobin; glycosylated (A1c) by device cleared by FDA for home use
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CMS has assigned a national limitation amount for 83037, based on cross-walking the national limitation amount for 82985 to the new code. See CMS Manual System Pub. 100-04 Medicare Claims Processing, Transmittal 1122 (December 8, 2006) Change Request 5362. This is effective January 1, 2007.

Consistent with CMS' policy for abbreviated updates of NCDs, (Vol. 70 Fed. Reg. No. 37 (Feb. 25, 2005) at page 9355), we note that the new code – 83037 flows from the

existing narrative indications in the laboratory NCD 190.21. The indications section of the NCD 190.21 applies equally for codes 82985 and 83036 as for the new code 83037.

More specifically, the indications section reads as follows:

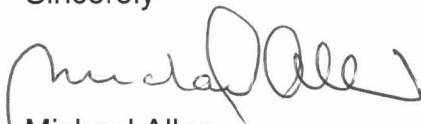
Glycated hemoglobin/protein testing is widely accepted as medically necessary for the management and control of diabetes. It is also valuable to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia. Glycated protein testing may be used in place of glycated hemoglobin in the management of diabetes patients, and is particularly useful in patients who have abnormalities of erythrocytes such as hemolytic anemia or hemoglobinopathies.

The new code – 83037 – fits precisely into this indication as it reflects a test that measures glycated (glycosylated A1c) hemoglobin just like 83036. CPT 83037 enables a physician to perform the same test in the physician office setting, while typically 83036 requires the physician to send the patient sample to a reference lab.

Based on our discussion with Maria Ciccanti in your office, we ask that this request be reviewed in your abbreviated procedure so that the update can be accomplished in the first quarter of 2007.

Thank you for your consideration. Jeff Voigt will follow up with Maria next week to discuss any appropriate follow up.

Sincerely



Michael Allen

Cc: Maria Ciccanti (CMS)  
Jeff Voigt (Metrika/Bayer)  
Gordon B. Schatz (Reed Smith LLP)