

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: PAY.020
REVISION DATE: 07/09
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SUBJECT: Real Time HbA1C Glycosylated Hemoglobin Test (Medicare Only)
INDEX TITLE: Medical Management
ORIGINAL DATE: August 2007

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()		POS ()		PPO ()	
Fully Insured ()		Self-funded/ASO ()		HSA ()	
Medicare Select ()		Medicare Supplement ()			
DPW-MA:					
Health Choices ()			Voluntary ()		All ()
CMS-MA:					
OH ()		WV ()		PA ()	All (X)
HMO (X)	PPO (X)	Specialty Needs Plan (X)		Part D ()	PFFS (X)
PID-CHIP:					
Free ()		Sub ()		Full ()	All ()
APPLICABLE TO:					
Community Care ()			Work Partners ()		

I. POLICY

It is the policy of UPMC Health Plan to recognize coverage for services mandated through Medicare regulations. Based on the review of literature and clinical trials conducted, UPMC Health Plan recognizes the value of ongoing management of members with Type I or II diabetes in order to monitor blood sugar levels and to work toward the long-term health of its members. The use of Real Time HbA1C Glycosylated Hemoglobin Test in the home setting or in the physician office setting has not been well established in studies, and UPMC Health Plan considers Real Time HbA1c Glycoslated Hemoglobin Test experimental and investigational and therefore, provides **coverage only for Medicare members as outlined in this policy.**

Coverage for Medicare members will be considered for the specific indications detailed in this policy and covered under the member's benefit plan.

II. DEFINITIONS

Real Time HbA1C Glucose Monitor is a portable, easy-to-use device that provides immediate access to HbA1C hemoglobin testing results.

III. PURPOSE

The purpose of this policy is to define the indications for medical necessity for Real Time HbA1C Glycosylated Test.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committees. These include, but are not limited to: Medical Management, Benefit Configuration and Claims Departments.

V PROCEDURE

A. Medical Description

The Real Time HbA1C Glycosylated Hemoglobin Monitor is a portable, easy-to-use device that provides immediate access to HbA1C testing results in members with suspected or confirmed diabetes. HbA1C is formed when glucose in the blood binds irreversibly to Hemoglobin (Hb) to form stable glycates hemoglobin HbA1C complex. Since the normal life span of a red cell averages 120 days, the HbA1C level will change as new red cells develop. The ability to access and interpret blood sugar results is the most important tool utilized in the control of blood sugars. This glucose monitor is marketed as a critical asset to the member's doctor's office visit, as it eliminates the need to order outside laboratory testing and does not delay the physician's response to the test results. However, HbA1C values are directly proportional to the average concentration of glucose in the blood over two to three months, and are not subject to daily fluctuation seen in typical blood sugar monitoring. It is also established that home monitoring of HbA1C is inappropriate without adequate professional oversight of the testing, and there is no necessity for immediate response to HbA1C levels as would be needed with blood sugar levels. The Centers for Medicare & Medicaid Services (CMS) has also established that this device, although called a "**Home**" device, should only be used in the physician's office setting.

The Real Time HbA1C Now+® Glucose Monitor was the first single-use, quantitative test available for physician offices, and over-the-counter consumer usage to measure glycosylated hemoglobin. It is a multiple use monitor, and uses disposable test cartridges, which uses fingerstick or whole venous blood samples.

B. Indications

- The Real Time HbA1C Glycosylated Hemoglobin Test must be done in the physician's office based on the following: Test to be performed every three (3) months for members with HbA1C values at or above 7%.
- For members with values below 7%, test every six (6) months.
- Test during treatment changes or after periods of elevated glucose levels.

C. Limitations

Charges for the use of the Real Time HbA1C Glycosylated Hemoglobin Monitor and physician interpretation of the testing results will only be reimbursed if conducted in a physician's office setting.

D. Variations

This policy applies to Medicare members only.

E. Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the UPMC Health Plan's Technology Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

H. References

1. MLN Matters Number: MM5362, Annual Update for Clinical Laboratory Fee Schedule and laboratory Services Subject to Reasonable Charge Payment, Effective January 1, 2007
2. Bristol-Myers Squibb and Metrika Announce Exclusive US Supply Agreement for A1C – A1c Now® Added to ChoiceDM™ Line of Consumer Care Products for Diabetes.; April 21, 2004
3. Letter to Medicare Carrier Medical Directors Regarding Carrier Pricing of New CPT Code 83037; December 2005, American Academy of Family Physicians; Policy & Advicact
4. 10 New CLIA Waived Tests; Effective Jan. 1.2006; Implementation Date: Jan 3, 2006
5. CPT 2006: Another Year, Another Round of Updates; The E/M Codes for Consultations & Nursing Facility Visits Reflect Some of This Year's Significant Changes
6. American Diabetes Association Clinical Practice Recommendations
7. 2007 Annual Update for Clinical Laboratory Fee Schedule & Laboratory Services Subject to Reasonable Charge Payment; Palmetta GBA, 6939d
8. MLN Matters Number MM5987, Clinical Laboratory Fee Schedule, Effective 04/01/2008

Disclaimer:

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

UPMC Health Plan reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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